UNIVERSITY OF SOUTHAMPTON

FACULTY OF BUSINESS LAW AND ART

Southampton Law School

FUTURE UNSPECIFIED USE OF TISSUE AND DATA IN BIOBANK RESEARCH

by

SIMISOLA. O. AKINTOLA

Thesis for the degree of Doctor of Philosophy

January 2016

UNIVERSITY OF SOUTHAMPTON

ABSTRACT

FACULTY OF BUSINESS LAW AND ART

LAW

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Simisola Oluwatoyin Akintola

Although the concept of ownership of human tissue as well as the question of the rights of the tissue source to excised tissue have not been fully developed in law either in Nigeria or in England, recent developments in genetic science and biobank research have made this a contemporary controversy in the sense that biobank research has become an integral part of the process of developing diagnoses and therapies for complex diseases. Biobanks can be used not only for basic research aimed at developing therapeutic products or understanding fundamental biological principles such as molecular mechanisms etc., but also for clinical and epidemiological research. They are now a prerequisite for conducting Genome Wide Association Studies (GWAS) that explore connections between genotypes and phenotypes in order to identify genetic risk factors for common diseases such as heart disease, autoimmune diseases and psychiatric disorders. In spite of the growing importance of biobank research and the attendant significance of the role of the tissue source to the development of science, the law has not developed clear-cut principles that protect the interests of a tissue source who contributes valuable samples or data to biobank research. In the context of biobank research, this discussion engages two intersecting interests: the individual interest of the tissue source, and the communitarian interests of the overall public good that the prospect of biobank research brings. Within this discussion, the thesis discusses protecting the tissue source, his entitlement to privacy of his data; as well as his entitlement to choosing when and if he wants his data or samples used in future research. The thesis also proceeds from a supposition that the tissue source should be given a say in the decisions relating to secondary uses of the samples and data. By this position, the thesis is not advancing a case for an abolition of biobank research, but that the autonomous choice of the tissue source in relation to future research be recognised and protected.

Contents

Declaration of Authorship

I, Simisola Oluwatoyin Akintola declare that this thesis and the work presented in it are my own and has been generated by me as the result of my own original research.

FUTURE UNSPECIFIED USE OF TISSUE AND DATA IN BIOBANK RESEARCH

I confirm that:

1. This work was done wholly or mainly while in candidature for a research degree at this University;
2. Where any part of this thesis has previously been submitted for a degree or any other qualification at this University or any other institution, this has been clearly stated;
3. Where I have consulted the published work of others, this is always clearly attributed;
4. Where I have quoted from the work of others, the source is always given. With the exception of such quotations, this thesis is entirely my own work;
5. I have acknowledged all main sources of help;
6. Where the thesis is based on work done by myself jointly with others, I have made clear exactly what was done by others and what I have contributed myself;
7. None of this work has been published before submission.

Signed: ……

Date: ……

Acknowledgements

First and foremost, I am most grateful to the most high God through Jesus Christ for the salvation of my soul and also for his direction through the Holy Spirit for inspiration strength and wisdom for this journey.

This thesis could not have been written without Dr Remigius Nwabueze, who not only served as my supervisor but who encouraged and challenged me throughout this programme with his constructive criticism and helpful suggestions. He, Prof John Coggon and Prof Niyi Olatubosun guided me throughout the dissertation process, never accepting anything less than the best. I cannot thank you enough for the support you gave me throughout the course of this programme. I am also appreciative of the helpful feedback from Dr Natasha Hammond Browning following my upgrade examination.

I would also like to thank the University of Ibadan for their generous financial and administrative support without which I may not have been able to embark on a doctoral study. My sincere gratitude goes to my colleagues at the Faculty of Law of the University of Ibadan for their support and forbearance during my leave of absence, particularly to Prof Niyi Olatubosun, Prof Oluyemisi Bamgbose, Mrs Jadesola Lokulo-Sodipe and Mrs A Aregbesola for supporting and cheering me on.

I would also like to express my gratitude to the church of God the Redeemed Christian Church of God Holy Ghost Zone and particularly to Pastor and Mrs Frank Abu for their labour of love.

To my friends Femi and Bola Ogunbiyi, I cannot thank you enough. I am most grateful for you for the support and kindness you showed to my son and husband throughout the period of my sojourn.

A very special thank you, to Prof Isaac Adewole for always believing in me and for enabling this opportunity to embark on this programme.

Finally to my family, my children Olapeju, her husband Toye, Omotola and Kanyinsola and my adorable grandson Timilehin; I am thankful for your unfailing love forbearance

and support. To the love of my life, my helpmate and consort Ladiran, words cannot express my love and appreciation for constant encouragement and support both emotional and financial. Thank you for believing in me. Thank you for being there.

Chapter Outline

This thesis proposes an alternative framework policy for protecting the tissue source regarding the use of his sample and data in future unspecified biobank research. This discussion proceeds from the premise that the public interest inherent in the pursuit of biobank research which dictates that the interest of the public is more important than that of the individual must be balanced against the individual interest of the tissue source whose samples and data are being used. By the inherent nature of biobank research, future unspecified research is inevitable, but this must be balanced by the use of appropriated consent procedures that enable the choice of the tissue source.

The thesis is split into six chapters.

Chapter 1

This chapter examines biobanks as a phenomenon, and in particular population biobanks which act as a research platform for future research, both nationally and internationally. These population biobanks consists of human genetic samples and associated data from individuals. The chapter also examines the legal challenge of consent, and the tensions created by population biobanks and their potential use of those samples and data in future unspecified research. In general the chapter argues for a more individualist approach to consent in biobank research.

Chapter 2

Chapter 2 examines the phenomenon of biobank research and the doctrine of consent along the lines of the legal challenges and the tensions on the conventional and traditional understanding of consent that biobank research exerts. In particular, the chapter examines the legal concept of informed consent with a view to assessing whether it adequately protects the interest of the tissue source and their right to make a choice on whether their samples and data are used in future unspecified research. In so doing, the chapter critically reviews the operation of consent principles as they apply to biobank research. This analysis revealed that broad consent does not adequately reflect the features of consent, and therefore does not protect the interest of the tissue source. This in turn led to the chapter proposing an alternative mid-way option between the traditional specific consent mode and the prevailing broad consent mode in biobank

research. The chapter argues for a more individualist, participant-centred approach which allows for a dynamic consent approach in situations where-consent is required. The underlying objectives of the chapter are to ensure that the rights of the tissue source to choice and privacy are protected, and at the same time that research development is not impaired.

Chapter 3

The future unspecified use of samples and data in biobank research challenges the existing law on privacy. These challenges make it more difficult to guarantee the privacy of the tissue source. To move forward there is a need to review the means of consenting to biobank research to further guarantee the privacy of the tissue source and to give the source an opportunity to assess the risk of privacy infringement. This chapter explores this privacy protection within the context of biobank research by examining whether the interest of a tissue source in not having their sample or data used in future unspecified research without their consent is a protectable privacy interest in law. This question will be examined through the lens of the various understandings of privacy. The chapter charts the values and interests that come into play with the challenges of biobank research, and proposes viable means of granting access to samples and data that will protect the interest of the source

Chapter 4

Since the claim for protection of the right of the tissue source to control over future unspecified research is based on having a protectable legal interest in the sample, this chapter examines the question of whether property rights exist over excised tissue. It also considers whether the interest of the tissue source qualifies as a proprietary interest, and argues for the protection of the claim of the tissue source to entitlement of protection based on a property interest. This analysis will entail an examination of the nature of property, and its significance to the debate of the rights of the tissue source within the biobank research context.

Chapter 5

This chapter critically assesses the appropriateness of two governance paradigms to biobank research: one that gives the tissue source consultative prerogatives, and the other (proposed by Winickoff) that gives representative and partnership rights-holders the decision authority over future use of tissue in biobank research. The chapter examines Winickoff's partnership models as well as his charitable trust models for governance of biobanking. The chapter also examines the concept of stewardship and custodianship against this charitable trust model. It proposes the application of the concept of stewardship within the legal framework of the law of trusts as a governance mechanism which would ensure the protections of the rights of the tissue source to privacy, accommodate the dynamic consent model, and protect the proprietary entitlements of the tissue source.

Chapter 6

The Conclusion draws together the various concepts and principles that run through this thesis and make some suggestions for further work.

1. The Biobank Phenomenon and its Challenge to Informed Consent

1.1 Introduction

There is little consensus in academic literature or international research ethics regulations regarding consent and the future use of tissue and data in population biobank research. This has led to less attention being paid to downstream issues such as the rights of the tissue source and the future use of their tissue and data. While consent has been accepted as a solution to issues arising from the peculiarities of biobank research, it has not answered the questions on the future unspecified use, and neither has it addressed concerns related to the entitlement of the tissue source to exercise autonomous choice in the future use of excised tissue and data.

According to Dickenson, ‘‘consent is normally conceived as consent to the initial procedure, not to downstream uses of tissue: as a one off requirement rather than an ongoing set of powers and duties’’.[1] At the moment, once someone has consented to participate in biobank research, the only right that they have in terms of the future unspecified use of their tissue samples and data is the right to withdraw from the research. Although the right to withdraw as well as the requirement for consent are significant in ensuring the autonomy of the tissue source, especially in matters relating to participation in research, they have not adequately provided a means for the source to influence the choice of how their tissue and data are used in any future research. Moreover, as scientific advancement and statistical tools have enabled the interpretation, storage and multiple uses of data which impinges on the informational privacy of the tissue source as well as the confidentiality of their data, it has also raised questions about the use of samples and data in future unspecified biobank research, especially where such use is enabled by a broad consent model. These include:

- What is the nature of the relationship between the biobank, the researchers, and the tissue source?

[1]Dickenson, D. (2007). Property in the body: Feminist perspectives. Cambridge University Press.

- Does the legal concept of informed consent and more specifically broad consent protect the interest of the tissue source in future unspecified biobank research?
- Can the tissue source's right to have a say in the secondary use of tissue be protected?
- If so, can such protection be based on the recognition of tissue as property?
- Is the interest of the tissue source in not having the sample and associated data used in future unspecified research a protectable privacy right in law?
- Is there an entitlement of the tissue source to ground a property right claim on excised tissue within the context of biobank research?
- What role can stewardship and custodianship serve in engaging individual participation as an aspect of biobank governance within a charitable trust model?

The purpose of this first chapter is to provide context. It begins with a discussion of the biobank phenomenon and provides an overview of concepts and issues that are raised and discussed in the thesis, such as the development, definition and types of biobanks. It also provides a background to the discussion of the concepts and legal issues surrounding the future use of samples and data in biobank research. It will argue for greater recognition and protection of the interests of tissue sources from the violations inherent in biobank research, which are present notwithstanding the positive public perception of biobank research.

1.2 Background

The need to catalogue information is obvious in many fields of human endeavour. In the health sector, this need is manifested in the collection and storage of samples and data of a population, and this has led to a new way 'of organising life, of collecting, storing, and assembling life in the form of human materials known as biobanks'. Increasingly, biobanks have become a strategic tool in the field of biotechnology and genomics. In fact, this century has been referred to by Francis Collins[2] as the 'genome era' both in

[2] Collins, F. (2003) Keynote address, XIX International Congress of Genetics- Melbourne July 7 reported in Australian Biotechnology News, 8

science and in the field of medicine. Ever since the completion of the Human Genome Project,[3] biobanks containing human tissue samples and associated data have become an important means of further understanding the multifactorial nature of disease. Authorities in many countries, including the German National Ethics Council,[4] have noted the potential of biobanks in the identification of causes and the treatment of diseases.

Although the definition of a biobank is not settled and is multifaceted, it often refers to large collections of human biological tissue specimens and related data.[5] This thesis focuses on biobanks that store human tissues and data that have been established for research purposes, the value of which has gained them the appellation of the 'encyclopaedia of tomorrow'.[6] As large collections of both tissue samples and data, they serve as a platform for research into the nature of disease which will ultimately lead to improved health outcomes and to personalised medicine.[7] Tissue samples in the form of DNA, cell lines, tissue, plasma and blood have become essential tools for pharmacogenetic research and analysis that seeks to identify biomarkers and drug targets for diseases. Biobank-related research is thus of significance, not only for medical and scientific research that may benefit us in the short term, but also for all research, particularly long term and future unknown research.[8] This is because the research on stored tissue impacts not only on the genetic testing, diagnosis and treatment of diseases, but also on other complex ethical, legal, and social implications inherent in such research.[9]

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[3] The Human Genome Project was an international research effort to determine the sequence of the human genome and identify the genes that it contains. The Project was coordinated by the National Institutes of Health and the U.S. Department of Energy. Additional contributors included universities across the United States and international partners in the United Kingdom, France, Germany, Japan, and China. The Human Genome Project formally began in 1990 and was completed in 2003. http://ghr.nlm.nih.gov/handbook/hgp/description.

[4] German National Ethics Council (ed.). Biobanks for Research: Opinion. Berlin (2004), 9.Also available online at http://www.ethikrat.org/files/der_opinion_human-biobanks.pdf

[5]Sampogna, C. (2006). Creation and governance of human genetic research databases. OECD Publishing.

[6] Lyotard, J. F. (1984). The postmodern condition: A report on knowledge (Vol. 10). U of Minnesota Press.

[7] Swede, H., Stone, C. L., & Norwood, A. R. (2007). National population-based biobanks for genetic research. Genetics in Medicine, 9(3), 141-149.

[8]Kaiser, J. (2002). Population databases boom, from Iceland to the US. Science, 298(5596), 1158-1161.

[9] Greely, H. T. (2007). The uneasy ethical and legal underpinnings of large-scale genomic biobanks. Annu. Rev. Genomics Hum. Genet., 8, 343-364.

In spite of the significance of biobanks as a tool for research, much of the literature in this area has been on more upfront issues such as benefit sharing, intellectual property issues and commercial access, just to name a few, with less ink being spilt on the downstream issues that arise after enrolment in biobank research. While consent has been seen as a solution to many of the issues raised by biobank research, it has not resolved and neither has it addressed the question of informed consent both for use of databases and biological samples as well as the right of the tissue source to have a say in future research. Generally uses of biological material or information should not extend beyond those for which consent has been given. However in biobanking the problem of secondary use of tissue and data is dealt with at the time of the initial consent by obtaining broad consent permitting as yet unanticipated uses in the future. Once consent is obtained and samples and data obtained from the tissue source, the only right remaining for the tissue source is the right to withdraw from the study. From a utilitarian perspective, the right of participants to withdraw will probably be seen as unhelpful and wasteful of resources. However, it might be much worse where the withdrawal is in respect of tissue that are difficult to replace. In the opinion of the utilitarian the most efficient consent would be one that is broad enough to enable researchers use tissue without having to return to the tissue source for authorisation.

Art 1 of the International declaration on Human genetic data, states that

> The aims of this Declaration are: to ensure the respect of human dignity and protection of human rights and fundamental freedoms in the collection, processing, use and storage of human genetic data, human proteomic data and of the biological samples from which they are derived, referred to hereinafter as "biological samples",

In this regard, biobanks must adopt a rights approach using the property approach to protect the privacy of the tissue source as well as resolve the consent issues in biobank research.[10] This position has been a source of debate with utilitarians and human rights theorists lined up on opposite sides. The utilitarian continue to emphasise that once a biobank has the biological material, the source participant has no right to prevent the utilization of the material for whatever research purposes the biobank sees fit; and,

[10] Brownsword, R. (2007). Biobank governance: property, privacy, and consent in Lenk, C., Hoppe, N., & Andorno, R. (Eds) (2007). *Ethics and law of intellectual property: current problems in politics, science and technology* (90-93). Ashgate.

because there is no such covering right, there is no requirement on the biobank to seek the participant's fresh authorization for secondary research purposes. [11] However, where the tissue source is aggrieved by downstream exploitation or privatization, or the assertion of intellectual property rights and the like, in the absence of their own proprietary stake in the source materials they are in no position to object.

The following section will examine the meaning of 'biobank'. It will also examine types of biobanks which will be categorised as large-scale population biobanks, clinical biobanks, and commercial and private biobanks.

1.3 What is a biobank?

While there appears to be a consensus about what constitutes a biobank, there is very little agreement on its definition.[12] However, the focus of this thesis is on large-scale population collections of human biological materials and associated data; this is known here as a biobank.[13] The term 'biobank' is, however, being increasingly used as an umbrella term to describe *any* collection of biospecimens or human genetic information that can be used for research purposes.[14] One of the more general ways in which the term is being used[15] is as 'an organised collection of human biological material and associated information stored for one or more research purposes'.[16] The Nigerian policy statement on storage of human samples in biobank and biorepositories, for instance, defines a biobank as a type of repository that stores biological samples that may be from human or non-human sources.[17] Such samples may be derived from research, medical or

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[11] Ibid

[12] Shaw, D. M., Elger, B. S., & Colledge, F. (2014). What is a biobank? Differing definitions among biobank stakeholders. *Clinical Genetics*, 85(3), 223-227.

[13] Gibbons, S., Kaye, J., Smart, A., Heeney, C., & Parker, M. (2007). Governing genetic databases: Challenges facing research regulation and practice. *Journal of Law and Society*, 34(2), 163-189 at 172

[14] Richard Tutton and Oonagh Corrigan, *Genetic Databases: Socio-Ethical Issues in the Collection and Use of DNA* (London: Routledge, 2004). 'Biospecimen repositories' also refers to repositories of fluid and human tissue biospecimens, but whether it functions like a human genetic database depends on whether these repositories also collect personal health data for the purpose of genomics research.

[15] Cambon-Thomsen, A., Rial-Sebbag, E., & Knoppers, B. M. (2007). Trends in ethical and legal frameworks for the use of human biobanks. *European Respiratory Journal*, 30(2), 373-382.

[16] Hewitt, R. E. (2011). Biobanking: the foundation of personalized medicine. *Current Opinion in Oncology*, 23(1), 112-119; Kauffmann, F., Cambon-Thomsen, A. (2008). Tracing Biological Collections: Between Books and Clinical Trials. *JAMA: the Journal of the American Medical Association*, 299 (19): 2316–2318.

[17] The Nigerian Policy statement on biobanks. Available at http://nhrec.net/nhrec/NHREC_Policy_Statement_on_Biobanks_FINAL.pdf last accessed 14/10 2014

veterinary practice.[18] This definition defines a biobank in terms of its feature as a long-term storage facility, as well as a platform for access to research. This definition is peculiar in terms of the type of samples it accommodates; it encompasses both human and veterinary samples and data. Mats Hansson has described a biobank as 'collections of human biological material within the health care system and the medical sciences'.[19] This definition does not take into account information linkage as a feature of biobanks which distinguishes it from the more traditional collection of biospecimens such as a tissue bank which stores tissue samples only, without collecting and banking associated genealogical and personal health data.

As can be seen from Hansson's[20] definition, a broad use of the term biobank to cover all types of collections of human biological samples may pose challenges. This is because the various types of collections with their different structures and purposes raise different technological, ethical and legal issues for secondary uses in future research. For instance, the collection of human tissue samples must be carried out in accordance with accepted legal and ethical standards, one of which is the requirements of consent. In relation to existing collections, privacy rules and principles restrict the use of data other than for the purposes for which they were collected. However, for pre-existing collections which may have been held in long-term storage without any definite consent, such collections may be used for other research subject to institutional review board (IRB) approval.[21]

The Organisation for Economic Co-operation and Development (OECD)[22] defines biobanks as:

> 'structured resources that can be used for the purpose of genetic research and which include:

[18] Available at http://nhrec.net/nhrec/NHREC_Policy_Statement_on_Biobanks_FINAL.pdf last accessed 14/10 2014

[19] Hansson, M. ed. *The Use of Human Biobank: Ethical, Social, Economic and Legal Aspects* (Uppsala: Uppsala University, 2001) Available at http://www.bioethics.uu.se/biobanks-report.html.

[20] Ibid

[21] Hansson, M. G., Dillner, J., Bartram, C. R., Carlson, J. A., & Helgesson, G. (2006). Should donors be allowed to give broad consent to future biobank research? *The Lancet Oncology*, 7(3), 266-269.

[22] OECD Guidelines on Human Biobanks and Genetic Research Databases. (2009). Available at http://www.oecd.org/sti/biotech/44054609.pdf.

(i) human biological materials and/or information generated from the analysis of the same; and

(ii) extensive associated information'.

This definition recognises that the field of biobanking is very broad and defines it in terms that are encompassing to make it applicable to many kinds of human biobanks, reflecting their diversity of purpose and operation which includes therapeutic and non-therapeutic, as well as forensic enquiry. In the report on *Best Practices for Biospecimen Resources* published by the U.S. National Cancer Institute (2007), a 'biospecimen resource' is defined as 'a collection of human specimens, the physical structure where the collection is stored, associated data for research purposes, and all relevant processes and policies'.[23] This definition is very similar in terms to the OECD definition and it recognises the diversity of uses and characteristics of a biobank.[24] The UK Biobank Ethics and Governance Council, by contrast, has stated that 'the most robust contemporary definition of 'biobanks' is rich collections of data plus biospecimens, specifically developed as resources for research'.[25]

These varying definitions are indications of the plethora of available definitions and meanings of the term. The broad use of 'biobank' to cover all types of collections of human specimens and associated data creates difficulties as the different types of collections with different structures and purposes raise different technological, ethical and legal considerations.[26] Many collections of human tissue were developed for purposes other than future research, primarily for limited research, diagnostic and clinical purposes. These collections were usually developed with limited consent regimes that did not conceive secondary use of these samples and associated data.[27] Collections of this nature raise legal questions of the validity and legality of such reuse

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[23] National Cancer Institute Office of Biorepositories and Biospecimen Research, National Institutes of Health, U.S. Department of Health and Human Services, 'Best Practices for Biospecimen Resources,' (2007). P. 58, see: http://biospecimens.cancer.gov/bestpractices/2011-NCIBestPractices.pdf (Last visit: 2 April 2014)

[24] National Health and Medical Research Council Australian Government, 'Biobanks Information Paper,'(2010). 9

[25] UK Biobank Ethics and Governance Council. Report on Public meeting of the UK Biobank Ethics and Governance Council, 11th June 2007

[26] National Health and Medical Research Council Australian Government, 'Biobanks Information Paper,'(2010). 9 Corrigan, O., & Tutton, R. (eds) (2013). *Genetic databases: Socio-ethical issues in the collection and use of DNA*. Routledge. 2

[27] Widdows, H., & Mullen, C. (eds) (2009). *The Governance of Genetic Information: Who Decides?* (Vol. 9). Cambridge University Press.

without the consent of the tissue source. Biobanks today are established generally with the aim of conducting long term research that is not specific, but may also cover a spectrum of future research purposes. Existing collections of samples and data, if collected for a particular research purpose, may require re-consent or ethics review board approval if the samples or data are to be used for research or purposes which are at variance with that covered by the original consent.[28]

The following section examines the peculiar features of a biobank with a view to highlighting how these features challenge the traditional approaches to obtaining consent for research on humans and consequently, challenge the protection of the tissue source in biobank research.

1.4 Features of a biobank

Although biobanks are a relatively new phenomenon, they have risen in number and now operate even across borders. This expansion has been fuelled by a growing recognition by scientists of the need to carry out studies of normal genomic variation across populations to understand the complexity of diseases and human health.[29] Commentators like Knoppers and Gibbons[30] have noted that the move from genetic to genomic research[31] requires increasingly large collections of samples and associated medical data that only biobanks can provide.[32]

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[28] Coughlin, S. S. (2011). Broad consent and biorepositories for molecular epidemiology and genomics research. *International journal of molecular epidemiology and genetics*, 2(4), 401. S.32 of the 2013 revised declaration of Helsinki states:

> 'For medical research using identifiable human material or data, such as research on material or data contained in biobanks or similar repositories, physicians must seek informed consent for its collection, storage and/or reuse. There may be exceptional situations where-consent would be impossible or impracticable to obtain for such research. In such situations the research may be done only after consideration and approval of a research ethics committee'.

The UK Biobank ethics and governance framework contains an assurance that only research uses that have been approved by both UK Biobank and a relevant ethics committee will be allowed, and that data and samples will be anonymised before being provided to research users. Available at http://www.ukbiobank.ac.uk/wp content/uploads/2011/05/EGF20082.pdf

[29] Knoppers, B. M., Abdul-Rahman, M. N. H., & Bédard, K. (2007). Genomic databases and international collaboration. *KLJ*, 18, 291.

[30] Gibbons, S. M., & Kaye, J. (2007). Governing genetic databases: collection, storage and use. *KLJ*, 18(2), 201.

[31] World Health Organisation. (2002). *Genomics and world health: Report of the Advisory Committee on Health Research*, the difference between genomics and genetics is that genetics scrutinises the functioning and composition of a single gene whereas genomics addresses all genes and their inter relationships in order to identify their combined influence on the growth and development of the organism.

[32] Knoppers, B. M., Abdul-Rahman, M. N. H., & Bédard, K. (2007). Genomic databases and international collaboration. *KLJ*, 18, 291 at 292-293

1.4.1 Size

Biobanks vary in size, scale and research scope. They range from small hospital- or academia-based repositories to large-scale population-wide collections.[33] Hospital and academic collections, including pathology archives, are usually smaller in size than population wide collections and have usually evolved to support clinical health care, whereas others such as population wide collections have been developed primarily to support research.[34] Research biobanks may be disease-specific, they may contain samples from individuals who have the same disease, or they may be population based such as the Icelandic Health Sector Database (IHSD), the Estonian Genome Project and the UK Biobank. The purpose of these collections is to provide a resource for other research by investigating the correlation between SNPs[35] or haplotypes[36] and the pattern of common diseases.[37] These collections contain specimens from individuals who may or may not be suffering from disease. Large-scale population biobanks are generally specifically created as resources for unknown future research projects.[38] Population-based biobanks are not necessarily research projects, but rather infrastructures designed to support a number of studies. This feature provides a platform for prospective studies in which researchers can draw conclusions about relationships between risk factors and disease from the large numbers of samples made available for research into complex disease-susceptible genes.[39] These types of biobanks typically recruit healthy donors who are representative of a specific region, country, or ethnic group.[40]

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[33] Maschke, K. J. (2005). Navigating an ethical patchwork human gene banks. *Nature biotechnology*, 23(5), 539-546.

[34] Watson, H., Wilson-McManus, J. E., Barnes, R. O., Giesz, S. C., Png, A., Hegele, R. G., et al. (2009). Evolutionary concepts in biobanking—the BC BioLibrary. *Journal of Translational Medicine*, 7(1), 95.

[35] A Single Nucleotide Polymorphism (SNP) is a DNA sequence variation occurring commonly within a population (e.g. 1%) in which a single nucleotide in the genome (or other shared sequence) differs between members of a biological species or paired chromosomes.

[36] A haplotype is a set of DNA variations, or polymorphisms, that tend to be inherited together. It can also refer to a combination of alleles or to a set of single nucleotide polymorphisms (SNPs) found on the same chromosome.

[37] Gibbons, S. M., & Kaye, J. (2007). Governing genetic databases: collection, storage and use. *KLJ*, 18(2), 201.

[38] Otlowski, M., Nicol, D., & Stranger, M. (2009). Biobanks information paper 2010. JL Inf. & Sci., 20, 87.

[39] Swede, H., Stone, C. L., & Norwood, A. R. (2007). National population-based biobanks for genetic research. *Genetics in Medicine*, 9(3), 141-149.

[40] Asslaber M, Zatloukal K., Biobanks: transnational, European and global networks, *Briefings in Functional Genomics and Proteomics.* 2007, Vol. 6, No. 3, 193-201; Riegman PH, Morente MM, Betsou F, de Blasio P, Geary P, Biobanking for better healthcare and the Marble Arch International Working Group on Biobanking for Biomedical Research, *Molecular Oncology.* (2008), Vol. 2, No. 3, 213-222.

The need for these large biobanks, as opposed to smaller ones, has been questioned with some commentators dismissing the need for large biobanks as needless for common disorders.[41] Nevertheless, large population biobanks have come to be acknowledged as useful tools in genomic research not only as repositories but also as a means of measuring non-genetic environmental factors and their impact on diseases.[42] The more comprehensive types of population-based biobanks are those designed to link biomarkers with medical history and lifestyle information. This is because diseases that arise from single gene mutations are rare.[43] Most diseases are caused by multiple genetic factors or multiple genes, hence population biobanks provide the tool that can contribute to our understanding of the genetic and environmental determinants leading to diseases such as diabetes, Alzheimer's disease, asthma, schizophrenia, and cancer, and to adverse outcomes such as preterm birth and congenital birth defects.[44] These biobanks are known to range in size from several thousand samples, to huge collections containing nearly a million biospecimens and related health information data.[45] A notable example of a large-scale population biobank created at the national level is the UK Biobank.[46]

In spite of the growing significance of the size of biobanks, they raise a number of ethical and legal issues such as types and modes of consent, implications of data sharing, privacy and confidentiality of the tissue source. As Cambon-Thomsen has remarked,

> 'The trend towards larger biobanks also raises concerns about how to ensure the ethical use of human samples and the associated information. Most researchers agree on the great potential of biobanks, but realise that the principal obstacle to their success depends on their acceptance by the public. Even lawmakers are

[41] Ibid.

[42] Caulfield, T. (2007). Biobanks and blanket consent: the proper place of the public good and public perception rationales. *KLJ*, 18, 209 at 213

[43] Burke W., Khoury M.J., Stewart A, Zimmern R.L., (2006) Bellagio Group. The path from genome-based research to population health: development of an international public health genomics network. *Genet Med*, 8, 451–458.

[44] Swede, H., Stone, C. L., & Norwood, A. R. (2007). National population-based biobanks for genetic research. *Genetics in Medicine*, 9(3), 141-149.

[45] The UK Biobank contains diverse samples from at least 500,000 citizens from across the UK

[46] https://www.ukbiobank.ac.uk/

> hesitant to proceed as long as the ethical environment and public acceptance remain unclear'.[47]

Since the involvement of tissue sources is essential for the success of biobank research it is important that adequate safeguards are put in place to protect the interest of the tissue source. As Winickoff and Neumann have pointed out, 'the sustainability of large-cohort genomics will require institutional, procedural and substantive legitimacy in order to secure […] the willing participation [and enduring trust] of volunteer subjects over time'.[48]

1.4.2 Open-ended feature of biobanks

Biobanks, whether they are population based research biobanks or biobanks based on biological specimens from patients or donors, are typically projects involving research which is not only ongoing but also future oriented.[49] This research may be unspecified at the time of the establishment of the biobank, and even at the time of tissue and data collection.[50] This feature of biobank research challenges the concept of consent as a tool of ensuring the autonomous decision of the tissue source in the research. Consent is one of the cardinal principles in health research which is designed to promote self-determination and autonomy by allowing the research participant to make informed choices in relation to participation.[51]

Express informed consent has been the standard requirement in research on humans to protect the research subject's freedom of choice and autonomy.[52] According to Pattinson,[53] it is a precondition for autonomous decision making, ethics and law demand that people have a right to self-determination and choice about matters relating to

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[47] Cambon-Thomsen, A. (2004). The social and ethical issues of post-genomic human biobanks. *Nature Reviews Genetics*, 5(11), 866-873 at 867

[48] Winickoff, D. E., & Neumann, L. B. (2005). Towards a social contract for genomics: Property and the public in the 'biotrust' model. *Life Sciences Society and Policy*, 1(3), 8 at 8 and 10.

[49] Gottweis, H., & Petersen, A. (eds)(2008). *Biobanks: Governance in comparative perspective*. Routledge. 5

[50] Elger, B. S., & Caplan, A. L. (2006). Consent and anonymisation in research involving biobanks. *EMBO reports*, 7(7), 661-666.

[51] World Medical Association. (2008). Declaration of Helsinki. Ethical principles for medical research involving human subjects. Available at *http://www.wma.net/e/policy/b*3.*htm*.

[52] Council for International Organisations of Medical Sciences. (2002). International ethical guidelines for biomedical research involving human subjects. *Bulletin of Medical Ethics*, 182, 17; Secko, D. M., Preto, N., Niemeyer, S., & Burgess, M. M. (2009). Informed consent in biobank research: a deliberative approach to the debate. *Social Science & Medicine*, 68(4), 781–789.

[53] Pattinson, S. D. (2009). *Medical law and ethics*, at 97

themselves. In biobank research, the principle of consent is not at all clear cut. Individuals who consent to participate in biobanks cannot be fully informed of future research involving their samples or data, because biobanks are set up to collect samples and act as a platform for future open-ended research.[54] Also, the open-ended nature of biobank research, the almost endless list of possible research that may be carried out on stored samples and data makes it difficult for the tissue sources to choose which research they want their sample used in. The right to choice is predicated on disclosure of information about the future research which is usually unknown at the point of enrolment.

In *Chester v Afshar*,[55] Lord Steyn, quoting Ronald Dworkin, argues that full information is:

> '…the most plausible [account] that emphasises the integrity rather than the welfare of the choosing agent; the value of autonomy, on this view, derives from the capacity it protects: the capacity to express one's own character – values, commitments, convictions, and critical as well as experiential interests – in the life one leads'.

In the same vein, to protect the autonomous choice of the tissue source, biobanks should at the time of enrolment provide information to participants before obtaining broad consent for the research purposes of the biobank.[56] Such consent, though broad in nature, requires full information as well as the voluntary participation of the participant before enrolment.[57] According to the *Ethics and Governance Framework of the UK Biobank*, such consent for such future research purposes remains applicable until it is withdrawn by the applicant. There have been suggestions that the issue of the long term commitment to future research purposes of a biobank relates not only to the

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[54] Hansson, M. G., Dillner, J., Bartram, C. R., Carlson, J. A., & Helgesson, G. (2006). Should donors be allowed to give broad consent to future biobank research? *The Lancet Oncology*, 7(3), 266-269.

[55] *Chester v. Afshar*, [2004] UKHL 41.

[56] Hansson, M. G., Dillner, J., Bartram, C. R., Carlson, J. A., & Helgesson, G. (2006). Should donors be allowed to give broad consent to future biobank research? *The Lancet Oncology*, 7(3), 266-269.

[57] Biobank, U. K. (2007). *UK Biobank ethics and governance framework*. S.26 of the declaration of Helsinki Revised (2013):

> 'In medical research involving human subjects capable of giving informed consent, each potential subject must be adequately informed of the aims, methods, sources of funding, any possible conflicts of interest, institutional affiliations of the researcher, the anticipated benefits and potential risks of the study and the discomfort it may entail, post-study provisions and any other relevant aspects of the study. The potential subject must be informed of the right to refuse to participate in the study or to withdraw consent to participate at any time without reprisal. Special attention should be given to the specific information needs of individual potential subjects as well as to the methods used to deliver the information'.

voluntariness of the initial consent, but also to the need to revisit the idea of specific consent to research projects.[58] The specific consent approach has been extensively argued to be inappropriate for biobank research because it hampers research.[59] Another issue that has been argued to complicate the use of specific consent in biobank research is that strict adherence to this traditional model of consent would require that the tissue source be contacted again every time there was a future use for their sample or data. This has been argued, would be difficult for financial and logistic reasons; moreover, the physical risk to the tissue source is very low – much lower than in clinical research – and the potential of a valuable outcome generally is so high that the requirements for participation in biobank research should not require renewed consent for each instance of further research.[60]As Kaye and Caulifield have noted, 'there is a broad spectrum of diverse opinion and conflicting positions in bioethics literature and policy documents in relation to the appropriateness of broad consent'.[61]

Within this broad spectrum are positions that support the use of broad consent as a suitable means of consenting to biobank research as well as a growing counter position that broad consent to future unspecified research is legally and ethically unacceptable,[62] and that the only legitimate form of consent for research biobanks is to contact the tissue source and request fresh consent.[63] Even if broad consent does not require a researcher to seek specific consent to use the samples and data in future research, common law and statute may be invoked to safeguard the source's right to control the disposition of their body parts. In spite of the extensive literature on the topic of consent and biobank research, existing ethical conventions remain inadequate to guide the appropriate consent for open-ended use and future uses of tissue in biobank research.

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[58] Kaye, J. (2004). Abandoning informed consent. *Genetic databases: socio-ethical issues in the collection and use of DNA*. Routledge, London, 117-138.

[59] Elger, B. S. (2008). Consent and use of samples. *Ethical Issues in Governing Biobanks: Global Perspectives*, 57-87.

[60] Hansson, M. G., Dillner, J., Bartram, C. R., Carlson, J. A., & Helgesson, G. (2006). Should donors be allowed to give broad consent to future biobank research? *The Lancet Oncology*, 7(3), 266-269. Helgesson, G., & Eriksson, S. (2008). Against the principle that the individual shall have priority over science. *Journal of Medical Ethics*, 34(1), 54-56.

[61] Kaye, J. (2004). Abandoning informed consent. Genetic databases: socio-ethical issues in the collection and use of DNA. Routledge, London, 117-138

[62] Árnason, V. (2004). Coding and consent: moral challenges of the database project in Iceland. *Bioethics*, 18(1), 27-49.

[63] Cambon-Thomsen, A., Rial-Sebbag, E., & Knoppers, B. M. (2007). Trends in ethical and legal frameworks for the use of human biobanks. *European Respiratory Journal*, 30(2), 373-382.

This conflict between the traditional requirement of specific consent for research on humans and the peculiarity of biobank research as being open-ended in nature challenges the traditional understanding and modes of informed consent[64] (see Chapter 2).

Generally, consent traditionally authorises a researcher to have physical contact with the participant. Consent also protects the rights of research participants to exercise autonomy and retain control over what happens to them.[65] However, in relation to biobank research, when research participants provide tissue and information to biobanks, they cannot give informed consent to future unspecified research projects because at the point of enrolment that future research is unknown. Rather they give broad consent to a plethora of research purposes which is in effect consenting to no specific research. Consequently, because classical research ethics[66] requires that participants should give consent for each new research after having been informed about the details, this traditional specific consent approach has been argued by some to be not only costly,[67] but also to endanger the scientific value of the entire biobank project, as it is highly probable that a considerable percentage of participants may be lost in the process.[68]

1.5 Sharing biobank samples and data in research

Another of the defining features of biobanks is that, by their nature, they are primarily established for sharing resources. They provide access to researchers other than the custodians of the biobank for ethically approved research purposes.[69] This important feature of biobanks poses some challenges to both researcher and tissue source. It creates challenges of striking a happy balance between the freedom to conduct research

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[64] Otlowski, M., Nicol, D., & Stranger, M. (2009). Biobanks information paper 2010. *JL Inf. & Sci.*, 20, 87.

[65] Beauchamp, T. L., & Childress, J. F. (2001). *Principles of biomedical ethics*. Oxford University Press.

[66] Annas, G.J., Glantz, L.H., & Roche, A. (1995). Drafting the Genetic Privacy Act: science, policy, and practical considerations. *The Journal of Law, Medicine & Ethics*, 23(4), 360-366.

[67] Korn D (1999) Contribution of the Human Tissue Archive to the advancement of medical knowledge and the public health. In *National Bioethics Advisory Commission, Research involving Human Biological Materials: Ethical Issues and Policy Guidance*, Vol II pp E1–E30. Rockville, MD, USA: National Bioethics Advisory Commission.

[68] Bathe, O. F., & McGuire, A. L. (2009). The ethical use of existing samples for genome research. *Genetics in Medicine*, 11(10), 712-715.

[69] Wolf, S. M., Crock, B. N., Van Ness, B., Lawrenz, F., Kahn, J., Beskow, L. M., & Wolf, W. A. (2012). Managing incidental findings and research results in genomic research involving biobanks and archived data sets. *Genetics in Medicine*, 14(4), 361-384.

for the public good and the rights of the tissue source to privacy, dignity and autonomy.[70] Global data sharing of biobank research challenges the traditional mechanism of protecting the privacy and autonomy of tissue sources in the sense that it challenges the requirement of guaranteeing anonymity.[71] For instance, the genetic research database used for the HapMap Project[72] stored and published de-identified genetic information compiled from multiple donors. The samples and cell lines used in this project can only be identified on the face of it as coming from one of the four populations that took part in the study. The data was not linked to any specific individual participant, which distinguishes it from a biobank where re-identification and data linkage are both possible and necessary. This distinction helps to clarify the use of the term biobank in this thesis; it refers to large collections of human biological materials that may be linked with personal information.

Generally, biobanked information is anonymised and not identifiable. However, it remains potentially re-identifiable. Biobanks that can be linked to Electronic Health Records have an especially rich resource from which to draw a wealth of data.[73] This is primarily for the purpose of fulfilling ethical and legal obligations to act on new information such as incidental findings (IF) that may impact on the health of the tissue source.[74] An IF is 'a finding concerning an individual research participant [or here, a tissue source] that has potential health or reproductive importance and is discovered in the course of conducting research but beyond the aims of the study.'[75] There is very little consensus on managing incidental findings from biobank research and in particular its implications for confidentiality of the tissue source in secondary research. IF may be discovered at any stage of research. Where it is discovered during secondary use as a

[70] Kaye, J. (2012). The tension between data sharing and the protection of privacy in genomics research. *Annual review of genomics and human genetics*, 13, 415-431.
[71] Ibid.
[72] The International HapMap Project is a multi-national effort to identify and catalogue genetic similarities and differences in humans. Using the information in the HapMap, researchers will be able to find genes that affect health, disease, and individual responses to medications and environmental factors. It is a collaboration between scientists and funding agencies from Japan, the United Kingdom, Canada, China, Nigeria, and the United States.
[73] Olson, J. E., Bielinski, S. J., Ryu, E., Winkler, E. M., Takahashi, Y., Pathak, J., & Cerhan, J. R. (2014). Biobanks and personalized medicine. *Clinical genetics*, 86(1), 50-55.
[74] Wolf, S. M., Lawrenz, F., Nelson, C. A., Kahn, J., Cho, M. K., Clayton, E. W., & Wilfond, B. S. (2008). Managing incidental findings in human subjects research: analysis and recommendations. *The Journal of Law, Medicine & Ethics*, 36(2), 219-248.
[75] Ibid.

result of sharing information and data with other researchers, the privacy of the tissue source may be compromised in the sense that their otherwise confidential health status is known to a researcher who has no direct connection with the source. In the context of a biobank research system, primary researchers and biobanks should anticipate how they will handle identification or re-identification of contributors for return of IFs. They should also strive to reach an agreement on this in advance, which should be reflected in the informed consent process.[76] They will also need to consider how any consent process will address whether any IFs identified in the biobank research will be offered back to tissue sources, what type of findings will potentially be returned, whether individual tissue sources consent to return, whether those sources are willing to share samples and data, and reversible identification of data.[77] Under the framework, this is done by ensuring that all identifying information is held centrally in a restricted access database by UK Biobank which is controlled by senior UK Biobank staff. Only a few people within the UK Biobank have access to the code which would allow the relinking of the participants.[78]

1.6 Interwoven governance arrangement of biobanks

Biobanks are characterised by a network of laws, contracts, guidelines, protocols and procedures. This can be attributed to their scale of operations. Population biobanks often include the information of a significant proportion of the population.[79] Underscoring this are the sensitivities that surround biobank research.[80] Biobanks consist of highly complex and multi-connected networks whose interrelated operations depend on a multitude of factors. Thus, the need for biobank research, the related, substantial investments in them, and the expectations connected with them raises issues that cut across several areas of the law, science and medicine.

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[76] Wolf, S. M., Lawrenz, F., Nelson, C. A., Kahn, J., Cho, M. K., Clayton, E. W., & Wilford, B. S. (2008). Managing incidental findings in human subjects research: analysis and recommendations. *The Journal of Law, Medicine & Ethics*, 36(2), 219-248.

[77] For example para 11 of the *UK Biobank and Governance Framework* (2007) provides for a reversible identification of data.

[78] Biobank, U. K. (2007). UK Biobank ethics and governance framework Para 8(c) 1-3 Available at http://www.ukbiobank.ac.uk/wp content/uploads/2011/05/EGF20082.pdf last accessed 19 Jan 2015.

[79] Cambon-Thomsen, A. (2004). The social and ethical issues of post-genomic human biobanks. *Nature Reviews Genetics*, 5(11), 866-873.

[80] Greely, H. T. (2007). The uneasy ethical and legal underpinnings of large-scale genomic biobanks. *Annu. Rev. Genomics Hum. Genet*, 8, 343-364.

The processes of governance of biobank research are complex because there is a lack of uniform and established systems and procedures for decision-making. This is true even if there is national legislation in place, because the regulations capture only a fraction of the relevant issues that come up in the governance of biobank research.[81] Therefore, the search for governance solutions becomes inseparable from a search for adequate and legitimate procedures for decision making in biobank research. Hajer and Wagenaar termed this an 'institutional void', a situation in which:

> 'there are no pre-given rules that determine who is responsible, who has authority over whom, [and] what sort of accountability is to be expected raising issues of specificity and uniformity of governance in a field that cut across national boundaries'.[82]

Brownsword [83]offers three options for governance: 1. An across-the-board regime of strong provisions on property and consent; 2. a mixed regime of provisions relation to property, privacy and consent; and 3. an across-the-board regime of weak provisions on property, privacy and consent. Under a rights ethic regime option 1 rather than 3 would be preferred, but within a more utilitarian ethic approach, options 1 and 2 might be a ready compromise in the sense that they support the interest of the research community as well as protect biobank operators. This is because the general approach of utilitarian ethics is that governance regimes should seek to maximize utility and minimize disutility. In other words, regulators should aim more at optimizing welfare such as public health and happiness than making provision for privacy property and consent.[84]

In *Greenberg v. Miami Children's Hospital Research Institute, Inc.,*[85] the claimants included a group of parents who gave birth to children afflicted with Canavan disease, as well as three non-profit community groups dedicated to assisting those affected by the condition. All claimants supplied tissue, autopsy reports, blood, urine, and other

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[81] Gottweis, H., & Lauss, G. (2012). Biobank governance: heterogeneous modes of ordering and democratization. *Journal of Community Genetics*, 3(2), 61-72.

[82] Hajer, M. A., & Wagenaar, H. (eds)(2003). Deliberative policy analysis: understanding governance in the network society. Cambridge University Press.

[83]Brownsword, R. (2007). Biobank governance: property, privacy, and consent in Lenk, C., Hoppe, N., & Andorno, R. (eds)(2007). *Ethics and law of intellectual property: current problems in politics, science and technology* (90-93). Ashgate.

[84]Brownsword, R. (2007). Biobank governance: property, privacy, and consent in Lenk, C., Hoppe, N., & Andorno, R. (Eds.). (2007). *Ethics and law of intellectual property: current problems in politics, science and technology* (pp. 90-93). Ashgate.

[85] Greenberg v. MIAMI CHILDREN'S HOSPITAL RES. INST., INC., 264 F. Supp. 2d 1064 (S.D. Fla. 2003).

pathology samples, personal data, funding, and other resources in order to advance medical research on the disease. The claimants alleged that the defendants, a scientific researcher and a hospital, breached both their duty of informed consent and their fiduciary duty when they failed to disclose to the claimants their intention to patent the gene and the diagnostic test for Canavan disease. The claimants also asserted that the defendants wrongfully converted the claimants' property by using their contributions to reap personal economic benefit rather than to promote widely affordable and accessible carrier and prenatal testing for Canavan disease in accordance with the claimants' goals. According to the claimants, had they known of the defendants' intention to patent the gene associated with Canavan disease, they would have imposed restrictions on the researchers' use of their genetic material in order to avoid commercialisation of the Canavan disease gene, or would have chosen to donate their samples to researchers who pursued objectives compatible with their own. Based upon these same facts, the claimants also asserted claims of unjust enrichment, fraudulent concealment, and misappropriation of trade secrets. The court dismissed their claims but upheld the unjust enrichment cause of action.

From this it be seen that biobank operations and the governance of biobanks necessarily cuts across many areas of law. It raises questions of governance as a result of which issues such as type of consent for future unspecified research, possible privacy infringement arising from future use of samples, and data and property rights in tissue have arisen. A biobank governing body should, therefore, establish policies and guidelines on access of researchers to data and samples consistent with the governance aims of the biobank to prevent privacy infringement.[86] The access granted to researchers should also be monitored to ensure that its use by these researchers is consistent with the consent of the participant. In furtherance of this, biobanks guidelines and Material Transfer Agreement (MTA) should prescribe the allowable research purposes for the data and samples.[87]

[86] Chalmers, D. (2011). Genetic research and biobanks. In *Methods in Biobanking* (1-37). Humana Press.

[87] Corrigan, O., & Tutton, R. (eds)(2004). Genetic databases: Socio-ethical issues in the collection and use of DNA. Psychology Press.

1.7 Biobank public research focus.

Another characteristic of biobanks is that they have a public interest focus, being less concerned about individual benefit for the participants themselves and more about benefitting the general public. This feature of biobanks presents challenges to the individualist protection of the tissue source. For example, biobanking adopts a collectivist principle that emphasises utilitarian public good based benefits, while the approach to the protection of the tissue source is based on an individualist ethic that emphasises a rights ethic of autonomous decision making, which may also be for personal benefit.[88] This creates a conflict, particularly in the case of biobank research, where a collectivist and communitarian approach implies that the individual interest and that of the public are interconnected, and so imposes a responsibility on the individual beyond their personal interest. The stand point of the individual, on the other hand, is that even under this circumstance, the individual has a right to decide whether or not their samples and data are used in future research. This opposing standpoint may give rise to a deadlock in which individual rights and the public good may appear irreconcilable. It should be borne in mind that certain individual interests are also public interests, and both can only be achieved through striking a balance between the two positions. In addition, as biobanks are more concerned with the public benefit of the fruits of research to future generations rather than with the individual benefit of tissue sources, they have a common good focus, but this raises the need for biobanks to have mechanisms for balancing individual and collective interests in their research.

Some biobanks have been established to support both public and private research, and some of this research may have commercial outcomes.[89] There is evidence that people are sceptical about commercialisation, because they are uneasy about having their altruism converted into money making ventures for multinational companies.[90] Recognising that commercialisation affects public trust in research, most biobanks have embedded in their governance procedures mechanisms that protect the interests of the

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[88] Meslin, E. M., & Garba, I. (2011). Biobanking and public health: is a human rights approach the tie that binds? *Human genetics*, 130(3), 451-463.

[89] Andrews, L. B. (2005). Harnessing the benefits of biobanks. *The Journal of Law, Medicine & Ethics*, 33(1), 22-30.

[90] Chalmers, D., & Nicol, D. (2004). Commercialisation of biotechnology: public trust and research. *International Journal of Biotechnology*, 6(2), 116-133.

tissue source. These mechanisms include the requirement for review by a research ethics committee. For instance, the *UK Biobank and Ethics Governance Framework* contains provisions requiring that the core scientific protocol and operational procedures of the UK Biobank resource, as well as the proposed uses of it, will have approval from appropriate ethics committees in accordance with guidance from relevant bodies such as the National Health Research Ethics Service.[91]

Beyond these shared characteristics, there are a number of significant variations between biobanks, such as:

- the scale of the biobank;
- the health status of participants – the biobank may target healthy people, those with a specific disease or condition, or a combination of both;
- the approach to coding and privacy and the extent to which data linkage is possible; and
- the nature of the collection – whether it is purely prospective, comprises pre-existing collections, or is a combination of both.

These variables will influence a range of biobank activities, including recruitment of participants; consent (and re-consent); data management, including issues with respect to privacy and recontact; governance arrangements; and access, commercialisation and benefit sharing. Even though the primary focus of this thesis is on public biobanks as opposed to private banks, the following paragraphs will itemise and examine the various types of biobanks as reference may be made to some of this biobanks in other chapters of this thesis.

1.8 Types of biobank

1.8.1. Population/large scale biobanks.

A population-based biobank has been described as a repository consisting of a large collection of biological tissue donated by thousands of individuals from the general

[91] UK Biobank, (2007). UK Biobank ethics and governance framework.

population who might or might not have a specific disease.[92] Examples of population biobanks include, the UK Biobank, LIFE Gene in Sweden and DeCode Genetic in Iceland. The main research objective of a population based biobank is generally to discover biomarkers for disease susceptibility within a specific population through epidemiology research. The UK Biobank, for example, has collected samples and health data from 500,000 individuals between 40 and 69 years of age. According to the biobank's homepage, it is a major national health resource:

> '…with the aim of improving the prevention, diagnosis and treatment of a wide range of serious and life-threatening illnesses, including cancer, heart diseases, stroke, diabetes, arthritis, osteoporosis, eye disorders, depression and forms of dementia'.

The European Committee of Ministers to member states on research on biological materials of human origin defined population biobanks in Art. 17 of its recommendation as a collection of biological materials that has the following characteristics:[93]

- A collection that has a population basis;
- It is established, or has been converted, to supply biological materials or data derived therefrom for multiple future research projects;
- It contains biological materials and associated personal data, which may include or be linked to genealogical, medical and lifestyle data and which may be regularly updated;
- It receives and supplies materials in an organised manner.

1.8.2 Clinical biobanks

Biobanks vary in size and in the nature of the activities that they carry out. Clinical biobanks are usually hospital based and may include pathology archives. These collections have usually evolved to support clinical care while others have developed to support ongoing research within their host institutions.[94] Clinical biobanks often contain

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[92] Corrigan, O. (2006). Biobanks: can they overcome controversy and deliver on their promise to unravel the origins of common diseases? *Medical education*, 40(6), 500-502.

[93] Recommendation Rec(2006)4 of the Committee of Ministers to member states on research on biological materials of human origin at https://wcd.coe.int/ViewDoc.jsp?id=977859 last accessed 16 May 2014

[94] Watson, H., Wilson-McManus, J. E., Barnes, R. O., Giesz, S. C., Png, A., Hegele, R. G., et al. (2009). Evolutionary concepts in biobanking—the BC BioLibrary. Journal of translational medicine, 7(1), 95.

leftover samples from health care which are stored and possibly used in research, or dedicated to research biobanks built up during the course of a particular study. Clinical biobanks also include collections of tissue and data which may have been held in long-term storage or obtained from left over specimens of routine clinical investigations.[95] Historically hospitals holding tissue did not presume refusal of consent to use body samples obtained for diagnostic or routine medical purposes for further use by these hospitals as long as such use was consistent with good stewardship to allow reasonable and respectful use in research.[96] Clinical biobanks also focus on specific disease categories, enabling efficient case control studies (e.g. for investigating gene environment interactions) as well as prognostic studies.[97] Again, the scale and standardisation of data collection is crucial in clinical biobanking, suggesting the establishment of prospective collaborative biobanks for patients with specific disease entities. With support at the national level, in some countries it has been shown to be possible to establish a large blood-based clinical collaborative biobank of well-phenotyped patients who will be followed on a regular basis for natural course, health outcomes, morbidity and mortality.[98] This also raises the issue of access, which is central in biobanking. Researchers, who target a set of interesting material and data especially in the clinical setting, must meet certain ethical and legal requirements to access them. An access culture for biobank data should require that the custodians properly manage the massive amount of potentially sensitive information in a way that will be of optimal use for the scientific community, while also ensuring proper protection and respect for the privacy and confidentiality of the tissue source.

Where the clinical biobank contains existing collections, the issue of participant consent becomes problematic. The debate about biobank research and informed consent raises the question of participation and consent to the reuse of samples and data. In existing collections, tracing the participant may be difficult or impossible, in which case IRB or Research Ethics Committee may waive express consent for its use in a de-identified or anonymised state.

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[95] Helgesson, G., Dillner, J., Carlson, J., Bartram, C. R., & Hansson, M. G. (2007). Ethical framework for previously collected biobank samples. *Nature biotechnology*, *25*(9), 973-976.

[96] See the discussion of this point in BAC in Singapore Report on Human Tissue (2002) (85)at para 9.1- 9.6.

[97] Zielhuis, G. A. (2012). Biobanking for epidemiology. *Public Health*, 126(3), 214-216.

[98] The 'String of Pearls' initiative. Available at: http://www.stringof-pearls.org accessed 07 Nov 2014.

The Swedish PKU Biobank is an example of a clinical biobank which has been used in epidemiological research, and 'Pap smears' (cytological samples from the cervix) have been used to prove a relationship between Human Papilloma Virus (HPV) infection and cervical cancer.[99]

1.8.3 Commercial and private biobanks

If funding sources and business models are taken into account, the categorisation may be further refined into distinctions between public or private biobanks, and between commercial and non-commercial. [100] Private companies are known to act as tissue and data procuring agents for researchers.[101] These privately owned business and commercial biobanks raise additional issues for public distrust[102] and concern.[103] For instance, whether or not a biobank is commercially oriented may have a significant influence on people's willingness to participate, as the business model of profit maximisation may not be accepted by a participant who might otherwise like to contribute her or his samples to a public and non-commercial biobank. The Icelandic biobank is an illustration of the issues that may arise from biobanks as businesses. As researchers have increasingly come to collaborate between institutions and across national borders, the ethical implications of disseminating sensitive data need to be reassessed. In 1998, the Icelandic government granted exclusive rights to the information contained within this database to deCODE Genetics Inc. which included the medical records and genetic data from members of the Icelandic population, relying on the 'presumed consent' of its citizens.[104] This implied that their samples were automatically included unless a particular individual stated otherwise. These actions sparked national and international criticism from a variety of sectors due to the perceived commercial interests of deCODE Genetics Inc., and other ethical concerns

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[99] Wallin, K. L., Wiklund, F., Ångström, T., Bergman, F., Stendahl, U., Wadell, G., & Dillner, J. (1999). Type-specific persistence of human papillomavirus DNA before the development of invasive cervical cancer. *New England Journal of Medicine*, 341(22), 1633-1638.

[100] For example, in the United States there are several biotechnology companies that have collected large numbers of biological tissue samples from hospitals or through other means such as the CARTAGeNE biobank

[101] Winickoff, D., & Winickoff, R. (2003). The charitable trust as a model for genomic biobanks. *New England Journal of Medicine*, 12, 1180–1184.

[102] Anderlik, M. (2003). Commercial biobanks and genetic research: ethical and legal issues. *American Journal of Pharmacogenomics*, 3(3), 203–215.

[103] Kaiser, J. (2002). Biobanks. Population databases boom, from Iceland to the U.S. *Science*, 298(5596), 1158–1161.

[104] Greely, H. T. (2000). Iceland's plan for genomics research: facts and implications. *Jurimetrics*, 153-191 at 178.

such as consent, privacy, commoditisation of the population, and benefit sharing.[105] A major shortcoming in the deCODE plan, as implemented in the enabling Act, was and remains the lack of informed consent. Icelanders are presumed to consent to becoming research subjects for an unspecified range of research, unless they, or their parents or guardians, file a form opting out of the database. Presumed consent that enrols the tissue source into biobank research without initial consent violates the autonomy of the individual. A presumed consent model, as exemplified in the deCODE genetics of Iceland, does not require a face-to-face discussion that gives the source the opportunity to ask questions or to make a choice.

In summary, biobanks and tissue repositories are diverse. They vary in size, scope, and in the type of sample, as well as funding and governance mechanisms. This diversity raises numerous concerns over the ethical and legal aspects of biobanking which, to some degree, are common to all biobanks.

1.9 Legal and ethical issues in biobank research

In the recent past, there has been a rise in the number and use of biobanks in biomedical research. This has generated discussions regarding the controversial issues related to such research, particularly issues such as consent, privacy, property rights over tissue, and data sharing.

> 'The rapid pace of change has produced conflicting, social reactions. On the one hand, there is very strong public support for breakthroughs promising better medical diagnosis and treatments and, on the other; there are anxieties about the increased loss of privacy and the potential for genetic discrimination, as well as about the capacity to regulate genetic science in the public interest.'[106]

One of the most contested and controversial of the issues arising from biobank research is the principle of consent.[107]

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[105] Winickoff, D. E. (2006). Genome and Nation: Iceland's Health Sector Database and its Legacy. *Innovations*, 1(2), 80-105.

[106] Australian Law Reform Commission. (2003). *Essentially yours: The protection of human genetic information in Australia*. Executive Summary Retrieved Jan 20th, 2014, from http://www.austlii.edu.au/au/other/alrc/publications/reports/96/.

[107] Barr, M. (2006). I'm not really read up on genetics: biobanks and the social context of informed consent. Biosocieties, 1, 251–262. Brekke, O., & Sirnes, T. (2006). Population biobanks: the ethical gravity of informed consent. *BioSocieties*, 1, 385–398.

1.9.1 Informed consent in population biobanks

The main purpose of informed consent is to provide research participants with an opportunity to make free and informed choices about whether or not to participate in a specified research study. In relation to population biobanks, ethical claims over the role of informed consent have come to the fore in discussions around biobanking.[108] These discussions on the modality and type of informed consent in relation to population biobanks have in turn raised questions of balancing the interests of the individual and the interest of the society in the context of biobank research. The main rationale put forward for the need to balance the public health interest against the human right interest of the individual tissue source using the broad consent model is that the strict application of consent rules hinders socially beneficial research.[109] Proponents of broad consent continue to argue to balance the goals of science against the rights of the tissue source.[110] While appreciating the arguments in favour of balancing communitarian interest over the interest of the tissue source, the objectives of research do not always supersede individual interests. Art. 5 of the Declaration of Helsinki, notes that the interests of research participants 'should take precedence over the interests of science and society'. Similarly, Art. 3 of the Additional Protocol to the Council of Europe's Convention on Human Rights and Biomedicine states that the 'interests and welfare of the human being participating in research shall prevail over the sole interest of society or science'. Even though biobanks are seen as a promising way to untangle the links between genetics and environmental factors, and as a means to understand the causes of common diseases in the hope of developing new treatments and preventions through biobank research, there is a need to reconcile these provisions in order to ease the tensions that exist between communitarian interests of biobank research and protecting the human rights interests of the tissue source.

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[108] Ibid.

[109] Editorial, 'Striking the Right Balance between Privacy and the Public Good' (2006) *The Lancet* 367(9507) 275.

[110] Academy of Medical Sciences, Personal Data for Public Good: Using Health Information in Medical Research (January 2006) 4. Available at http://www.acmedsci.ac.uk/images/project/Personal.pdf.

Informed consent is one of the cornerstones of ethical requirements for research on human subjects.[111] According to the Nuremberg Code[112] and the Declaration of Helsinki,[113] a research participant must provide voluntary informed consent before the study begins to satisfy the underlying principle of respect for autonomy of the individual.[114] Informed consent, in this regard, would include an explanation of the proposed research, its purpose, a description of potential risks and benefits to the individuals participating, and a statement that participation is voluntary and that consent can be withdrawn at any time. Contemporary discussions of informed consent requirements seek to extend this requirement to the new types of research that are being conducted, including as biobank research.

In population biobanks, however, informed consent is not as clear cut as the traditional consent model proposed under the Nuremberg Code and the Declaration of Helsinki. Generally, most population biobanks operate a broad consent approach whilst the Nuremberg Code and the Declaration of Helsinki prescribe a specific consent approach. In effect, the Declaration of Helsinki requires researchers to use explicit written and documentary procedures in obtaining consent, and to seek specific consent for envisaged research. In biobank research, research proposals for secondary research and data analysis on previously collected samples may not be formulated until well after samples and data were obtained from the tissue source. Biobank collections can also be used for many years and in many different kinds of research, therefore a one-time broad consent approach in which participants agree to the use of their samples and health information in any future research deemed appropriate by the biobank or relevant oversight bodies, is considered by many to be well suited to the open and evolving nature of biobank-supported research.[115] This approach has been the subject of much debate. While it is acknowledged that biobank research challenges the traditional

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[111] Kapp MB. Ethical and legal issues in research involving human subjects: do you want a piece of me? *J Clin Pathol* 2006;59:335–339.

[112] United States Counsel For War Crimes, *Trials of War Criminals Before The Nuremberg Military Tribunals Under Control Council Law*. Washington, DC: U.S. Government Printing Office. Available at http://ohsr.od.nih.gov/guidelines/nuremberg.html. Accessed 16 May 2014.

[113] World Medical Association Declaration of Helsinki. *Ethical principles for medical research involving human subjects*, 1964. Available at: http://www.wma.net/e/policy/b3.htm. Accessed 16 May 2014.

[114] Hansson, M. G., Dillner, J., Bartram, C. R., Carlson, J. A., & Helgesson, G. (2006). Should donors be allowed to give broad consent to future biobank research? *The Lancet Oncology*, 7(3), 266-269.

[115] Murphy, J., Scott, J., Kaufman, D., Geller, G., LeRoy, L., & Hudson, K. (2009). Public perspectives on informed consent for biobanking. *American Journal of Public Health*, 99(12), 2128.

approach of specific consent to research, there remains a need to adopt alternative approaches to the prevailing broad consent approach to biobank research. Several alternatives to broad consent have been proposed and these include tiered consent, dynamic consent, and study specific consent.

In a tiered consent model, participants are asked to choose from a list of disease categories of research or study to participate in at the time of initial consent.[116] In an open-ended variation of tiered consent, individuals can also be asked to state in which areas of research their samples or data should not be used. This model of consent has been considered by many to be a 'best practice' model that enhances autonomy by allowing for greater choice and control over research participation but has also been criticised for being unwieldy and burdensome.[117] In biobank research, tiered consent is increasingly being advocated.[118] It is a model that gives an opportunity to the tissue source to narrow down to a specific kind of research, a specific study or a broad based research if they so please. It is a model of consent that enhances autonomy by giving the tissue source an opportunity to express choice in the kinds of research in which their samples or data will be used, but it requires that the biobank has appropriate mechanisms to track the individual choices and to ensure that data and samples are used in a manner consistent with the choices made.

Study-specific consent models are more in tandem with the traditional format for obtaining informed consent. In this model, biobank participants are recontacted, provided with detailed information about a study for which they are eligible, and asked to consider participation in that study. However to effectively operationalise study-specific consent, research participants need to be identifiable and contactable whenever researchers request specimens or health information for protocols requiring informed consent. Study-specific consent is preferred by some experts because it bears the traditional hallmarks of informed consent, namely the capacity to thoroughly inform individuals of the various elements of the research in question, including specifics on

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[116] Hohmann E, O'Rourke P, Stayn S. *Advanced tissue (biospecimen) banking*. Paper presented at Public Responsibility in Medicine and Research (PRIM&R). San Diego, CA, December 6–8, 2010.

[117] Simon, C. M., L'Heureux, J., Murray, J. C., Winokur, Weiner, G., Newbury, E., & Zimmerman, B. (2011). Active choice but not too active: public perspectives on biobank consent models. *Genetics in Medicine*, 13(9), 821-831.

[118] Eiseman, E., Bloom, G., Brower, J., Clancy, N., & Olmsted, S. S. (2003). *Case studies of existing human tissue repositories: best practices' for a biospecimen resource for the genomic and proteomic era*. Rand Corporation.

the potential risks and benefits of the research. However, it has been criticised because in the evolving long-term context of biobank research, participants may need to be recontacted many times, raising questions about the inconvenience of re-consenting research participants. The re-consent model does indeed gives the tissue source the opportunity to make a choice to participate in new research or not, and despite the possibility of wearing out participants by repeatedly seeking consent for research each time the need arises, it remains a model that gives the participant a chance to make a choice.[119] In the United Kingdom, a broad consent approach is used in which re-consent for future research projects is not required if individual data has been made permanently unidentifiable, and if an ethics committee deems that the research is unlikely to harm the individual.[120]

While these are alternative proposals to consent in biobank research a more individualist approach to consent will better protect the tissue source. In order to fully appreciate the issues of consent in biobank research, some of the factors which contribute to the strain on traditional consent principles in the context of biobank research will be noted in the following paragraphs.

1.9.2 Advances in technology and bioinformatics

Advances in technology and bioinformatics have enabled research to be carried out in new ways. This has made it possible to have highly advanced sequencing of cell lines which immortalises them, thereby increasing the scope and range of possible research purposes that these samples and specimens may be used for.[121] For instance, previously obtained specimens either from routine medical procedures or from other studies may be reused in other studies not known to the tissue source.

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[119] Kaye, J., & Martin, (2000). Safeguards for research using large-scale DNA collections. *BMJ: British Medical Journal*, 321(7269), 1146.

[120] Maschke, K. J. (2005). Navigating an ethical patchwork human gene banks. *Nature Biotechnology*, 23(5), 539-546. In contrast to the United Kingdom, the Icelandic legislation challenged the traditional model of informed consent by incorporating a presumed consent model. This model restricted the opt-out clause by stating that anyone who decides to withdraw from the study after 6 months cannot have personal health information removed from the database. Objections to this legislation continue, despite the view of some that presumed consent has greatly facilitated the gathering of information and maximised the quality of Iceland's database.

[121] Khoury, M., Millikan, R., Little, J., & Gwinn, M. (2004). The emergence of epidemiology in the genomics age. *International Journal of Epidemiology*, 33(5), 936–944; Greely, H. T. (2007). The uneasy ethical and legal underpinnings of large-scale genomic biobanks. *Annual Review of Genomics and Human Genetics*, 8, 343–364.

1.9.3 Use of data in biobank research

Another problem that stems from the nature of biobanks is that it typically involves large-scale population based research from which data needs to be potentially identifiable for data linkage. Irreversible anonymisation can be problematic for effective genetic research as researchers prefer to have data at least potentially identifiable because anonymisation may put at risk the scientific value of the biospecimens and data. It has been argued that, apart from anonymisation not being particularly appropriate for protecting the interests of the tissue source, it has a negative impact on research.

Added to this are advances in technology which have greatly increased the capacity for linking data. This tension is further reflected in other areas of biobank research, such as future unspecified research, privacy and confidentiality. The long-term nature of these collections and the range of future unspecified uses to which the samples and data can be put, add to the complexity of consent in biobank research. This position is very different from clinical research where-consent is obtainable for the use of data for a specific study which is ascertainable at the time of granting consent. In the case of biobanks, there is a disconnect between the tissue source and the end point of secondary uses of the sample and data in the future. In point of fact, informed consent could only have been given for taking of the sample and its storage and possibly for details in relation to the tissue source. These factors have contributed to the tensions of consent in biobank research.[122]

A researcher's use of samples and data without specific permission arguably intrudes on the source's personal space and life in a manner that violates their right to privacy in common law and under statute. According to Warren and Brandeis,[123] the right of privacy makes cognisable the individual's right to 'decide whether that which is his shall be given to the public'. Regardless of their inherent value, certain things are protected from exposure or exploitation merely because exposure would disturb a person's peace of mind. In other words, the right of privacy recognises a person's right to be left alone and not have their information or data shared without their consent. In

[122] Eriksson, S., & Helgesson, G. (2005). Potential harms, anonymization, and the right to withdraw consent to biobank research. *European Journal of Human Genetics*, 13(9), 1071–1076.
[123] Warren, S. & Brandeis L. (1890). *The right to privacy, Harvard Law Review*, 4, 193-220.

the context of biobank research and use of data in future research, the right to be left alone can be waived through the consent of the tissue source. However where such consent is exceeded or where it is obtained without adequate information it would not serve as a defence to the researcher.

In the light of this, the right to control the use of one's tissue samples and data by preventing non-consensual use is consistent with other legally protected spheres such as the right to determine what medical treatment to undergo, and in the same vein should be recognised as a protectable right in law.

1.9.4 Privacy and confidentiality in biobank research

The physical risk to the tissue source are low in biobank research. Often samples are collected by the least invasive procedures such as blood draws or cheek swabs. The main risks associated with biobank research are informational, stemming from breaches of confidentiality or the infringement of the right to privacy. This may arise when information is shared with third parties and in the process sensitive information winds up in the wrong hands. The resulting effects are usually social economic and or psychological.[124]

Biosamples such as tissues, cells, DNA, and related information have become essential raw materials for the advancement of biotechnology, human health, and research and drug development in biomedical sciences.[125] This has resulted in increased amounts of bioinformation being collected, stored and shared for the purpose of personalising medicine through collaborative biobank research, and so biobanks can be considered key points for privacy-related issues in an age of genomic research. It also seems that there are unique issues that arise from the convergence and use of bio-information, medical information and biosamples in biobank research which has privacy and confidentiality implications for the tissue source. For instance, comprehensive data sets establish informatics links among genome sequences and extensive phenotype analysis, thereby increasing the risk for identification of individuals by the DNA sequences

[124] Eriksson, S., & Helgesson, G. (2005). Potential harms, anonymization, and the right to withdraw consent to biobank research. *European Journal of Human Genetics*, 13(9), 1071-1076.

[125] Lauss, G., Bialobrzeski, A., Korkhaus, M., Snell, K., Starkbaum, J., Vermeer, A. E., & Dabrock, (2013). *Beyond genetic privacy past, present and future of bioinformation control regimes*. Available at: http://private-gen.eu/uploads/media/Private_gen_final-report_2013_02.pdf last accessed 27/03/2015

contained in the analyses.[126] This creates risks of privacy infringement which have been identified:

> 'as including the possibility of exposure of individual tissue source's information, such as revealing disease status, predicted future likelihood or past presence of other traits, or attempts to link another DNA result with a participant, for example, to determine presence or absence in a research cohort, ancestry, and relatedness (e.g., paternity/nonpaternity).[127]

To protect individuals from these risks, it is important that their medical information and samples are not shared with third parties without their consent. One of the features of biobanking is the necessity to link information from analysis of biosamples to other types of information such as health information. Although information about the tissue source and their samples are not provided to the researchers in an identifiable form, they must remain potentially re-identifiable by the custodians of the biobank to allow for ongoing linkage of different sources of data.[128] This coupling of information creates challenges to confidentiality and privacy of the tissue source because the combination of biological samples and other types of information makes it possible to trace research subjects even though samples have been anonymised.[129] The difficulty with such enormous and detailed datasets is that indirect disclosure risks increase over time. With the addition of whole genome sequencing information, the potential to distinguish an individual in a dataset increased.[130] There are challenges in how to handle genetic information so that the interests of the tissue source is not compromised.

The question of maintaining the privacy and confidentiality of tissue sources in biobank research is difficult because of the nature of biobanks as sharing platforms for research which make it difficult to guarantee the confidentiality of information. Furthermore, the

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[126] Snell, K., Starkbaum, J., Lau, G., Vermeer, A., & Heln, I. (2012). From protection of privacy to control of data streams: a focus group study on biobanks in the information society. *Public Health Genomics*, 15(5), 293.

[127] Johnson, A. D., Leslie, R., & O'Donnell, C. J. (2011). Temporal trends in results availability from genome-wide association studies. *PLoS Genetics*, 7(9), e1002269; Avard, D., & Knoppers, B. M. (2009). Genomic medicine: considerations for health professionals and the public. *Genome Med*, 1(2), 25.

[128] Gottweis. H., et al. (2012) *Biobank for Europe a challenge for Governance*. Available at http://ec.europa.eu/research/swafs/pdf/pub_governance/biobanks-for-europe_en.pdf

[129] Lindberg, B. S. (2003). Clinical data–a necessary requirement for realising the potential of biobanks. *Biobanks as Resources for Health. Research Program Ethics in Biomedicine, Uppsala*, 21-31; McGuire, A. L., & Gibbs, R. A. (2006). No longer de-identified. *Science*, 312(5772), 370. Gymrek, M., McGuire, A. L., Golan, D., Halperin, E., & Erlich, Y. (2013). Identifying personal genomes by surname inference. *Science*, 339(6117), 321-324.

[130] Malin, B., Karp, D., & Scheuermann, R. H. (2010). Technical and policy approaches to balancing patient privacy and data sharing in clinical and translational research. *Journal of Investigative Medicine*, 58(1), 11.

character of genetic information contained in DNA means that sequence information has implications for other biologically related family members. The privacy interests of the tissue source's relations are further implicated in the realm of biobank research where there are numerous threats to privacy and confidentiality through inferring phenotype through genotype, identification of relatives, or accidental data release from associating data.[131] Genetic information concerns not only the tissue source but also direct relations of the tissue source.[132] In this sense, genetic information challenges individuality and individual autonomy as a basis of decision making and participation in biobank research. For instance, since genetic information relates to individuals other than the tissue source, there is the question of whether the tissue source's broad consent will affect the use of genetic information which relates to others. The joint nature of genetic information and the broad consent that the tissue source gives when enrolling in biobank research are not the only challenges to privacy and confidentiality.

Anonymisation of biological samples by removing all identifying information has been suggested to address or help protect the privacy of tissue sources.[133] However, advanced computing technology has shown that anonymisation is not fool proof. It is possible to identify the tissue source from other sources in spite of anonymisation.

1.9.5 Anonymisation

Anonymisation has been seen as the best way to provide privacy in the biomedical context. It has also been a preferred way of protecting the privacy of tissue sources by the researcher. The reasoning behind this is that data protection norms are applicable to identifiable data, however where the identity cannot be revealed, no harm is done to anyone. In 2001 Ellis and Mannion[134] observed that the key to permissibility for the use of genetic samples for research without consent is anonymisation.[135] This position held sway until the frontiers of the use of tissue in research were extended to genetic and

[131] Lunshof, J. E., Chadwick, R., Vorhaus, D. B., & Church, G. M. (2008). From genetic privacy to open consent. Nature Reviews. *Genetics*, 9(5), 406–411.
[132] Taylor, M. J., & Townend, D. (2010). Issues in protecting privacy in medical research using genetic information and biobanking: the PRIVILEGED project. *Medical Law International*, 10(4), 253-268.
[133] Elger, B. S., & Caplan, A. L. (2006). Consent and anonymization in research involving biobanks. *EMBO reports*, 7(7), 661-666.
[134] Cited in Sándor, J., & Bárd, (2011). Anonymity and privacy in biobanking. In *Biobanks and Tissue Research* (213-230). Springer Netherlands
[135] Ibid.

then genomic, research and biobank research. In *R v Department of Health ex parte Source Informatics Ltd*,[136] the Court of Appeal held that there was no breach of confidentiality where the information is anonymised. In that case the applicant, Source Informatics Ltd, was a data company concerned with gathering medical prescription information to sell to pharmaceutical companies details of the prescribing practices of doctors. It obtained this information regularly and for a modest fee from pharmacists who compiled their own computer databases of information taken from patients' prescription forms. The information from each form was processed by a software package designed to remove details of the patient's identity, leaving only the doctor's name and the type and quantity of product prescribed. The applicant would then aggregate the information for sale to companies wishing to improve their targeting of marketing initiatives.

The respondent, the Department of Health, was concerned that the practice of targeted marketing would encourage doctors to increase their prescribing and thereby increase the cost to be met by the NHS. In 1997, the Department of Health issued a policy document condemning the disclosure of information to companies such as the applicant on the grounds that it constituted a breach of patient confidentiality, notwithstanding that patients' identities were withheld. On an application for declaratory relief by the applicant, the High Court (Latham J) upheld the Department's concerns, holding that disclosure of information in this way without a patient's consent could give rise to a cause of action on the part of the patient.

On appeal, Source Informatics contended that no breach of confidentiality had occurred since the information was not confidential unless it could be identified with the particular patient; that there was no risk of identification; that the intended use, namely the pursuit of more accurate marketing strategies, was not misuse; that it was beneficial rather than detrimental to patients; and that it required neither the patients' consent nor any public interest justification.

This position is controversial in the light of advances in science that have shown that, despite the best efforts of researchers to meet the demands of anonymisation, a number

[136] *R v Department of Health ex parte Source Informatics Ltd*, (2000 All E.R. 1 786.

of features of biorepository research combine to make it increasingly hard to achieve in practice.[137] These include the availability and access to a variety of genotypic information from biospecimens,[138] linkage to clinical data, and the use of sophisticated bioinformatics tools for data mining and amalgamation.[139] The recent demonstration that individual participants' identities can be determined from aggregate genotypic data has underlined further the inadequacy of most traditional approaches to anonymisation.[140]

In the context of biobank research, anonymisation as a means of protecting the tissue source from informational privacy infringement raises issues because of the limited confidentiality and privacy protection it offers the source. Sandor noted that, in the case of biobank research, anonymisation has only a limited use because it is necessary to accompany DNA analysis with healthcare data to provide a meaningful conclusion.[141] Therefore the question arises whether traditional data protection methods such as anonymisation are effective tools against the misuse of genetic information in biobank research. It is now known that anonymisation is not enough to guarantee anonymity.[142] For instance, if demographic and clinical data accompany the anonymised sample, as is explicitly assumed in the recommendations from the European Society of Human Genetics ESHG,[143] it may be possible in some cases for individuals possessing sufficient knowledge to identify a donor.

Anonymisation raises other issues, such as:

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[137] Ohm, (2010). Broken promises of privacy: Responding to the surprising failure of anonymization. *UCLA Law Review*, 57, 1701.

[138] McGuire, A. L., & Gibbs, R. A. (2006). No longer de-identified. *Science*, 312(5772), 370.

[139] Fullerton, S. M., Anderson, N. R., Guzauskas, G., Freeman, D., & Fryer-Edwards, K. (2010). Meeting the governance challenges of next-generation biorepository research. *Science Translational Medicine*, 2(15).

[140] Jacobs, K. B., Yeager, M., Wacholder, S., Craig, D., Kraft, Hunter, D. J., & Chatterjee, N. (2009). A new statistic and its power to infer membership in a genome-wide association study using genotype frequencies. *Nature genetics*, 41(11), 1253-1257. Gymrek, M., McGuire, A. L., Golan, D., Halperin, E., & Erlich, Y. (2013). Identifying personal genomes by surname inference. *Science*, *339*(6117), 321-324.

[141] Ibid at 218.

[142] Eriksson, S., & Helgesson, G. (2005). Potential harms, anonymization, and the right to withdraw consent to biobank research. *European Journal of Human Genetics*, 13(9), 1071-1076.

[143] Godard, B., Schmidtke, J., Cassiman, J. J., & Aymé, S. (2003). Data storage and DNA banking for biomedical research: informed consent, confidentiality, quality issues, ownership, return of benefits. A professional perspective. *European Journal of Human Genetics*, 11, S88-S122.

- It makes it difficult for the tissue source to withdraw consent in the event that they want to discontinue involvement of their sample or data in the biobank research;[144]
- Anonymisation makes it impossible to recontact sources in the event of significant incidental findings relating to the health of the tissue source;[145]
- It may not decisively cut the link to a specific individual;[146] and
- It may limit the research capacity of the biobank.

Thus, in terms of biobank research, anonymisation can no longer suffice as a means of protecting participants' privacy, nor will it provide a satisfactory basis for forgoing research oversight, particularly when broad data sharing is anticipated. Instead, renewed attention to privacy provisions as contained in the governance mechanism of biobanks, combined with innovative approaches to data security and research oversight, will be required.

This thesis will argue that biobank research should be conducted in a manner that respects the autonomy of the tissue source by taking into account the fact that the accepted mode of protecting the privacy of the tissue source through anonymisation does not adequately protect the source. At the moment, there appears to be no detailed and specific provisions on this. One solution that will be proposed is the recognition of the right of the tissue source to confidentiality and privacy of genetic information in biobank research.

1.9.6 Secondary use of sample and data sharing

In recent years, the significance of data sharing to the advancement of biomedical research has come to be recognised. National governments, funders and researchers have suggested that the more researchers have access to biodata and bio samples, the

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[144] Ravitsky, V., & Wilfond, B. S. (2006). Disclosing individual genetic results to research participants. *The American Journal of Bioethics*, 6(6), 8-17.

[145] Eriksson, S., & Helgesson, G. (2005). Potential harms, anonymisation, and the right to withdraw consent to biobank research. *European Journal of Human Genetics*, 13(9), 1071–1076.

[146] Homer, N., Szelinger, S., Redman, M., Duggan, D., Tembe, W., Muehling, J., & Craig, D. W. (2008). Resolving individuals contributing trace amounts of DNA to highly complex mixtures using high-density SNP genotyping microarrays. *PLoS genetics*, 4(8), e1000167.

more quickly biomedical advances can be achieved.[147] Though this move by stakeholders had earlier focussed on pre-publication release of genomic data, data sharing in publicly accessible databases has since expanded to include sharing of proteomic, metabolomic and chemical structure, as well as annotated clinical resources.[148] Other advantages of data sharing include its promotion of transparency. Data sharing allows peer evaluation and validation of research findings, which encourages an open and critical discussion of results. In economic terms, data sharing ultimately reduces duplication of effort.

To achieve the laudable ideals of data sharing, researchers have been asking tissue sources to give broad consent to biobank research because broad consent allows both the original researcher as well as future researchers to use and share biobanked samples and data in a wide range of research.[149] While this practice maximises the value of biobank research by making samples and data available to a greater number of researchers for a greater number of research projects, as the Human Genome project has,[150] opponents of broad consent argue that it does not give the tissue source an opportunity to assess the specific nature of risk, especially to their privacy. It also does not enable the source to exercise their right to autonomy in that they have no say in the decision to share data and samples in future research. It conflicts with, and supresses, the right of the individual by putting the interests of wider society ahead of those of the individual. When biobank data is shared, tissue sources may experience a lack of control over their donated specimen and data as well as an inability to withdraw their specimen from research studies.[151]

The UK Biobank is an example of a biobank that has implemented a grant-back policy in which all data users are ‘required to put results from all analyses made on

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[147] Welcome trust, *Sharing research data to improve public health: full joint statement by funders of health research*, Available at http://www.wellcome.ac.uk/About-us/Policy/Spotlight-issues/Data-sharing/Public-health-and-epidemiology/WTDV030690.htm

[148] Birney, E., Hudson, T. J., Green, E. D., Gunter, C., Eddy, S., Rogers, J., & Mooser, V. (2009). Prepublication data sharing. *Nature*, 461(7261), 168-170.

[149] Allen, C., Joly, Y., & Moreno, G. (2013). Data Sharing, Biobanks and Informed Consent: A Research Paradox. *McGill JL & Health*, 7, 85 at 89

[150] During the development of the draft human genome sequence, the data was shared on an ongoing basis such that the sequence of 100 base pairs was released and made public within 24 hours of being read. This has resulted in new information on 30 disease genes.

[151] Hoffman, B. (2009). Broadening consent and diluting ethics? *Journal of Medical Ethics*, 35, 125–129.

participants' data and samples, and any relevant supporting information, in the U.K. Biobank database so that they are subsequently available to all researchers with appropriate scientific and ethics approval' and must ultimately place all research findings using its data into the public domain, after a limited period of exclusivity.[152] One of the problems with this policy is the difficulty of policing such a grant-back arrangement for an open source biobank. The ability to control access to some degree so as to deny access to violators is essential for effective protection of the data of the tissue source.

Privacy risks within the context of data sharing and biobank research have been identified to include exposing individual research participant information by revealing disease status, predicted future likelihood of presence of other traits, or any attempt to link another DNA result with that of the participant to determine presence or absence of trait in research cohort.[153]

Data sharing can also create tensions between the biobanks and its quest for research development, and the rights of the tissue source to self-governance and privacy. The fundamental obligation of respecting the autonomy of the research participant can become difficult in relation to the tissue source especially in the context of biobank research.[154] Data sharing implies that because researchers within the context of biobank research cannot be aware, at the time of enrolment, of the full extent of future uses of the data that the tissue source provides, or of the psychosocial risks involved, data sharing inhibits researchers from fully respecting the subject's autonomy, as it prevents the consent process – the primary locus of the tissue source's self-governance in the context of health research – from being sufficiently informed.[155] Thus, while broad consent supports a central purpose of biobanking insofar as it allows for the open sharing of subject data and materials between researchers, there is a question as to

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[152] UK Biobank, *Ethics and Governance Framework* Available at: http://www.ukbiobank.ac.uk/docs/EGFlatestJan20082.pdf. 12-13,

[153] Kaye, J. (2015). The tension between data sharing and the protection of privacy in genomics research. In *Ethics, Law and Governance of Biobanking* (101-120). Springer Netherlands at 102-103

[154] Caulfield, T. (2007). Biobanks and blanket consent: the proper place of the public good and public perception rationales. *KLJ*, 18, 209.

[155] Caulfield, T. (2007). Biobanks and blanket consent: the proper place of the public good and public perception rationales. *KLJ*, 18, 209 at 212-215

whether it truly satisfies the current legal and ethical norms regarding consent. This will be further examined in subsequent chapters.

The question of whether or not to recognise property rights over tissue, especially as a means of control over excised tissue, is a source of controversy and the literature abounds with support for both sides of the question. The following section will sketch the contours of the legal issues relating to property rights in tissue in biobanking research.

1.9.7 Property rights in tissue

The opaqueness of the common-law on the actual status of body parts in property law has endured over the years. This stems from a line of early case law suggesting that there is no property in human bodies,[156] and this line of cases continues with the judicial recognition of an exception to the no property rule in the Australian case of *Doodeward v Spence.*[157] In this case, a distinction can be drawn between a corpse awaiting burial and a body or body part that had, through the application of work and skill, acquired some attributes differentiating it from a mere corpse. In the UK, the court in the case of *R v Kelly*[158] followed the line of argument in *Doodeward v Spence* and held that body parts held at the Royal College of Surgeons were the property of the College and capable of being stolen. The situation, however, gets more complicated when considering body parts and the living person. It may seem very normal to talk of 'my body' and to relate and infer that because it is 'my body' I can determine what happens to it or its parts. However the position in law is very unclear on whether the individual actually owns their body and its parts. While there is evidence in the case law which suggests that regenerative body parts such as hair,[159] faeces,[160] blood,[161] and urine[162] can be property, the 'no property in a corpse' rule persists in law, subject to exceptions of application of sufficient work and skill being exercised on the sample to qualify as

[156] Matthews, (1983). Whose body? People as property. *Current Legal Problems*, 36(1), 193-239.
[157] *Doodeward v. Spence*, 6 C.L.R. 406 (1908).
[158] *R v Kelly* [1999] 2 WLR 384
[159] *R v Herbert* (1961) 25 JCL 163
[160] *Venner v. State*, 354 (1976) A.2d 483, 30 Md. A599 (Ct. Spec. App
[161] *R v Rothery* [1976] 63 Cr App R 231
[162] *R v Welsh* [1974] RTR 478

being capable of being subject to ownership. In relation to biobanking and excised biological samples, the position of the law on what constitutes sufficient work and skill that would qualify biobank samples as being capable of ownership remains unsettled.

A series of cases relating to sperm deposits have challenged the 'no property in tissue' notion. There has been some equivocation in these cases, and while some jurisdictions have granted recognition of property rights in human tissue samples, others have resorted to property rights as a means to an end, such as in *Yearworth v North Bristol NHS Trust*[163] where the Court of Appeal, in acknowledging the existence of bailment relationship between the NHS and the defendants, recognised property rights in sperm. Currently, apart from recognising bailment as a model of transferring tissue as a form of property, abandonment and gifting have also been used as legal models to transfer human biological samples as property.

1.9.7.1 Abandonment

Abandonment is the voluntary surrender, relinquishment, disclaimer or cession of property with the intention of not reclaiming it.[164] In common law tradition,excised tissue was regarded as having been abandoned by its original owner and was thefore open to all claims.[165] This voluntary abandoning of property with no intention of returning to it includes the idea of it being possibly appropriated by another or by a finder. A finder of property is generally entitled to possession and ownership of the property against all others.[166] Abandonment is usually distinguished from lost, misplaced or treasure trove property in the sense that with abandonment, the true owner is believed to remember where the property is, but to have given up his claim to it, whilst with misplaced or lost property that is not the case. In the U.S. case of *Venner v Maryland,*[167] the Maryland Court of Special Appeals found that Charles Venner had abandoned balloons filled with hashish oil when he did not attempt to exercise any right of possession or control over them after excreting them from his digestive system. It

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[163] *Yearworth v. North Bristol NHS Trust* [2009] E.W.C.A. Civ 37.

[164] Garner, B. A., & Black, H. C. (2004). *Black's Law Dictionary*. St. Paul, MN: Thomson/West.

[165]Dickenson, D. (2007). Property in the body: Feminist perspectives. Cambridge University Press. At p.19

[166] Gottlieb, K. (1998). Human biological samples and the laws of property: the trust as a model for biological repositories. *Stored Tissue Samples: Ethical, Legal and Public Policy Implications*, 183-97 at 189-190.

[167] *Venner v. State*, 354 (1976) A.2d 483, 30 Md. A599 (Ct. Spec. App).

was held that the nursing staff were the finders and were entitled to ownership and possession of balloons of hashish and could lawfully pass them on to the police. In this case the finding of the Court that human waste could be abandoned and that it was capable of possession made human waste a subject of property. In the context of biobank research abandonment as an approach to transferring property rights does not protect the rights of the tissue source to having a say in future uses of sample data. This position has been echoed by Dickenson that where a tissue source has not been informed about what specific future uses will be made of his tissue, there is no room to stipulate what might be considered respectful uses of the tissue.[168]

1.9.7.2 Gifting

A gift is the voluntary transfer of property to another made freely without receiving anything in return.[169]A voluntary transfer is one that is not supported by consideration. One of the characteristics of gifts is that it is effective currently and are not a promise to give personal property in the future, and the intention to donate is necessary to constitute a valid gift. There are several ways of conveying a gift. A gift *inter vivos* is one completed during the lifetime of both parties, whereas a gift *causa mortis* is done in contemplation of death. A gift *inter vivos* is absolute and unconditional and must be accepted before the transfer is considered a gift. The nature of the gift also influences the method of conveying it. A gift of an interest in land must be done by deed according to, for example, S. 52 of The Law of Property Act 1925, in the UK, and the Statutes of Frauds 1677 in Nigeria. However, gifts of goods generally do not require a deed and neither is there a need that they be evidenced in writing before they can be validly conveyed. In *Hecht v Kane*[170] in deciding whether fifteen vials of sperm in a sperm bank were part of the deceased's estate or had been gifted to a girlfriend at the time of deposit, the U.S. court held that a deceased man who had previously deposited sperm for the use of his partner had an interest in the nature of ownership of the sample that would render it to be property within the meaning of the probate code.

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[168] Dickenson, D. (2007). *Property in the body: Feminist perspectives*. Cambridge University Press.at p.19
[169] Garner, B. A., & Black, H. C. (2004). *Black's Law Dictionary*. St. Paul, MN: Thomson/West
[170] *Hecht v. Kane*, 20 Cal. Rptr. 2d 275 (1993).

Biobanks raise the question of whether a tissue source has rights in tissue that can enable them to exercise control or ownership over excised tissue, and whether ownership rights remain with the individual donor or can be transferred to the researcher.[171] Cases such as *Hecht v Kane*[172] have shown that property rights can be exercised over tissue, which in turn can enable a tissue source to exercise some elements of control in relation to future use of his samples and data in future unspecified research. More so it has been argued that the very purpose of gifting in its classical anthropological formulation, is to create ongoing interests and relationships between donor and recipient. As Mause[173] depicts it, a gift remains alive and that in the sense of tissue, the gifting of tissue does not totally extinguish the connection of the tissue source to the excised tissue.[174] According to him, what imposes an obligation in the gift received and exchanged is the fact that the thing received is not inactive but that it contains something through which the giver can exercise control over the recipient.

Furthermore, since some transfers of biological samples can be considered to be gifts – for instance the donation of blood for transfusion – then it should be possible to recognise tissue as property capable of being controlled by the tissue source. However it is questionable whether the transfer of human tissue using the legal model of gifting applies across the board to samples given for diagnostic purposes or research. This is because many informed consent forms contain provisions that allow the tissue source to voluntarily withdraw from the research at any point, in which case the transfer will no longer remain a gift.

A gift *inter vivos* in the real sense of the word is absolute. It is also worth noting that property can be gifted or donated in equity. Equity allows the gifts of property which were not assignable at common law to be completed in equity as long as the donor manifested a complete and irrevocable intention to give the property.[175] An example is a

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[171] Tutton, R. (2007). Banking expectations: the promises and problems of biobanks.

[172] *Hecht v Kane*, 20 (1993) Cal. Rptr. 2d 275.

[173] Mauss, M., & Cunnison, I. G. (1954). Essai Sur Le Don. *The Gift. Forms and Functions of Exchange in Archaic Societies... Translated by Ian Cunnison. With an Introduction by EE Evans-Pritchard. London. Cited in Dickenson, D. (2007). Property in the body: Feminist perspectives.* Cambridge University Press.at p.19

[174] Penner, J. E. (1997). *The idea of property in law*. Oxford University Press. At p.90 'Giving is not mere abandonment, involving no further interest of the donor'.

[175] *Kekewich v Manning* (1851) 42 ER 519 at 524

trust where the legal owner either declares themselves to be a trustee holding the property for the benefit of another, or where they transfer property to a trustee for the benefit of another. The trust is a fiduciary relationship in which one person (the trustee) holds title to the property and has an obligation to keep or use the property for the benefit of another, the beneficiary. In the analogy of a biobank, the settlor will be the tissue source, the res of the trust will be the biological sample, and the trustee will be the biobank. The beneficiaries will be those who will benefit from the research. Can a trust model be applied to biobanks? It will be argued in Chapter 5 that a charitable trust model can accommodate the transfer of human biological samples to biobanks acting as stewards of these samples and data. In applying the law of gifts to biobanking research the starting point is to determine the proprietary nature of human tissue. In Chapter 4, it will be argued that human tissue is capable of being recognised as property. Informed consent forms can be modified to include trust-creating language for future use of samples.

1.10 Autonomy issues in biobank research

1 There appears to be no single accepted definition of 'autonomy', although as Onora O'Neill notes, most definitions are based on a notion of independence and personal responsibility.[176] To Kant, autonomy meant the human capacity for rational thought and action in accordance with the moral law. It is this capacity which underlies the moral imperative to treat individuals as 'ends in themselves': In his words, "So act that you use humanity, whether in your own person or in the person of any other, always at the same time as an end, never merely as a means".[177] Moreover, "he is under obligation to acknowledge, in a practical way, the dignity of humanity in every other human being". Hence, according to Kant, the human capacity for autonomy and the value we place on it underpin the moral requirement to treat all human beings with dignity. John Stuart Mill, while rarely using the actual term 'autonomy', places great weight on the 'free development of

[176] O'Neill O (2002) *Autonomy and Trust in Bioethics* (Cambridge: Cambridge University Press,p28

[177] . Gregor M (Translator and Editor) (1997) *Kant: Groundwork of the Metaphysics of Morals*, (Cambridge: Cambridge UniversityPress), p38

individuality' as being one of the leading essentials of well-being.[178] Frankfurt,[179]on the other hand, emphasised the idea of self-governance, describing autonomy as the ability to live our lives in the way we 'truly' wish them to be, instead of simply following our first, perhaps more basic, instincts. In all these definitions, it is useful to note that there is the human being's *capacity* for autonomy and the political and material conditions which make it possible for individuals to *exercise* their autonomy.

In liberal western democracies, even though autonomy is recognised as a central value, there are fundamental disagreements both in how we should understand autonomy and in the value and respect we attach to autonomy relative to other important values. For instance, McQuillan et al. have suggested that "specific consent must be obtained if an individual's autonomy is to be respected in biobanking research especially in relation to future research.[180] This position O'Neill has pointed out represents a limited view of autonomy as "there are many distinct conceptions of individual autonomy, and their ethical importance varies"[181] Knoppers and Chadwick at the other extreme, have also argued, that we need to "move away from autonomy as the ultimate arbiter," even if we should pay attention to other fundamental notions related to biobank research, such as solidarity, reciprocity and citizenry.[182] These opinions reflect the varied views of autonomy and the value we attach to it especially as it relates to research. It would appear however, that the position of McQuillan et al is based on a view of autonomy derived from ancient Greece where autonomy represent a political concept of independence that emphasises self-rule. The idea that autonomy applies to an individual is relatively new. The term autonomy gained resonance in contemporary literature and political thought probably from the role that Kant gave it in his views on moral

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[178] O'Neill O (2002) *Autonomy and Trust in Bioethics* (Cambridge: Cambridge University Press), p30.

[179] . Frankfurt H (1971) Freedom of the will and the concept of a person Journal of Philosophy **68**: 5–20, reprinted in Christman J(Editor) (1989) *The Inner Citadel: Essays on individual autonomy*, pp63–90 (Oxford University Press).

[180] Mcquillan, Geraldine M., Kathryn S. Porter, Maria Agelli, and Raynard Kington. "Consent for genetic research in a general population: the NHANES experience." *Genetics in Medicine* 5, no. 1 (2003): 35-42.at p.40

[181] O'Neill, O. (2003). Some limits of informed consent. *Journal of Medical Ethics*, *29*(1), 4-7.at p.4

[182] Knoppers, B. M., & Chadwick, R. (2006). Human genetic research: emerging trends in ethics. *Nature Reviews Genetics*. **6**, 75–79.

philosophy. Autonomy, was traditionally used in the ancient Greek city-states to describe the ability to govern and make laws free from external influences. The central idea behind autonomy in this respect is revealed by the etymology of the term; *autos* (self) and *nomos* (rule or law). The Greek city state had *autonomia* when it was free of outside influences and could formulate its own laws. It is also seen as the aspect of people that prevents, or ought to prevent, paternalistic interventions in their lives.[183]

Today, to be autonomous is to be one's own person, to be directed by considerations, desires, conditions, and characteristics that are not imposed externally upon one, but are part of what can somehow be considered one's authentic self. Autonomy can also be interpreted as having an irrefutable value, especially since its opposite — being guided by forces external to the self and which one cannot authentically embraces the opposite of which seems to signify oppression. Taking it a step further, it is also seen as the aspect of persons that prevents or ought to prevent paternalistic interventions in their lives.[184] Individual autonomy is an idea that is generally understood to refer to the capacity to be one's own person, to live one's life according to reasons and motives that are taken as one's own and not the product of manipulative or distorting external forces. Allmark[185] has distinguished two main strands of autonomy: one belongs in the Kantian tradition, the other to the Millian. Mill's conception of autonomy is allied to his conception of freedom. In self-regarding matters the individual ought to be free to develop his or her own individuality. In other words, to be autonomous, means to be law to oneself; an autonomous agent therefore is a self-governing agent. According to Mill, autonomy is associated closely enough with well-being to conclude that it makes the individual sovereign. In this sense, autonomy can be said to be a tool for the exercise of freedom of choice. Even though autonomy enables the exercise of freedom, it is not an absolute right. It is qualified by legitimate interests, law, and the expectation of others. In the context of biobank-based research, there are issues of autonomy relating to limits that are set on the right to control the body parts housed in biobanks. The Human Tissue Act 2004 for instance, prohibits the trafficking in human material in spite

[183] Dworkin, G. (1988). *The Theory and Practice of Autonomy*, New York: Cambridge University Press, 121-129
[184] Dworkin, G. (1988). *The Theory and Practice of Autonomy*, New York: Cambridge University Press,
[185] Allmark, (2006). Choosing Health and the inner citadel. *Journal of Medical Ethics*, 32(1), 3-6.

of the autonomous right to determine what happens to one's body. In *R v Brown*[186]the House of Lords ruled that ritual physical abuse for sexual pleasure was criminal even when undertaken with consenting adults. Inspite of this, a global and widespread debate on the protection of donors' basic human rights of dignity, autonomy and privacy in relation to excised tissue is still ongoing.

1.10.1 The idea of autonomy

According to Gerald Dworkin[187], autonomy can be equated to liberty (positive of negative) … dignity, integrity, individuality, independence, responsibility and self-knowledge self-assertion, … critical reflection, freedom from obligation absence of external causation and knowledge of one's own interests. In the following paragraphs, the autonomy of tissue sources will be argued based on the notion of autonomy as meaning self-government and independence, and representing liberty. This position is debatable. Some philosophers argue that autonomy in medicine should be restricted if there is threat to patients well-being.[188] While others seem to be of the view that there are no limits to patient autonomy where there is no risk of harming others.

Ruth Faden and Thomas Beauchamp[189] also suggest that autonomy can be identified with privacy, voluntariness, self-mastery, choosing feely and accepting responsibility for one's choices. There are other schools of thought such as the such as the determinist, behaviourists and structuralists who think autonomy is an illusion. There are also feminists and communitarians who doubt whether autonomy is always of value. In spite of this varied conceptions of autonomy, there are threads of agreement about it in bioethics.[190] In bioethics, autonomy is seen as a feature of an individual, as a matter of or a capacity for independent decisions and actions.[191]

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[186] 24 E.H.R.R. 39 (1997).
[187] Dworkin, G. (1988). *The Theory and Practice of Autonomy*, New York: Cambridge University Press.p.121-129
[188] Beauchamp, T. L., & Childress, J. F. (2001). *Principles of biomedical ethics*. Oxford University Press, USA.p.185-187
[189] Faden, R. R., Beauchamp, T. L., & King, N. M. (1986). A history and theory of informed consent.at p.7
[190] Oneil onora
[191] Matthews, E. (2000). Autonomy and the psychiatric patient. *Journal of applied philosophy*, *17*(1), 59-70.

Individual autonomy is an idea that is generally understood to refer to the capacity to be one's own person, to live one's life according to reasons and motives that are taken as one's own and not the product of manipulative or distorting external forces. Allmark[192] has distinguished two main strands of autonomy: one belongs in the Kantian tradition, the other to the Millian. Mill's conception of autonomy is allied to his conception of freedom. In self-regarding matters the individual ought to be free to develop his or her own individuality. In other words, to be autonomous, means to be law to oneself; an autonomous agent therefore is a self-governing agent. According to Mill, autonomy is associated closely enough with well-being to conclude that it makes the individual sovereign. In this sense, autonomy can be said to be a tool for the exercise of freedom of choice. Even though autonomy enables the exercise of freedom, it is not an absolute right. It is qualified by legitimate interests, law, and the expectation of others. In the context of biobank-based research, there are issues of autonomy relating to limits that are set on the right to control the body parts housed in biobanks. The Human Tissue Act 2004 prohibits the trafficking in human material in spite of the autonomous right to determine what happens to one's body. In *R v Brown*[1] the House of Lords ruled that ritual physical abuse for sexual pleasure was criminal even when undertaken with consenting adults. A global and widespread debate on the protection of donors' basic human rights of dignity, autonomy and privacy is still ongoing.[1]

According to Kant, respect for people's autonomy, entails, a respect for their capacity to participate in the formulation of the moral principles that every human being would wish to endorse. In this respect, human beings are self-governing, but it is a question of laws and rules within principles, of universal application. Kant incorporates the law-like aspect by connecting autonomy with universal principles. He appeals to the idea that we ought not to base our actions on principles that others cannot share. Kant calls this the 'Categorical Imperative'. He holds that the fundamental principle of all reasoning and acting is that one ought to act 'only in accordance with that maxim through which you can at the same time will that it become a universal law' Autonomy in accordance with the Kantian tradition thus involves taking account of the well-being of others through a judgment of how one's own decisions affect other people's ability to act in a morally

[192] Allmark, (2006). Choosing Health and the inner citadel. *Journal of Medical Ethics*, 32(1), 3-6.

responsible way and to attain their own goals. It can be said that Kant in his concept of autonomy has incorporated an element of inter-relativity. In the sense that the individual is a member of a community and as result has to consider how his interests affects other members of the community. Autonomy in relation to biobank research in this regard is social with the implication that that the tissue source is an individual with individual autonomy which should take into cognisance that of the society. This also implies that in working out legal protection for self-determination of the tissue source with respect to future unspecified research on his samples and data, respect must be had to both the independence of the tissue source in making decisions concerning future use of tissue and data and its effect on the public's interests in research. This means that the individual wish of the tissue source in biobank research to enjoy a private sphere from insight should be recognised and at the same time ensure that the tissue source can take part in research as well as the production of medical knowledge and treatment opportunities that is provided through large population-based biobank research platforms.[193] In the same vein, O'Neill has suggested that respect for autonomy implies control over how one's samples are used, she acknowledges, that this implies requesting affirmation using broad consent for future research without the need for reconsent. In my view, there should be an opportunity for the tissue source to have a say in after initial sampling has taken place so that those who desire can be recontacted for future research.[194]

Taking into consideration the Kantian view on autonomy, where the individual tissue source is called upon to take into consideration the interests of it may be needful to employ a collective democratic instrument such as the charitable trust that ensures the individual tissue source's interest in how biobank research is organised and that principles for balancing the tissue source's interest in future use of his samples and data are taken into account.

[193] Hansson, M. G. (2006). Combining efficiency and concerns about integrity when using human biobanks. *Studies in History and Philosophy of Science Part C: Studies in History and Philosophy of Biological and Biomedical Sciences*, *37*(3), 520-532.

[194] Dillner, J. (Ed.). (2011). *Methods in biobanking*. Humana Press.at p.45

A conceptual analysis might link the notion of autonomy to concepts such as privacy, voluntariness, self-determination, choosing freely, the freedom to choose, and accepting responsibility for one's choices a position which is reviewed in following chapters.

1.10.2 Laws regulating biobanks

There is currently no specific law governing biobanks in the UK or in Nigeria. As Gibbons et al[195] observed, there is no dedicated framework, neither is there a single bespoke legal instrument that governs biobanking. Rather, the existing law on biobanks is made up of a complex web of generally applicable statutes, regulations, codes of practice and other instruments.

In England, Wales and Northern Ireland, the main statutes that relate to biobanks are the Human Tissue Act 2004 (HTA), The Data Protection Act 1998 (DPA), The Human Rights Act 1998 and The Mental Capacity Act 2005. The HTA 2004 regulates the storage and use of relevant material. Relevant material as defined under the Act consists of material which consists of human cells other than gametes.[196] Biobanks, such as the UK biobank, that store and use human tissue must by law be licensed by the Human Tissue Authority. The Data Protection Act, on the other hand, governs the processing of information relating to identifiable individuals. The DPA protects the information rights of the public. Because biobanks deal with human tissue samples and associated data, both statutes are relevant. In spite of these Acts there remains a certain degree of inconsistency in relation to biobank research, in particular the different consent and anonymisation standards, procedures and requirements, which creates a confusing legal environment.[197] For example, the fundamental principle of both Acts is consent for storage and use of tissue and processing of personal information. There are a number of exemptions to this requirement in both Acts,[198] which allow for the use of biological

[195] Gibbons, S., Kaye, J., Smart, A., Heeney, C., & Parker, M. (2007). Governing genetic databases: Challenges facing research regulation and practice. *Journal of Law and Society*, 34(2), 163-189.
[196] S.53(1).
[197] Gibbons, S., Kaye, J., Smart, A., Heeney, C., & Parker, M. (2007). Governing genetic databases: Challenges facing research regulation and practice. *Journal of Law and Society*, 34(2), 163-189. at 177
[198] Human Tissue Act 2004 c. 30 Part 1 s.9. Consent is not required for research on collections of human tissue that were held before the HTA 2004 came into effect on 1 September 2006. Data Protection Act s.9 provides for research exemption where the processing of personal data is only for research purposes.

samples or data without consent or ethics approval, most notably for research. It would thus appear that the protection afforded by these Acts is not absolute.

1.11 Conclusion

This chapter has provided an overview of biobanks and biobank research, the related controversies, and proposals for resolving the ongoing debate on future unspecified uses of tissue in biobank research, providing a foundation for further discussions of these issues in greater detail in subsequent chapters.

In response to these issues, a number of approaches have been developed. These approaches include developing appropriate and comprehensive governance structure for biobanks to resolve ethical and legal concerns.[199] It will be argued later on in this thesis that governance structures could ensure that ethical principles, human rights and dignity are maintained. It could also resolve the inconsistencies of the informed consent process.[200]

[199] Corrigan, O., & Tutton, R. (eds)(2013). *Genetic databases: Socio-ethical issues in the collection and use of DNA*. Routledge.
[200] Swede, H., Stone, C. L., & Norwood, A. R. (2007). National population-based biobanks for genetic research. *Genetics in Medicine*, 9(3), 141-149.

2. The Dialectics of Consent

> To give a description of each and every research protocol which might be performed on a patient's tissue is an unreasonable burden for the patient and the researcher. The current informed consent doctrine.. is not well suited to research that does not involve patient therapy. General consent for use of the tissue should be sufficient. Society has a strong interest in research involving the use of human tissue which may be hampered by well-intended but intrusive regulations.
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> College of American Pathologists, 'Uses of Human Tissue,' unpublished policy statement, August 1996, 6-7.

2.1 Introduction

In a world where millions of people suffer from untreatable diseases, where curable diseases become incurable due to drug resistance, and where new diseases continuously evolve, there is a clear need for medical advances and research on humans is essential if advances in health care are to be achieved.[201] Biobank research gives the hope of providing medical advances and novel insights into the genetic component of diseases, which may ultimately lead to a more personalised and effective approach to healthcare as well as the needed medical advances. Biobanks are collections of human biological tissue specimens and related health data. Undoubtedly, however, biobank research has raised debates over the legal and ethical implications surrounding the use of samples and data. One such debate relates to consent, and that issue is the focus of this chapter, viewed from a Nigerian national perspective, and more from the international context in which this issue is being debated.

From whichever perspective consent is viewed, it is of fundamental importance in research. For instance, consent features as one of the principles to which the Human Genetics Commission is committed. It is also regarded as one the fundamental principles that underlie the Human Tissue Act 2004 as well as the Human Fertilisation and Embryology Act 1990.[202] In dealings between medical professionals and patients and more significantly in dealings between researchers and research participants, wherever possible, It is axiomatic in bioethics that those who are subjects of medical

[201] Biggs, H. (2009). *Healthcare research ethics and law: regulation, review and responsibility*. Routledge.
[202] *Evans v Amicus Healthcare Ltd* [2003] EWHC 2161 (Fam) at para 37, Wall J.

treatment or research should participate on the basis of free and informed consent.[203] Article 6.2 of UNESCO Universal Declaration on Bioethics and Human Rights provides that 'Scientific research should be carried out only with the prior, free, express and informed consent of the person concerned'. This is a position on consent that Brownsword[204] suggests is based on a human rights perspective. By contrast, there is the utilitarian view, that consent is much less important., In that, from a practical point of view, obtaining specific consent from each tissue source for each separate research project in which the samples or data are to be used is impracticable in the context of biobanks (as research platforms for future unspecified research).[205] This position is responsible for the arguments that are being put forward in favour of broad consent, notwithstanding that broad consent allows for future research at the expense of ethical and legal principles.[206]Accordingly, the following paragraph will examine both perspectives on consent and then address the question of whether moving away from traditional, informed consent to a 'broad consent' regime for participation in large-scale biobanks is legally and ethically justifiable, especially from the angle of ensuring the autonomous choice of the tissue source in future unspecified uses of his samples and data which this thesis argues for.

As a follow-up to the position of Brownsword[207] that 3 leading bioethical positions on regulating technological innovations are represented as a bioethical triangle of 1.goal oriented consequentialism, 2. rights based and 3. duty based forms. Each of these positions are open to a variety of articulations with different goals, rights and duties being advocated. The 3 ethical views that make up the bioethical triangle are the utilitarian view which advocates the pursuit of human welfare and happiness; the human

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[203] Article 6(1) of the UNESCO Universal Declaration on Bioethics and Human Rights provides that 'Any preventive, diagnostic and therapeutic medical intervention is only to be carried out with the prior, free and informed consent of the person concerned, based on adequate information'; and, in parallel language.

[204] Brownsword, R. (2008). *Rights, regulation, and the technological revolution*. Oxford: Oxford University Press.at p.40-45

[205] Hansson, M. G., Dillner, J., Bartram, C. R., Carlson, J. A., & Helgesson, G. (2006). Should donors be allowed to give broad consent to future biobank research? *The Lancet Oncology*, 7(3), 266-269. Hofmann, B. (2009). Broadening consent—and diluting ethics? *Journal of Medical Ethics*, 35(2), 125-129. Petrini, Carlo. 'Broad' consent, exceptions to consent and the question of using biological samples for research purposes different from the initial collection purpose.' *Social Science & Medicine* 70.2 (2010): 217-220.

[206] Otlowski, M. F. (2012). Tackling legal challenges posed by population biobanks: reconceptualising consent requirements. *Medical Law Review*, 20(2), 191-226.

[207] Brownsword, R. (2008). *Rights, regulation, and the technological revolution* . Oxford: Oxford University Presss. P.41-43

rights view and the dignatarian view. The bioethical triangle sketches the basic matrix for the articulation of bioethical debates. Brownsword however admits that the articulations represented are by no means exhaustive of all the ethical possibilities that they address.[208] In relation to consent issues in biobanking research, this section will sketch the contours of how consent is viewed from, 2 of the positions of the bioethical triangle- a utilitarian, and a human rights, ethical perspective with a view to showing that each of these perspectives takes a rather different view on consent and, unless we appreciate that consent is contested in these ways, there is the likelihood that matters such as arguing for informed consent as opposed to broad consent in biobanking research may be confusing. Thereafter, the chapter will view and place consent squarely within the rights perspective and consider the issues arising from consent in biobanking research.

Essentially, utilitarianism holds that there is just one moral principle: to seek the greatest benefit of the greatest number. It is thus one form of consequentialism, where the morality of any action is judged solely in terms of its consequences. A central feature of utilitarian perspective is to assess actions in terms of its consequences. Classic utilitarianism claim that an act is morally right if that act maximizes the good, that is, if the total amount of good for all minus the total amount of bad for all is greater than this net amount for any incompatible act available to the agent on that occasion. This position can be summarized in the slogan that an act is right if and only if it causes the greatest happiness for the greatest number. This slogan can be misleading, in the sense that an act can increase happiness for the greatest number of people and yet fail to maximize the good in the world if the smaller number of people whose happiness is not increased lose much more than the greater number gains. Another objection to utilitarianism in general, and even to the simplest version of it, hedonistic utilitarianism, is that it is not applicable in real life. It is also demanding of factual non-moral information that makes it doubtful to apply it with any confidence and deduce a practical recommendation. [209]

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[208] P.42

[209] Tännsjö, T. (2011). Why should we respect the privacy of donors of biological material?. *Medicine, Health Care and Philosophy*, *14*(1), 43-52.

Classic Utilitarians for instance, count utility (which includes individual pleasure and preference) and disutility; (individual pain and displeasure) [210]by seeking to maximize utility and minimize disutility, for utilitarians, utility and disutility is all that matters. In other words the main aim should be to maximize public health happiness and welfare while making provision for consent relative to the overriding utilitarian aim.[211] As such, from the point of view of maximising happiness, to this school of thought, there may be nothing special about consent in biobanking research. In principle, there is no harm to the tissue source by sharing his data and tissue. In general, it is easy to see the negatives in relation to consent collection. For instance it has been argued, that obtaining consent might not always be practicable; and that where it is, it incurs transaction costs; and, on some occasions, may become distressful. [212]For instance, waiting for participants consents to be cleared in future research might involve opportunity costs. Moreover, policies and the fruits of research might be frustrated if, instead of saying 'yes', those who are asked to consent refuse. Again, for utilitarians, there is no hard and fast rule, requiring that the consent of those upon whom an action or decision impacts should be obtained. For example, "requiring researchers or doctors to deal on an informed consent basis with research participants or others is not necessarily an improvement on compulsion, ignorance, or paternalism." The calculation always depends on context, convenience, contingency, and circumstance. Having said this, however in a culture where preferences strongly favor the expression of consent, even if there is no rule requiring consent, utilitarians might as well accept that in a the sense there is a general rule to this effect.

By contrast to the utilitarian's perspective, human rights perspective holds that what matters is respect for individual autonomy, which entails the recognition of the right of

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[210] Article 4 of the UNESCO Declaration—providing that '[i]n applying and advancing scientific knowledge, medical practice and associated technologies, direct and indirect benefits to patients, research participants and other affected individuals should be maximized and any possible harm to such individuals should be minimized' —speaks this kind of language.

[211] Brownsword, R. (2013). Biobank governance: property, privacy, and consent.in *Ethics and Law of Intellectual Property: Current Problems in Politics, Science and Technology*. C. Lenk, R. Andorno, & M. N. Hoppe (Eds.). Ashgate Publishing, Ltd. At p.72

[212] Tännsjö, T. (2011). Why should we respect the privacy of donors of biological material?. *Medicine, Health Care and Philosophy*, *14*(1), 43-52 at p.55

individuals to make their own choices, to exercise control over their own person, property, and privacy, and to consent or refuse consent.[213] Which, in other words, entails, taking individuals seriously, taking rights seriously, means taking consents and refusals seriously.

Consent from a human rights perspective signals a change of position or the creation of a new relationship, in the sense that it would convert what otherwise would be an invasion of their person or their rights into a harmless or justified activity. Broadly speaking, under a rights ethic perspective, consent functions not only as a justifying precept (page 80 post). it functions to preclude the consenting agent, from raising a complaint about the conduct of the recipient agent. It doubtful if a broad consent model can adequately preclude a consenting party from complaining. This is because the tissue source cannot be said to have consented to a research he is not aware of. Inspite of this, it would be difficult to say that consent is to be treated as a universal value even though in clinical and research settings, the bioethical consensus is that there should be no intervention unless the person directly concerned has consented.[214]

Broad consent as opposed to specific consent, has been justified on 2 main grounds. The first is that it supports the public good, in that adherence to strict requirements of traditional consent would impede the progress of research, as a public good.[215] The second is that it is practical and sensible given that biobank research poses minimal risk to the tissue source. This chapter argues that neither of these rationales are sufficient grounds for adopting wholesale broad consent in biobank research. It will advance arguments in favour of a consent model that reflects the legal principles of consent which protect choice of voluntary participation in research. Although there is no denying that broad consent is gaining acceptance in the field of biomedical research, the crux of the argument of this chapter is that the convenience of lack of specificity of broad consent should not discount the core principles of consent as a legal concept. The

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[213] Ibid at 73

[214] Article 5 of the Convention on Human Rights and Biomedicine which states as a general rule that 'An intervention in the health field may only be carried out after the person concerned has given free and informed consent to it', the information in question relating to 'the purpose and nature of the intervention as well as [to] its consequences and risks'.

[215] Hansson, M. G., Dillner, J., Bartram, C. R., Carlson, J. A., & Helgesson, G. (2006). Should donors be allowed to give broad consent to future biobank research? *The Lancet Oncology*, 7(3), 266-269. Caulfield, T. (2007). Biobanks and blanket consent: the proper place of the public good and public perception rationales. *KLJ*, 18, 209.

chapter argues examines the legal principles of consent as it plays out in some areas of law, to establish that broad consent does not fit the mould. It then goes on to argue for participation in biobank research in a way that ensures the autonomous choice of the tissue source with a consent-based justification

By way of background, the following paragraphs will highlight features of the growth and emergence of biobanks that are challenging the boundaries of established principles of consent. This analysis is taken within the historical context of the emergence of biobank research with reference to Nigeria, a jurisdiction which operates a common law legal system by reason of its colonial heritage. In the past, the search for solutions to diseases through human experimentation led to many people being included in research without their agreement.[216] However, today things have improved markedly and it is widely accepted that individuals should decide whether or not they will enrol in research.[217] Across jurisdictions, this position is subject to some legal exceptions, but the general rule holds true.[218]

The establishment of population biobanks has increased in the past decade, especially within the international research community. Compared to traditional tissue banks that collect data for specific fields of research, a biobank is intended for access by a wide range of health researchers across the world.[219] Data sharing is an important part of science and technology advancement in biobank research, but it presents a number of issues as was discussed in Chapter 1. It is undeniable that biobanks and biobank

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[216] *U.S. v Karl Brandt* cited in Katz, J. (1972). *Experimentation with human beings: The authority of the investigator, subject, professions, and state in the human experimentation process*. New York: Russell Sage Foundation, 292.

[217] Cambon-Thomsen, A., Rial-Sebbag, E., & Knoppers, B. M. (2007). Trends in ethical and legal frameworks for the use of human biobanks. *European Respiratory Journal*, 30(2), 373-382; Elger, B. S., & Caplan, A. L. (2006). Consent and anonymisation in research involving biobanks: differing terms and norms present serious barriers to an international framework. *EMBO reports*, 7(7), 661.

[218] Rickham, P. P. (1964). Human experimentation. Code of Ethics of the World Medical Association. Declaration of Helsinki. British Medical Journal, 2(5402), 177. Wear, S. (1993). Exceptions to Informed Consent. In Informed Consent (pp. 134-146). Springer Netherlands. P.134, Art 30 Declaration of Helsinki World Medical Association. (2008). World Medical Association Declaration of Helsinki: ethical principles for medical research involving human subjects. World Medical Association. Article 15 of the Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Biomedical Research states that 1. Research on a person without the capacity to consent to research may be undertaken only if all the following specific conditions are met :(i). the results of the research have the potential to produce real and direct benefit to his or her health;(ii) research of comparable effectiveness cannot be carried out on individuals capable of giving consent; (iii) the person undergoing research has been informed of his or her rights and the safeguards prescribed by law for his or her protection, unless this person is not in a state to receive the information. Informed of his or her rights and the safeguards prescribed by law for his or her protection, unless this person is not in a state to receive the information.

[219] Kaye, J. (2012). The tension between data sharing and the protection of privacy in genomics research. *Annual review of genomics and human genetics*, 13, 415-431 at 417

research promises solutions to a number of health problems, but these large scale population studies create a host of legal and ethical challenges over consent, ownership, governance, incidental findings, data sharing and rights of the tissue source.

By its very nature, biobank research is intentionally broad, and involves the collection and storage of vast amounts of genetic material and associated personal information for the purposes of future unspecified research.[220] This implies that not only are-consent questions implicated but also the privacy of the tissue source. A biobanks' scientific value is greatly enhanced if the samples are linked to identifiable data such as medical records. Also because biobank research is ongoing and open ended, the reality that most future unspecified research will be conducted in an evolving social environment raises concerns over the way in which data and samples may be used in the future.

There is a need to protect the privacy of participants as well as their data and samples within the governance provisions for its storage. There is a school of thought that suggests that applying informed consent and privacy to biobank research is restrictive and burdensome on potentially fruitful research,[221] and so broad consent has been accepted as the appropriate model in biobank research. However, this chapter will argue that the consent of donors should be structured in such a way that the essential purposes and processes of collection and processing of personal samples and data are disclosed as part of biobank research, and the tissue source knows what they are agreeing to when they provide their samples and data.

Nigeria presently has a number of organised collections that store a variety of human tissue and other samples, some linked with associated personal or medical data, and others not. These relatively small-scale collections are typically held by individual clinicians or research groups and were established for a particular purpose such as

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[220] Steinberg, K., Beck, J., Nickerson, D., Garcia-Closas, M., Gallagher, M., Caggana, M. & Sampson, E. (2002). DNA banking for epidemiologic studies: a review of current practices. *Epidemiology*, 13(3), 246-254. Godard, B., Schmidtke, J., Cassiman, J. J., & Aymé, S. (2003). Data storage and DNA banking for biomedical research: informed consent, confidentiality, quality issues, ownership, return of benefits. A professional perspective. *European Journal of Human Genetics*, 11(2), 88.

[221] Walley, T. (2006). Using personal health information in medical research: Overzealous interpretation of UK laws is stifling epidemiological research. *BMJ*, 332(7534), 130.

medical training or research into a specific disease.[222] The national policy statement on the storage of human samples in biobanks and bio repositories envisages that samples stored in biobanks may be derived from previous collections to be used for future unspecified research.[223] While some of the issues raised in this thesis may have some relevance to these more traditional collections, it is acknowledged that they are distinct from commercial and national biobanks which is the focus of this thesis.

Advances in genomic research have enhanced the awareness and commitment of the Nigerian government and its scientists to genome sciences and research.[224] The African Collaborative Centre for Micro Biome and Genomics Research at the University college hospital is an example of this commitment, and recently received a grant of $4.16 million from the National Institute of Health. Through government funding, the Nigerian Biotechnology Development Agency[225] in Abuja is one of the agencies promoting biotechnological breakthroughs across disciplines, especially in health and agriculture. Moreover, universities and research institutes receive foreign grants to fund training and research related to genomic technologies and tools. For example, the Institute of Human Virology (IHVN),[226] also based in Abuja, has received funding from the American National Institute of Health (NIH) to establish the H3Africa biorepository.[227] In the light of this move to population biobanking, there is a need for a more coordinated approach to biobanking research in Nigeria.

This thesis will advocate for a consent model that will enable tissue sources to express choice in terms of future research on their samples and data. This position will be advocated based on the premise that biobanks are custodians and stewards of the

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[222] Section 7(1) Anatomy Act Laws of the Federation of Nigeria 1990 Cap 17 can be accessed from http://www.nigeria-law.org/Anatomy%20Act.htm

[223] http://nhrec.net/nhrec/NHREC_Policy_Statement_on_Biobanks_FINAL.pdf

[224] www.genome.gov last accessed 21/11/2013

[225] http://www.nabda.gov.ng/ last accessed 17/11/2015

[226] Institute of Human Virology, Nigeria. Bio-repository Services. Available at: http://ihvnigeria.org/ihvnweb/webnew/index.php/departments/laboratory-department/implementation-science/biorepositoryservices.html [Accessed October 24, 2013].

[227] The Human Heredity and Health in Africa (H3Africa) is an initiative which aims to facilitate a contemporary research approach to the study of genomics and environmental determinants of common diseases with the aim of improving the health of African populations. To accomplish this, the H3Africa Initiative aims to put in place infrastructure and training which will contribute to the development of the necessary expertise among African scientists, and to establish networks of African investigators. See website of The Human Heredity and Health in Africa (H3Africa) Initiative at http://h3africa.org/

biosample and data on behalf of the tissue source. The following section will examine the sources of law of consent in Nigeria to see whether dynamic consent within a legal framework of a charitable trust based on stewardship principles can be accommodated within Nigerian legal jurisprudence.

2.2 Sources of the Law of Consent in Nigeria

In Nigeria, the concept of consent is governed by common law and statute. Section 32(1) of the Nigerian Health Act codifies the requirement of consent as a prerequisite for research on humans. It states:

> (1) Notwithstanding anything to the contrary in any other law, every research or experimentation on a living person shall only be conducted:-
>
> (a) in the manner prescribed by the relevant authority; and
>
> (b) with the written consent of the person after he shall have been informed of the objects of the research or experimentation and any possible effect on his health.

Under the Act, consent for research on humans has to be in writing. The section also recognises that there are other sources of law relating to consent but states that notwithstanding these laws, research on humans will be conducted subject to written consent, and in a manner prescribed by the relevant authority. The Act does not state what authority is relevant, but the *National Policy Statement On Storage of Human Samples In Biobanks and Biorepositories In Nigeria* designates the National Health Research Ethics Committee (NHREC) as the sole authority to provide oversight for the ethical aspects of biobanking establishment and operations.[228] The statement also acknowledges that NHREC supports broad consent, but not blanket consent. Broad consent implies consent in which the type or purpose of research is defined in broad terms, but includes research purposes not specified by time.

The concept of consent in Nigeria is also based on the common law doctrines in contract and torts. The concept has also found expression in matrimonial causes, criminal law and under indigenous customary law. The legal history of Nigeria as a former colony of the United Kingdom has informed the use of English authorities as

[228]Available at http://nhrec.net/nhrec/NHREC_Policy_Statement_on_Biobanks_FINAL.pdf accessed 14 Oct 2014.

highly persuasive in Nigerian courts. The Nigerian Legal System (NLS) is based on the English Common Law and legal tradition by virtue of colonisation and the attendant establishment of English law through legal transplant. English law has a tremendous influence on the NLS, and it forms a substantial part of Nigerian law. The reception of English law continued to be a feature of the NLS long after independence in 1960.[229] Section 45 (1) of the Nigerian Interpretation Act provides that:

> the common law of England and the doctrines of equity and the statutes of general application which were in force in England on 1st January, 1900 are applicable in Nigeria, only in so far as local jurisdiction and circumstances shall permit.

Consequently, legal issues evolving from common law in England and codes of conduct of the medical profession and professional ethics as a whole, such as confidentiality, consent, maleficence, beneficence, and duty of care, are applicable in Nigeria even though they have not been specifically legislated upon.

Generally, the decisions of foreign jurisdictions are not binding on Nigerian Courts but are persuasive authorities, particularly where there are local decisions on the matter in question,[230] and where there are no local decisions on a matter, then decisions of a superior court of record of a foreign common law jurisdiction are deemed to be highly persuasive. In the case of *Adetoun Oladeji (Nig) Ltd v Nigerian Breweries,*[231] the Supreme Court of Nigeria, in considering whether principles of law as laid down in the English case of *Hadley v. Baxendale*[232] is applicable in and binding on the courts in Nigeria, opined and stated as follows

> 'I agree with the view expressed in the lead judgment that generally speaking, decisions of English courts or any foreign courts are not binding on Nigerian court but they are merely persuasive. I will, however, like to add that where Nigerian courts have followed a particular principle adopted from a foreign decision over the years, such as the one in the *Hadley v. Baxendale* case, it will be totally erroneous to hold that such principle still remains, foreign in nature.

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[229] Nwabueze, R. N. (2007). *Biotechnology and the challenge of property: property rights in dead bodies, body parts, and genetic information*. Ashgate Publishing. 114.

[230] See Dada v. The State (1977) NCLR 135; Elioclin Nig. Ltd v. Mbadiwe (1986) 1 NWLR (Pt. 14) 47; National Supply Co. Ltd, v. Alhaji Hamajoda Sabana Co. Ltd (1938) 5 NWLR (Pt.40) 2005; Senator Adesanya v. President of the Federal Republic of Nigeria (1982) 2 NCLR 358.

[231] (2007) 5 NWLR (Pt.1027)405 at 415

[232] *Hadley-Baxendale Case*, 9 Exch. 341, 9 Ex. 341 (Supreme Court 1854).

> Thus in the *Hadley v. Baxendale* case, supra, the principle of law relating to remoteness of damages in breach of contracts enunciated in that case have been cited with approval and followed by this court in numerous decisions of this court: for example: *Imana v. Robinson* (1979) 3-4 SC (Reprint) 1; *Niger Insurance Co. Ltd. V. Abed Brothers Ltd.*(1976) 7 S. C. (Reprint) 20; *Omonuwa v. Wahabi* (1976) 4 S.C. (Reprint) 62; *Maiden Electronics Works Ltd. V. Attorney General of Federation* (1974) 1 S.C (Reprint) 37; S.P.D.C. v. *Jammal Eng. (Nig.) Ltd. (1974) 4 S. C. (Reprint) 24: and Yusuf.v. N. T. C. Ltd.(1977) 6 S.C.(Reprint) 25*. I believe and hold that the said principle has ceased to be regarded as foreign in Nigeria. It has, no doubt, become part and parcel of our case law of contract. This is because mere statement of the principles and citing any of the numerous decisions of this court where the principle had been adopted, some of which I have cited above, as authority to back up the principle, will be sufficient to make it binding on all courts in Nigeria'.

This chapter will discuss the concept of consent, focusing mainly on two jurisdictions, the United Kingdom and Nigeria, whilst discussions on a third, i.e. the U.S., will be mainly illustrative. It will discuss the issues of biobanking from the angle of secondary use of tissue and associated data. It will assess the law relating to the governance of biobanking in Nigeria and the UK with a view to suggesting effective steps to be taken by Nigeria in formulating a legal strategy for governance using the legal mechanism of a charitable trust to enable a strategy of stewardship for biobank research in Nigeria.

The focus of this chapter is the concept of consent in future unspecified research. To this end, it will discuss and emphasise the potential for the infringement of rights of privacy and autonomy or self-determination of individuals[233] in future unspecified research, and the rights of a tissue source to have a say over the secondary use of their tissue. In using this approach, the chapter will discuss these legal rights as well as the instruments supporting them where applicable. It will also relate the concept of consent to biobanking research to establish the significance of protecting the individual's interest and obtaining consent prior to research in biobanking research.

2.3 Historical background to consent in research

In order to examine the concept of consent in law and its operation in stored tissue research, I will briefly consider the historical events and antecedents of consent in biomedical research generally. This is not a comprehensive historical review, but a

[233] Hansson, M. G., Dillner, J., Bartram, C. R., Carlson, J. A., & Helgesson, G. (2006). Should donors be allowed to give broad consent to future biobank research? *The Lancet Oncology*, 7(3), 266-269.

background to connect the past and the on-going discourse on the law on consent especially in relation to the consent options for stored tissue research. Since the Second World War, several sets of guidelines and declarations have been influenced or created as a result of scandals involving human subjects in research.[234] Most of these guidelines are based on notions of dignity (Universal Declaration of Rights)[235] and informed consent (Nuremberg Code).[236]

The Nuremberg Code was one of the first authoritative declarations on human experimentation and came into force soon after the Second World War in response to the human experimentation abuses that had occurred during it.[237] Prior to the Nuremberg Code, there were no specific codes governing ethical conduct of human research[238] and so it could be described as one of the first attempts at curbing experimental abuses on humans. It has become one of the most influential codes over the years, making it a model for others to follow.[239] Ever since the formulation of the Nuremberg Code the requirement for informed consent has been considered as an absolute essential for human experimentation.

The first article of the Nuremberg Code states that:

> 'The voluntary consent of the human subject is absolutely essential.
>
> This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, over-reaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved, as to enable him to make an understanding and enlightened decision. This latter element requires that, before the acceptance of an affirmative decision by the experimental subject, there should be made known to him the nature, duration,

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[234] Utely G.J ., (Ed) (1992). *The Nazi Doctors and the Nuremberg Code: Human Rights in Human Experimentation: Human Rights in Human Experimentation*. Oxford University Press; U.S.A.

[235] UN General Assembly, *Universal Declaration of Human Rights*, 10 December 1948, 217 A (III), available at: http://www.refworld.org/docid/3ae6b3712c.html [accessed 18 November 2015]

[236] Code, Nuremberg. 'The Nuremberg Code.' Trials of war criminals before the Nuremberg military tribunals under control council law 10 (1949): 181-182.

[237] Brody BA. *The ethics of biomedical research. An international perspective*. New York, Oxford University Press; 1998

[238] Except for the Guidelines for Human Experimentation of 1931 which ironically was in force in Germany.

[239] Principles Of Medical Ethics. Judicial Council. American Medical Association. June 7, 1958. www.ama-assn.org. It also influenced the requirements of consent in the Clinical Trials Directive which became law in May 2004 as the Clinical Trials Regulations, see Sch 1 pt 2 para 1.

> and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonably to be expected; and the effects upon his health or person, which may possibly come from his participation in the experiment'.

The basic idea emanating from these provisions is that any risk associated with research must be accepted on voluntary basis. This need for an informed and voluntary assumption of risk precludes broad consent to future unspecified research.[240] In spite of its significance and the influence it has had on the research landscape, it has been argued that it has become inadequate to govern the complex variety of situations arising in biobank research.[241] For instance, the right to withdraw from research along with the necessity for informed consent is a vested right of a research participant granted by the Code. However, owing to the nature of biobank research which involves more networking data and human tissue rather than physical intervention, the right to withdraw is less clear and practicable in biobank research. Also, the risks associated with these new ways of carrying out research have less to do with direct physical harm than with disclosure of sensitive personal information.[242] As a result, it has been argued that the nature of the relationship between research scientists and research participants is also changing, and therefore a more nuanced and limited right of withdrawal has been said to better express what is desirable in the kind of long-term studies that biobank research portends.[243] Even though the landscape of human experimentation has changed from what it was when the Code was drawn up, it should not be forgotten that 'many of the worst research ethics controversies have involved studies without proper consent being undertaken'.[244]

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[240] Hansson, M. G., Dillner, J., Bartram, C. R., Carlson, J. A., & Helgesson, G. (2006). Should donors be allowed to give broad consent to future biobank research? *The Lancet Oncology*, 7(3), 266-269.

[241] Melham, K., Moraia, L. B., Mitchell, C., Morrison, M., Teare, H., & Kaye, J. (2014). The evolution of withdrawal: negotiating research relationships in biobanking. *Life Sciences, Society and Policy*, 10(1), 1-13; Eriksson, S., & Helgesson, G. (2005). Potential harms, anonymization, and the right to withdraw consent to biobank research. *European Journal of Human Genetics*, 13(9), 1071-1076.

[242] Melham, K., Moraia, L. B., Mitchell, C., Morrison, M., Teare, H., & Kaye, J. (2014). The evolution of withdrawal: negotiating research relationships in biobanking. *Life Sciences, Society and Policy*, 10(1), 1-13.

[243] Melham, K., Moraia, L. B., Mitchell, C., Morrison, M., Teare, H., & Kaye, J. (2014). The evolution of withdrawal: negotiating research relationships in biobanking. *Life Sciences, Society and Policy*, 10(1), 1-13.

[244] Caulfield, T. (2007). Biobanks and blanket consent: the proper place of the public good and public perception rationales. *King's Law Journal*, 18(2), 209-226 at 216

The Declaration of Helsinki,[245] like the Nuremberg Code, is another of the foundational documents of medical research. It was also one of the first attempts at formal self-regulation by a professional body. Apart from its historical significance, the Declaration has gone further than the Nuremberg Code. It promulgates more extensive standards and processes for seeking and obtaining informed consent from research subjects than those set out in the Nuremberg Code. Art. 26 of the Declaration requires researchers to use explicit written and documented procedures in obtaining informed consent, while the Nuremberg Code simply requires researchers to inform research participants about the risks and benefits of the study. The Declaration makes a distinction between therapeutic and non-therapeutic research, which the Code does not. Therapeutic research, according to the Declaration of Helsinki, is research combined with patient care, while non-therapeutic research is purely scientific research without therapeutic value for the patient. The declaration requires consent for all forms of non-therapeutic research unless the subject is incompetent, in which case the consent of the guardian is required.[246]

In relation to biobanking research and genome wide studies (GWAS), research proposals for secondary data analyses, for instance, may not be formulated until after tissue has been removed following initial written consent. This implies that if the provisions of the Declaration of Helsinki are applied to secondary uses of tissue, the research subject or tissue source would have to be recontacted.[247] Art. 6 of the Declaration of Helsinki,[248] notes that the interests of research participants should take precedence over the interests of science and society. In spite of the many endorsements of the principle of informed consent by various instruments and writers, it remains one of the most discussed and disputed concepts in ethical literature.[249] There would appear to be a consensus over the need to expand the frontiers of science through the use of

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[245] World Medical Association. (2013). *World Medical Association Declaration of Helsinki: ethical principles for medical research involving human subjects*. World Medical Association.

[246] See Declaration of Helsinki 1964,(1994) *BMJ* 1996;313:1448.2 Available at http://www.wma.net/en/30publications/10policies/b3/ last accessed 12 Nov 2013.

[247] Manson, N. C., & O'Neill, O. (2007). *Rethinking informed consent in bioethics* Cambridge: Cambridge University Press. 9; Sven Ove Hansson (2004). *The Ethics of Biobanks*. Cambridge Quarterly of Healthcare Ethics, 13, 319-326.

[248] World Medical Association. (2013). *World Medical Association Declaration of Helsinki: ethical principles for medical research involving human subjects*. World Medical Association.

[249] Lowrance, W. W. (2012). *Privacy, Confidentiality, and Health Research*, Cambridge University Press; Elger, B., & Mauron, A. (2003). *A presumed consent model for regulating Informed Consent of Genetic Research involving DNA Banking. Populations and Genetics: Legal and Socio-Ethical Perspectives*, 269-95

tissue samples and medical data in research,[250] but there are unresolved issues relating to how to engage consent while meeting that goal. The position of the tissue source, and their relationship, involvement and control over biological samples has been one of the major issues in the ethical debate surrounding the use of biobanks as resources for research, and this has been embodied in an extensive discourse on consent and consent processes in biobank research.[251] There appears to be no theoretical consensus on whether consent should be broad, blanket and open-ended, or whether it should be specific for the particular research or a one-size-fits-all model for present and future uses of samples and data.[252] In practice, however, the model termed 'broad consent' has been adopted by some biobank projects, such as the UK Biobank, CARTaGENE (Montreal, QC, Canada) and the Norwegian HUNT study.[253]

2.4 Types of consent in the context of biobank research

The following paragraphs will consider the types of consent and their approaches to enabling autonomy of choice in terms of the spectrum of options they offer the tissue source in biobank research. They range from specific consent, on the one hand, to blanket consent, on the other hand. In examining the various types of consent and approaches to biobank research, the essence of the analysis is to identify how well these approaches reflect the principles and values of consent which include autonomy, privacy and protection of the tissue source.

2.4.1 Specific consent

Specific consent is consent given for a particular research project or projects which can be clearly described at the time the consent is given. Where specific consent is given,

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[250] Clayton, E. W., Steinberg, K. K., Khoury, M. J., Thomson, E., Andrews, L., Kahn, M. J. E., & Weiss, J. O. (1995). Informed consent for genetic research on stored tissue samples. *Jama*, 274(22), 1786-1792; Zhang, X., Matsui, K., Krohmal, B., Zeid, A. A., Muthuswamy, V., Koo, Y. M., & Lie, R. K. (2010). Attitudes towards transfers of human tissue samples across borders: An international survey of researchers and policy makers in five countries. *BMC medical ethics*, 11(1), 16.

[251] Steinsbekk, K. S., Myskja, B. K., & Solberg, B. (2013). Broad consent versus dynamic consent in biobank research: Is passive participation an ethical problem. *European Journal of Human Genetics*, 21(9), 897-902.

[252] Hofmann, B., Solbakk, J. H., & Holm, S. (2009). Consent to biobank research: one size fits all? In *The ethics of research Biobanking*, p 3-23. Hofmann, B. (2009). Broadening consent—and diluting ethics? *Journal of Medical Ethics*, 35(2), 125-, Shickle, D. (2006). The consent problem within DNA biobanks. *Studies in History and Philosophy of Science Part C: Studies in History and Philosophy of Biological and Biomedical Sciences*, 37(3), 503-519.

[253] Master, Z., Nelson, E., Murdoch, B., & Caulfield, T. (2012). Biobanks, consent and claims of consensus. *Nature methods*, 9(9), 885.

any future use for other purposes not covered by specific consent is not usually permitted. Specific consent is the type of express informed consent that has become standard in biomedical research to protect participants from research risk, to ensure the autonomy of the participant, and to promote rational decisions that maintain the public's trust in research.[254]

This traditional mode of giving consent involves the provision of information by the researcher and the capacity of the research participant to make a voluntary choice. In research settings, specific consent for the particular study usually covers inter alia research aims, risks, harms, inconveniences and the right to withdraw.[255] However, there are difficulties in the operation of specific consent within the context of biobank research because the aims, risks and potential harm of the studies that the samples and data will be used for are not ascertainable at the point of enrolment.

Some writers have argued that specific consent is too onerous a requirement for biobank research.[256] Be that as it may, consent as a concept should be based on information relevant for an assessment of benefits, risks or harms associated with the study. Arnson argues that the more general is the consent, the less informed it becomes.[257] As Kaye and Caulfield[258] have observed, there is a diversity of opinion on the appropriateness of broad consent as opposed to specific consent. Governments, funding bodies and some scientists have suggested that the more researchers have access to biobank data and tissue samples via broad consent, the more quickly the biomedical advances promised by biobank research can be achieved.[259] Accordingly, researchers often ask tissue sources to provide broad consent. The primary rationale put forward for the use of a broad consent approach is that the strict application of consent rules would hinder

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[254] Hofmann, B., Solbakk, J. H., & Holm, S. (2009). Consent to biobank research: one size fits all? In *The Ethics of research biobanking*. Springer U.S. 3-23.

[255] Chadwick, R., & Berg, K. (2001). Solidarity and equity: new ethical frameworks for genetic databases. *Nature Reviews Genetics*, 2(4), 318-321.

[256] Hofmann, B. (2009). Broadening consent—and diluting ethics? *Journal of Medical Ethics*, 35(2), 125-129; Solbakk, J. H., Holm, S., & Hofmann, B. (eds)(2009). *The ethics of research biobanking*. New York: Springer.

[257] Árnason, V. (2004). Coding and consent: moral challenges of the database project in Iceland. *Bioethics*, 18(1), 27-49.

[258] Caulfield, T. (2007). Biobanks and blanket consent: the proper place of the public good and public perception rationales. *KLJ*, 18, 209.

[259] Wellcome Trust *sharing data to improve Public health: Full joint statement by funders of health research*. Available from http://www.wellcome.ac.uk/About-us/Policy/Spotlight-issues/Data-sharing/Public-health-and-epidemiology/WTDV030690.htm. Last accessed 02/12/2015

potentially socially beneficial research. There is a perceived need to balance the goals of science, particularly science that is framed as being for the public good, against the rights of research participants. While it is possible to sympathise with this line of thinking, allowing scientific goals, even those pursued in the interest of society, to take precedence over the interests of the tissue source offends a foundational pillar of research ethics which is based on notions of autonomy and human dignity. This is contained in both the Universal Declaration of Human Rights[260] and the Nuremberg Code.[261] The objectives of research should not, as a general rule, supersede individual rights as evidenced in Article 6 of the Declaration of Helsinki 2013, which states that the interests of research participants 'should take precedence over the interests of science and society'. [262]

This position is also supported by the provisions of Article 3 of the Additional Protocol to the Council of Europe Convention on Human Rights and Biomedicine,[263] which declared that the interests and welfare of the human being participating in research shall prevail over the sole interest of society or science. This also underpins the opinion that the only legitimate form of consent for research biobanks is to recontact the tissue source and request specific consent for each research that will use the sample or data.[264]

2.4.2 Blanket consent

Blanket consent is given only once, to conduct research without further authorisation, and so covers any use of the material at any time in the future.[265] Blanket consent may be understood as a generic consent that allows the use of sample or data for any type of research in general; it places no limit on the future use of the samples and data. These is particularly significant for biobank research in which studies might be devised years after individuals have given their consent and deposited their biological material; they

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[260] United Nations, Universal Declaration of Human Rights (GA/RES/217 A (III), 10 December 1948, Paris).

[261] Nuremberg Code 1947. For a transcript of the Code, see http://www.nihtraining.com/ohsrsite/guidelines/nuremberg.html

[262] World Medical Association. (2013). World Medical Association Declaration of Helsinki: ethical principles for medical research involving human subjects. *Jama*, 310(20), 2191.

[263] Available at http://www.ub.edu/recerca/Bioetica/doc/Protocol_Biomedical_research.pdf

[264] Cambon-Thomsen, A., Rial-Sebbag, E., & Knoppers, B. M. (2007). Trends in ethical and legal frameworks for the use of human biobanks. *European Respiratory Journal*, 30(2), 373-382.

[265] Kegley, J. A. K. (2004). Challenges to informed consent. *EMBO reports*, 5(9), 832-836 at 833.

may even have died in the meantime.[266] This raises questions as to the ethical appropriateness of blanket consent, in the sense that it runs contrary to the ideals of informed consent. In spite of this there appears to be agreement among most commentators,[267] that the blanket consent strategy is a move away from the traditional standards of consent and that the norms of informed consent, while ideal, cannot be satisfied in biobank research.[268] However, blanket consent is to be differentiated from broad consent in that the former gives an unrestricted right to use the sample or information in any research without any other information.[269]

2.4.3 Tiered consent

This is also seen as a type of blanket consent. It refers to consent given by a tissue source to agree to the future use of his or her tissue in unknown projects, but with a proviso specifying particular categories of research that are to be excluded. Where such options are offered to tissue sources, it is important that information systems are in place to ensure that the chosen exclusions are properly recorded and maintained. This category of consent envisages a wide range of future uses of samples.[270]

2.4.4 Broad consent

A topic at the centre of the biobank research debate is whether it is ethically and legally acceptable to use broad consent in biobank research. In contrast to traditional informed consent models which specify the details of the proposed research, broad consent, as the name suggests, is a mode of consent that depicts broadly, and authorises the use of samples in future research. Broad consent is different from blanket consent in the sense that broad consent is not consent to all types of research, but in its broadest representation it is consent to ethically approved research. To allow broad forms of consent means to make it possible for sample providers to submit consent not only to

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[266] Ibid.

[267] Árnason, V. (2004). Coding and consent: moral challenges of the database project in Iceland. Bioethics, 18(1), 27-49.

[268] Caulfield, T. (2007). Biobanks and blanket consent: the proper place of the public good and public perception rationales. *King's Law Journal*, 18(2), 209-226.

[269] Otlowski, M. F. (2012). Tackling legal challenges posed by population biobanks: reconceptualising consent requirements. *Medical Law Review*, 20(2), 191-226.

[270] Nuffield Council on Bioethics, (2011), *Human Bodies: Donation for Medicine and Research*, London: NCB.

specific studies but also classes of research.[271] Broad consent is often used in population biobanks which are research platforms whose significant role in the understanding of the role of genes in the development of human diseases has created ethical and legal dilemmas with its use of broad consent regime, one of which is that these research platforms will be used by a number of researchers for various research studies for many years to come.[272]

As a result it is truly difficult to obtain informed consent from the tissue source at the point of recruitment hence the use of broad consent. In this respect, broad consent as a framework for future unspecified research has precipitated a re-examination of basic principles of research, and challenged the foundational principles of research which had hitherto appeared immutable.[273] While this practice maximises the value of biobank research as a platform that gives access to a greater number of researchers and research projects, opponents of broad consent argue that it does not adequately inform the research subjects of the specific nature and risks of the research to which they are-consenting. Thus, according to its opponents, labelling broad consent to biobank research as 'informed' is a contradiction in terms,[274] as broad consent does not meet the legal or ethical requirements to ensure autonomy of the participant.[275] Some writers have taken the argument even further by describing broad consent as hindering the tissue source from exercising their fundamental human rights.[276] In spite of these issues, the position in Nigeria as well as that of the UK biobank seems to be based on the presumption that broad consent is both legally and ethically valid.

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[271] Helgesson, G. (2012). In defence of broad consent. *Cambridge Quarterly of Healthcare Ethics*, 21(01), 40-50 at 42.

[272] Allen, C., Joly, Y., & Moreno, G. (2013). Data Sharing, Biobanks and Informed Consent: A Research Paradox. *McGill JL & Health*, 7, 85.

[273] Otlowski M: 'Developing an appropriate consent model for biobanks: in defence of 'broad' consent' in: Kaye J, Stranger M (eds.): *Principles and Practice in Biobank Governance*. Burlington: Ashgate Publishing Company, 2009, pp 79-92.; Steinsbekk, K. S., & Solberg, B. (2011). Biobanks—when is re-consent necessary? *Public Health Ethics*, 4(3), 236-250.

[274] Caulfield, T., Upshur, R. E., & Daar, A. (2003). DNA databanks and consent: a suggested policy option involving an authorisation model. *BMC Medical Ethics*, 4(1), 1; Árnason, G., Nordal, S., & Árnason, V. (2004). *Blood & Blood & Data: Ethical, Legal And Social Aspects Of Human Genetic Databases. Iceland, University of Iceland Press*; Hofmann, B., Solbakk, J. H., & Holm, S. (2009). Consent to biobank research: one size fits all? In Solbakk, J. H. (2009). The ethics of research biobanking. S. Holm, & B. Hofmann (Eds.). Dordrecht: Springer. P.3-23

[275] Simon, C. M., L'Heureux, J., Murray, J. C., Winokur, Weiner, G., Newbury, E., & Zimmerman, B. (2011). Active choice but not too active: public perspectives on biobank consent models. *Genetics in Medicine*, 13(9), 821-831.

[276] Karlsen, J. R., Solbakk, J. H., & Holm, S. (2011). Ethical endgames: Broad consent for narrow interests; open consent for closed minds. *Cambridge Quarterly of Healthcare Ethics*, 20(04), 572-583.

There is a tension between the current practice of obtaining broad consent for biobank research and the traditional legal requirements of informed consent. This tension can be reduced by employing a consent mechanism such as a dynamic consent model and by engaging stewardship as a concept of governance within the legal framework of a charitable trust, as will be discussed in Section 2.5 and Chapter 5.

2.4.5 Dynamic consent

Dynamic consent is participant-centred consent that has been recently proposed as a model to resolve the apparent consent problem within biobanking.[277] It comprises an interactive follow-up process of tissue sources through the use of web based technology.[278] Obtaining specific consent from an individual tissue source for future research proposals has, until now, been deemed unachievable. Dynamic consent enables tissue sources to exercise autonomy by giving informed consent for new types of research in real time rather than being asked to give broad consent at the beginning of the research.

In the broad consent model, the tissue source gives consent to their sample being used at the beginning of a study.[279] If additional analyses need to be performed or new experiments are designed, the tissue source is not contacted again provided the new research is not a significant deviation from what was agreed to initially. In the dynamic consent model, donors are asked to re-consent to every new experiment or change in research. A dynamic longitudinal consent strategy for biobank research has been advocated for by some scholars who argue that dynamic consent 'will become an essential and sustainable component of research infrastructure'.[280]

Dynamic consent, in contrast to broad consent, employs a narrower and more specific mode of consenting to research using active opt-in requirements for each downstream

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[277] Kaye, J. (2011). From single biobanks to international networks: developing e-governance. *Human genetics*, 130(3), 377-382. Erdmann, J. (2013). As personal genomes join big data will privacy and access shrink? *Chemistry & Biology*, 20(1), 1-2.

[278] Steinsbekk, K. S., Myskja, B. K., & Solberg, B. (2013). Broad consent versus dynamic consent in biobank research: Is passive participation an ethical problem? *European Journal of Human Genetics*, 21(9), 897-902.

[279] Kaye, J., Whitley, E. A., Lund, D., Morrison, M., Teare, H., & Melham, K. (2014). Dynamic consent: a patient interface for twenty-first century research networks. *European Journal of Human Genetics*. 23, 141–146

[280] Kaye, J., Whitley, E. A., Kanellopoulou, N., Creese, S., Hughes, K. J., & Lund, D. (2011). Dynamic consent: a solution to a perennial problem? *BMJ*, 343, .

research project. Probably, one of the most recent examples of projects using a dynamic consent model is the Ensuring Consent Revocation (EnCoRe) project. This is an interdisciplinary project with actors from academia and business who envision giving individuals more control over their personal information. It is an information and communications technology (ICT) research project that examines the design and development of dynamic consent mechanisms[281] and is for the most part focused on biobanks derived from patients, especially those generated in university hospital settings,[282] although the discussion includes all research biobanks with a longitudinal design, particularly large population-based biobanks.

Unlike a broad consent model, where continual communication is not required, a dynamic consent model keeps participants up-to-date. Constant contact between the biobank and donors helps ensure participants are informed and involved in the research that they are enabling. Proponents of dynamic consent argue that this is better than broad consent because dynamic consent is not a mere communication exercise, but rather a bidirectional, ongoing and interactive process between the tissue source and the researcher.[283] It has also been argued by Kaye et al.[284] that, as the nature of biomedical research changes, the social contract between participants and researchers needs to evolve with it. If biobank research is open-ended and ongoing then information technologies offer the possibility for participant involvement similarly to extend through time. Individuals need no longer be passive human subjects but can be engaged over time and recognised as active, interested and valued research participants.[285]

This position has also been criticised by proponents of broad consent on the basis that that the dynamic consent model allows for re-consent of every future reuse of the data

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[281] Williams, H., Spencer, K., Sanders, C., Lund, D., Whitley, E. A., Kaye, J., & Dixon, W. G. (2015). Dynamic consent: a possible solution to improve patient confidence and trust in how electronic patient records are used in medical research. JMIR medical informatics, 3(1).

[282] Steinsbekk, K. S., Myskja, B. K., & Solberg, B. (2013). Broad consent versus dynamic consent in biobank research: Is passive participation an ethical problem & quest. *European Journal of Human Genetics*, 21(9), 897-902.

[283] Kanelloupoulou NK, Kaye J, Whitley E, Creese S, Lund D, Hughes K: Dynamic consent – a solution to a perennial problem? *BMJ Recent Rapid Responses* 2011. Available at: *http://www.bmj.com/content/*343*/bmj.d*6900*?tab=responses*

[284] Steinsbekk, K. S., Myskja, B. K., & Solberg, B. (2013). Broad consent versus dynamic consent in biobank research: Is passive participation an ethical problem? *European Journal of Human Genetics*, 21(9), 897-902.

[285] Kaye, J., Whitley, E. A., Lund, D., Morrison, M., Teare, H., & Melham, K. (2014). Dynamic consent: a patient interface for twenty-first century research networks. *European Journal of Human Genetics*.

or sample whether or not there is any need. Broad consent seeks re-consent only in situations where the ethics committee sees a requirement. The implication is that tissue sources engaged under a dynamic model will be asked to re-consent both for trivial and essential reasons, but more often the former. In a broad consent model, participants will seldom be asked to re-consent, but when they are asked it will be for a good reason.[286]

Dynamic consent models are promising tools for augmenting the role of participants as stewards of their own data which may increasingly be utilized as an answer to today's problems surrounding the practicability of contacting research participants and realizing the promises of biobank research. For large population biobanks, they will not alone solve the problem of unconsented participants, but they help these researchers to realize their potential and maintain trust with the public.

Putting the arguments in favour of dynamic consent together, it not only operates in real time but it will provide the necessary cover for the researcher by preventing the tissue source from denying the terms of the consent. The lifeline offered in this regard by the dynamic consent model should not be taken for granted. In developing economies such as Nigeria there is a need to guard against the routinisation of dynamic consent so that it does not become a directive to the tissue source to pick an option or tick the box. The collection of reconsent, no matter how simplified it becomes, should not become a perfunctory mechanical process. In Nigeria, where a significant percentage of the population are not literate and do not have access to computers, telecommunication through SMS may be the most expedient option of contacting tissue sources and updating consent using the dynamic model. According to a report of the Nigerian Telecommunication Commission, Nigeria ranks among the top seven countries in the world for mobile phone users, so SMS as opposed to emails is likely to work better in the Nigerian environment. Nevertheless steps should be taken to ensure that peculiarity of each region is considered in fashioning the policies to ensure the adequacy of a consent model.

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[286] Petrini, C. (2010). 'Broad' consent, exceptions to consent and the question of using biological samples for research purposes different from the initial collection purpose. *Social Science & Medicine*, 70(2), 217-220; Whitley EA, Kanellopoulou N, Kaye J: Consent and research governance in biobanks: evidence from focus groups with medical researchers. *Public Health Genome* 2012*;* 15*:* 232–242.

2.5 Biotrust model

The biotrust model is an attempt to address, among other things, the challenges of consenting to biobank research by focusing on issues of governance, constitutional powers, control of resources, and public benefit.[287] The biotrust model consists of a legal structure for handling the property rights and management of donated genetic and informational resources, and a social structure aimed at encouraging philanthropy, participation, and representation of the tissue source. It also engenders trust in genomic research governance which is a necessary condition for sustainable collaborations. The core idea of the biotrust model is to use the charitable trust as a legal framework to manage genomic resources and to govern genomic research.[288] Writers including Winickoff[289] have elaborated on the bio trust model, and explained it in terms of the institution of trust creating a relationship between the researcher, the tissue source and the community.[290] This proposal of a biotrust, they claim, will serve as a middle path between two extremes of commodification and inalienability.[291] The framework of a bio trust is based on a typical legal model of a trust, in which the principles of a legal trust framework are transferred to human bodies. While the notion of 'property' or 'ownership' presents as a core conception, 'the notion of absolute control, [...] and the ability to do what you like with your own, without having to account to anyone else for your actions'[292] is at the heart of the model. Biotrust connotes a form of cooperative human relations with respect to shared conditions and aims.[293] It is thought that this model will give the tissue source a say as well as a level of control over the tissue. It does, however, raise the issue of whether tissue is property capable of ownership whose interest can be shared or passed to another. The law remains unsettled on this. The

[287] Winickoff, D. E., & Neumann, L. B. (2005). Towards a social contract for genomics: Property and the public in the 'biotrust' model. *Life Sciences, Society and Policy*, 1(3), 8.
[288] Winickoff D. & Winickoff, R., (2003), The Charitable Trust as a Model for Genomic Biobanks. *New England Journal of Medicine*, 349: 1180-1184.
[289] Ibid.
[290] Winickoff, D. E., & Winickoff, R. N. (2003). The charitable trust as a model for genomic biobanks. *New England Journal of Medicine*, 349(12), 1180-1184.
[291] Winickoff, D. E. (2007). Partnership in UK Biobank: a third way for genomic property? *The Journal of Law, Medicine & Ethics*, 35(3), 440-456.
[292] Singer, J.W. (2000), *Entitlement: The Paradoxes of Property*, New Haven: Yale University Press, 29.
[293] Winickoff, D. E. (2007). Partnership in UK Biobank: a third way for genomic property? *The Journal of Law, Medicine & Ethics*, 35(3), 440-456. 443.

general rule is that there can be no property rights in tissue subject to two exceptions. The question of property rights in tissue will be discussed in chapter 4 of this thesis.

2.6 Functions of consent

This section will examine the functions of consent as a basis for justifying consent for future research as well as provide an indication of how far, if at all, broad consent fits into the consent functions.

Consent can be a voluntary acquiescence to the proposal of another;[294] it can be the act or result of reaching an accord; or an actual willingness that an act or an infringement of an interest shall occur.[295] The Oxford English Dictionary[296] defines consent as both a verb and a noun. As a verb it means to come to agreement on a matter, or to a proposal. As a noun it means a voluntary agreement to the proposal of another. In both senses of the word, the word agreement lies at the heart of its meaning. In the context of research, consent means a voluntary uncoerced decision made by a sufficiently competent or autonomous person on the basis of adequate information and deliberation to accept some proposed course of action that will affect him or her.[297] Consent will be described through the functions it performs in law, with a view to examining its functions in research on humans and, more specifically, whether broad consent fulfils these functions in biobank research.

2.7 Consent as a justificatory cover for actions

In this section, consent will be discussed in several ways, firstly as a justificatory cover that prevents an otherwise wrongful act from becoming a wrong against the consenter,[298] or creating new obligations. The operation of consent as a justification for what would otherwise have been unlawful or unacceptable is aptly echoed in the analysis of George Fletcher:

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[294] Fletcher, G. (1996). Basic concepts of legal thought New York. Oxford University Press at 109; see also *R v Wilson* [1996] *WLR* 3 125 where-consent was accepted as a defence to the infliction of bodily harm resulting from the branding of a wife by her husband.

[295] Re W (A Minor) (Wardship: Medical Treatment) [1992] 4 All ER 627, CA. at 635.

[296] Oxford English Dictionary (2013).

[297] Gillon, R. (1985). Philosophical medical ethics. Rights. *British medical journal (Clinical research ed.),* 290(6485), 1890.

[298] Hurd, H. M. (1996). The moral magic of consent. *Legal Theory*, 2(2), 121-146.

> 'When individuals consent to undergo medical operations, to engage in sexual intercourse, to open their homes to police searches, or to testify against themselves in court, they convert what otherwise would have been an invasion of their person or rights into harmless or justified activity'.[299]

In broad terms, consent converts act of another into a justified activity. Consent operates to allow the recipient to do what otherwise they would not be allowed to do. By consenting to another's touch, one puts that person at liberty to do what was previously forbidden. By consenting to another's intrusion onto one's land, one dispels the duty on that person to keep off private property.[300] Broadly speaking, consent functions in two ways: to preclude the consenting party from complaining about the conduct of another in relation to an act and to preclude the consenting party from denying that they are bound by the terms to which they consented. In the first instance consent operates as justifying reason whilst in the second case it operates as a shield.

Consent as a justifying reason

Precisely because the receiving party relies on the authorisation of the consenting party it operates as a procedural justification for carrying out the activity. As a procedural justification consent appears to be limited in personam. In the words of Brownsword, consent is 'agent relative'.[301]

In the context of biobanking research, researchers rely on broad consent as authorisation to include tissue and associated data in a bank, and simultaneously inform tissue sources that their sample may be used for future unspecified research without the need to obtain express consent to participate in subsequent studies. The primary purpose of consent is to grant permission to do an act; thus, if consent is to act as a permission that affects the legitimacy of an act then it must be given by the one whose interest is at stake. Where this is not the case, as in broad consent for future unspecified research, such consent loses its legal force of authorisation and at best becomes assent.[302] Broad consent to future unspecified research does not fit the mould of consent as defined in

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[299] Fletcher, G. (1996). *Basic concepts of legal thought* (Vol. 104). New York: Oxford University Press. 109-111

[300] Hurd, H. M. (1996). The moral magic of consent. *Legal Theory*, 2(2), 121-146 at 124.

[301] Brownsword, R. (2008) *Rights Regulation, and the Technological Revolution. P.90*

[302] Maclean, A., & Jur, M. (2009). *Autonomy, informed consent and medical law: A relational challenge* (Vol. 8). Cambridge: Cambridge University Press.

terms of an agreement to a proposal. A tissue source who gives broad consent to a class of research is not in tandem or in agreement with the multiple future studies that are unknown to them to which their samples and data may be used. In a bid to justify broad consent, proponents have argued[303] that the right to choice and autonomy is preserved by the broad consent obtained at the initial research.[304] This position is questionable, and has been challenged by commentators as 'diluting ethics'[305] because the tissue source will have no say in what is subsequently done to the sample or data. Where-consent functions as justificatory cover to the act consented to, such consent can only justify and cover the specific act consented to. For instance, where someone consents specifically to research on diabetes, as in the Tilousi/Havasupai tribe case,[306] the consent validly justifies the enrolment into the diabetes research, but it does not justify enrolments into other types of research for which consent was not specifically obtained. Broad consent to the initial research should not be taken as a blanket justification for any secondary research on stored tissue.

2.8 Consent as a defence

A claimant who fails to prove the necessary ingredients of a particular tort will fail in his action. Even where he proves his case his action may still fail if the defendant shows that he is entitled to rely on a certain defence.[307] There are many occasions in which harm may be inflicted on a person for which he has no remedy because he consented to it.[308] The effect of such consent is expressed in the maxim *volenti non fit i*njuria. So far as the citation of the maxim goes, most of its use in modern times is in connection with harm to the person rather than to property.

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[303] Steinsbekk, K. S., & Solberg, B. (2011). Biobanks—when is re-consent necessary? *Public Health Ethics*, 4(3), 236-250.

[304] Hansson, M. G., Dillner, J., Bartram, C. R., Carlson, J. A., & Helgesson, G. (2006). Should donors be allowed to give broad consent to future biobank research? *The Lancet Oncology*, 7(3), 266-269.

[305] Hofmann, B. (2009). Broadening consent—and diluting ethics? *Journal of Medical Ethics*, 35(2), 125-129.

[306] Tilousi v. Ariz. State Univ. Bd. of Regents, 2005 W.L. 6199562 (2005). cited in Mello, M., & Wolf, L. (2010). The Havasupai Indian tribe case-lessons for research involving stored biologic samples. *New England Journal of Medicine*, Georgia State University College of Law, Legal Studies of Research Paper No. 2010-12. Available at SSRN: http://ssrn.com/abstract=1626200

[307] Rogers, William Vaughan Horton, Percy Henry Winfield, and John Anthony Jolowicz. *Winfield and Jolowicz on tort*. Sweet & Maxwell, 2010. 1131

[308] *Smith v Baker* (1891) A.C. 325. PER Lord Herschell at 360

2.8.1 *Volenti* as a defence in biobank research cases

One of the defences to negligence is the defence of *volenti non fit injuria* which is essentially the voluntary assumption of risk. This defence can operate as a total exclusion in respect of most forms of tort liability. However, the relevant principles of voluntary assumption of risk or consent operate differently in cases of negligence and strict liability from the torts of intentional interference.[309] In negligence, where the court is asking the claimant whether they may have assumed the risk of damage flowing from the defendant's breach of duty, the court is engaged in a process of allocating the risk of loss between the parties. However, in intentional torts, where the question is whether the claimant can be said to have consented to the interference in question, the issues raises questions concerning the validity of such consent.

According to Prosser,[310] there are three situations that give rise to the defence of voluntary assumption of risk: when the claimant has expressly given his consent to relieve the defendant from a duty and takes his chances of injury from a known risk; when the claimant, with knowledge of the risk, voluntarily enters into some relation with the defendant which will probably result in encountering the known danger; and when the claimant becomes aware of a risk already created by the negligence of the defendant and elects to continue in the face of the danger.[311] In biobank research it would be difficult to infer that the tissue source gave consent via broad consent or that he voluntarily consented to the attendant risks as he cannot be said to have been unaware of the nature of the risk of a future unspecified research.

In *Daniel v Hamiliton*,[312] Asquith J regarded *volenti* as a denial of any duty and a denial of any breach of that duty. While it is possible for consent or assumption of risk to arise in a case of implied waiver, the claim will be defeated if the claimant is taken to have consented to running the risk of being injured. This is because the courts are very reluctant to accept that the claimant consented to the risk of being injured by the defendant's negligence. Within the context of biobank research this implies that broad

[309] Deakin, S. F., Johnston, A., & Markesinis, B. (2012). *Markesinis and Deakin's Tort Law*. Oxford University Press. 753.
[310] Prosser, W. L. (2010). Law of torts. Foundation Press; 12th edition
[311] scholarship.kentlaw.iit.edu/cgi/viewcontent.cgi?article=2050&context
[312] [1939] 1 KB 509,512

consent as a regime of consenting to research on its own is not sufficient justification for secondary uses of the tissue without consent and knowledge of the risks involved. Consent of the tissue source may not also avail the biobank in claims of negligence. A tissue source's consent to enrol in a study will hardly protect the researcher or biobank from the liability for civil or criminal action to redress invasions. A biobank is ethically bound to ensure that it does not expose the tissue source to risks that are disproportionate to benefits; however, in most biobank as opposed to therapeutic research, the benefits are futuristic and usually more socially oriented.

Consent also arises in various forms in law. It arises in the law of contracts in the form of promises. It validates the enforcement of certain commitments and promises. Barnet describes consent in contract as a theory that 'specifies the substance of the rights individuals may acquire and transfer, and the means by which they may do so'.[313] In other words consent is that component of contract that distinguishes valid from invalid transfer of interests. Transposing this to the biobank research context, based on the assumption that that a quasi-contractual relationship exists,[314] between the biobank and the tissue source, consent validates the enforcement of the commitments of the parties to the studies. As to the function of consent, O'Neill[315] characterises consent as a 'propositional attitude'; that is, a response to a proposition describing action yet to be undertaken. For O'Neill, the function of consent is to limit deception or coercion.

Consent arises in property law in the form of assignments of interests; it also arises in torts and criminal law and sometimes in medical law as defences to wrongdoing. The idea of consent as a consideration for mitigating wrongdoing is not absolute; it can be overridden by other considerations. The general theme of consent is one of volition and acceding to an act or situation from an individual which, in the context of biobank research, does not absolve researchers of the requirement to obtain consent for future research.

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[313] Barnett, R. E. (1986). A consent theory of contract. *Columbia Law Review*, 269-321.

[314] *Grimes v. Kennedy Krieger Institute, Inc.*, 782 A.2d 807, 366 Md. 29 (2001). Where the majority held that the consent form prepared by the investigator contained sufficient information to infer a valid bilateral contract.

[315] O'Neill, O. (2003). Some limits of informed consent. *Journal of Medical Ethics*, 29(1), 4-7.

Generally, consent operates as a defence where the defendant can argue that because of consent he had committed no wrong. For instance, consent can be a defence to all the non-fatal offences such as sexual offences, offences related to properly conducted games and sports,[316] lawful surgery including circumcision,[317] tattooing and branding,[318] and horseplay.[319] In medical and therapeutic settings, consent has been recognised as a defence to actions in negligence and assault and battery brought against a physician. In *Re W*, Lord Donaldson, in considering the appeal of a minor against the order of court to be treated against her wishes, defined the legal purpose of consent as 'providing those concerned in the treatment with a defence to a criminal charge of assault or battery or a civil claim for damages for trespass to the person'. [320] Consent neutralises what would otherwise be a wrongful act and provides a defence to the consentee.[321] The idea of consent as an objective, legal consideration for excusing wrongful behaviour can be overridden by other considerations, such as cases involving bodily harm, unethical medical research, sadomasochism, having sex with a child, slavery, and murder[322] to name but a few.[323] Consent will also not avail where there is physical harm.[324] Section 35 of the Nigerian Constitution guarantees the personal liberty of its citizens, albeit subject to exceptions that such liberties are permitted by law. John Locke in his writings on liberty,[325] also states that even though man that state has an uncontrollable liberty, to dispose of his person or possessions, yet he has not liberty to destroy himself or so much as any creature in his passion,

A Law Commission consultation paper also reiterates this position[326] that:

> '[T]he victim can consent to any act likely to cause such injury, but no more. That would exclude any act likely to cause serious injury. It also follows that it

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[316] *R v. Billinghurst* [1978] Crim L.R. 553; football player kicking a player off the ball commits a battery.
[317] *Re J (child's religious upbringing and circumcision* [2000] 1 Family Court Reports 307.
[318] *R v. Wilson* [1996] WLR 3 125.
[319] *R. v. Jones* [1986] SCR 2 284.
[320] *Re: W* [1992] 4 All ER 627 at p.633.
[321] Beyleveld, D., & Brownsword, R. (2007). *Consent in the law* (Vol. 10). Hart Publishing, 6.
[322] *Attorney General's Reference (No 6 of 1980)* [1981] 2 All ER 1057.
[323] O'Neill, O (2003) 'Some limits of informed consent' *Journal of Medical Ethics* 29, 4-7.
[324] *R v Brown* [1994] 1 AC 212.
[325] Locke, J. (1988). *Locke: Two Treatises of Government Student Edition*. Cambridge University Press, 270-271.
[326] Ormerod, D. (1994) Consent and Offences Against the Person: Law Commission Consultation Paper No 134. *MLR*, 57, 928.

> should not be possible to consent to any act that is intended by its doer to cause serious injury. It should also be the case that the victim can exclude from his consent to *likely* injury the *intentional* infliction of that or any injury by the defendant' (para 18.3).

In the case of *Halushka v University of Saskatchewan,*[327] the consent of the research participant did not relieve the researcher of his duty to disclose information related to the risks of the study. Consent would also not operate as a defence where the consenting party is deemed to have consented to the act under circumstances where he voluntarily puts himself at risk from negligent conduct. Indeed consent provides an objective basis for allowing an individual to make choices that may involve consenting to harm, but consent is not absolute. It does not allow a person to degrade or destroy themselves. This position suggests that valid consent on its own is not sufficient justification for negligence on the part of a researcher. For instance a tissue source's consent to research will hardly relieve the researcher of their duty of care.[328] Rational autonomy in the Kantian sense only allows:

> 'one set of principles which people can rationally legislate and they are the same for all. Nobody can escape [his or her] rule simply by being irrational and refusing to accept them. Personal autonomy, by contrast, is essentially about the freedom of persons to choose their own lives'.[329]

The ability to choose is the essence of liberty which consent protects. Consent ensures the exercise of choice in relationships such as marriage. As Fletcher puts it, consent testifies to the existence of personal rights to bodily integrity and privacy.[330]

As Manson and O'Neil[331] put it, the reason most commonly given for entrenchment and elaboration in contemporary discussions of consent requirements is that there is a need to secure respect for individual autonomy. Consent also gives the liberty to enter into relationships according to the desire of the individual within the stipulated regulations governing those relationships, such as marriage. Consent enables a person to exercise

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[327] *Halushka v. University of Saskatchewan* (1965) 53 DLR. (2d) 436; 52 WWR 608

[328] Kennedy, I. (1988). *Treat me right. In Essays in Medical Law and Ethics*. Clarendon Press Oxford.

[329] Beyleveld, D., & Brownsword, R. (1998). Human dignity, human rights, and human genetics. *The Modern law review*, 61(5), 661-680.

[330] Fletcher, G. (1996). *Basic concepts of legal thought* . New York: Oxford University Press. At P.109-110

[331] Manson, N. C., & O'Neill, O. (2007). *Rethinking informed consent in bioethics* (Vol. 1). Cambridge: Cambridge University Press.

autonomy in the sense of self determination and decision making.[332] In this sense, it has its bearing on the institutions of property, marriage and sexual access; it functions as a basis for legitimising transactions and relations within social and legal subsets. Consent gives individuals in these relations the liberty to choose to waive or even transfer those rights to others, as in the case of property rights. Consent can also operate as a tool of moral and political justification. In this sense, democracy can be said to be the expression of the governed to be governed by those they elected.

The social contract theory asserts that individuals consented or agreed at some supposed point to repose their rights in the state.[333] In the writings of John Locke, the social contract is the hypothetical construct that draws on the moral power of actual consent. It is a hypothetical consent that provides justification for existing political institutions.[334] In the context of biobanking research, viewing biobanking as a social contract suggests that the individuals (tissue sources) can repose their consent in an entity.[335] In population based genomic projects where group autonomy is an issue, the social contract view of consent can be used as a basis to propose the use of charitable trust[336] as a legal framework to manage genomic resources in biobanks, and to govern genomic research more justly by giving tissue sources a say in future uses of excised samples.[337] The charitable trust model, as advocated by Winickoff,[338] combines a series of individual trust instruments in which tissue sources give certain property interests to a trustee, who

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[332] 'Personal autonomy encompasses, at a minimum, self-rule that is free from both controlling interference by others and from certain limitations such as an inadequate understanding that prevents meaningful choice' (Beauchamp and Childress 2008, 100–1).

[333] The traditional social contract views of Hobbes, Locke, and Rousseau crucially relied on the idea of consent. See *The Second Treatise of Government* in *Two Treatises of Government*, Peter Laslett, ed. Cambridge: Cambridge University Press: 283-446.

[334] See note 27

[335] Winickoff, D. E., & Neumann, L. B. (2005). Towards a social contract for genomics: Property and the public in the 'biotrust' model. *Life Sciences, Society and Policy*, 1(3), 8.

[336] According to Black's Law Dictionary, a trust is a formal legal institution in which a property interest is held by one person or set of persons (the trustees) at the request of another (the settlor) for the benefit of a third party (the beneficiary). The property interest is conveyed to the trustee in a trust instrument that must clearly express the wish to create a trust. The settlor appoints a trustee of the property, who has legal fiduciary duties to keep or use the property for the beneficiary, creating a unique protective regime of trust law for safeguarding the interests of donors and other beneficiaries. The creation of a trust establishes a fiduciary relationship in which a trustee holds title to property, subject to an equitable obligation to keep or use the property for the benefit of the beneficiary. To be classified as a charitable trust, the purpose must be 'charitable' and aim at the public good.

[337] Winickoff, D. E., & Winickoff, R. N. (2003). The charitable trust as a model for genomic biobanks. *New England Journal of Medicine*, 349(12), 1180-1184.

[338] Winickoff, D. E., & Neumann, L. B. (2005). Towards a social contract for genomics: Property and the public in the 'biotrust' model. *Life Sciences, Society and Policy*, 1(3), 8.

holds and manages the biorepository in accordance with the stated charitable purpose to which the tissue source would agree. The charitable trust structure would also put a legally binding fiduciary obligation on the trustee to faithfully manage the resource according to the charitable purpose and the public benefit defined in the trust instrument. It would also give some control to the tissue source over the future use of the tissue. Based on the contents of the trust instrument, the bio repository would be managed according to the terms which the tissue source will agree and this will define the charitable purpose of the trust.

2.9 Hohfeldian rights and duty within the concept of consent

Consent can be a double-edged sword which creates rights and duties and, at the same time, absolves of wrongdoing. In modern legal systems where legal relationships are construed around rights, duties, and powers, the functions of consent are also shaped within these relationships. This being so, it would be useful to examine more precisely the functions of consent in law through the lens of the Hohfeldian analysis of legal relationships. Though Hohfeld was not concerned about how consent functions in legal relationships, his analysis isolates a number of legal relationships on the basis of which we can derive an understanding of how consent and informed consent function within the law. Consent functions to provide a reason for the recipient to rely on as a permission or justification for doing what he ordinarily would not have been able to do. For the purposes of this analysis, Hohfeldian relationships are simply presented as bilateral with reference to a particular act.

According to Hohfeld,[339] there are four basic components of rights: the privilege, the claim or right, the power, and the immunity. Each of these Hohfeldian incidents has a distinctive logical form, and the incidents fit together in characteristic ways to create complex 'molecular' rights. Hohfeld goes on to postulate that all fundamental legal relations are *sui generis* and can be expressed in a scheme of two tables of jural opposites and correlatives; one of the four jural correlatives is 'right' and its correlative is 'duty'. A right is therefore a claim correlative to a duty. However, consent can operate within this Hohfeldian relationship of rights and duty to alter the legal power

[339] Hohfeld, W. N. (1920). *Fundamental legal conceptions as applied in judicial reasoning: and other legal essays*. Yale University Press, at 35.

that a right confers on the right holder. This is done by the right holder (A) who has a claim or right that a second party (B) should not do a particular act without his consent, voluntarily relinquishing his right to claim against the other party. In so doing A converts the relationship between them from a rights/duty relationship to a privilege/no right relationship. In other words the giving of consent creates a privilege for B but no right for A, and means that B will not be violating any duty to A by exercising the privilege.

Consent-dependent actions involve, in effect, two 'levels' of rights;[340] a claim right and the power to waive it.[341] The person who holds the first-order right also has a second-order right – a *power* – to *waive* their claim right against others. As regards the second order right, 'the person (or persons) whose volitional control is paramount may be said to have the (legal) power to effect the particular change of legal relations'.[342]

A person who holds power, according to Hohfeld,[343] is able to change a legal relationship through an act of volition. The person whose position is changed by the exercise of power is said to have a liability which can be both positive and negative. Hohfeld gave the following as examples of legal powers:

> 'Thus, X, the owner of ordinary personal property 'in a tangible object' has the power to extinguish his own legal interest (rights, powers, immunities, etc.) through that totality of operative facts known as abandonment; and—simultaneously and correlatively—to create in other persons privileges and powers relating to the abandoned object,—e.g., the power to acquire title to the latter by appropriating it. Similarly, X has the power to transfer his interest to Y,—that is, to extinguish his own interest and concomitantly create in Y a new and corresponding interest. So also X has the power to create contractual obligations of various kinds. Agency cases are likewise instructive.. The creation of an agency relation involves, inter alia, the grant of legal powers to the so-called agent, and the creation of correlative liabilities in the principal. That is to say, one party P has the power to create agency powers in another party A,—for example, the power to convey X's property, the power to impose (so-called)

[340] Manson, N. C. (2007). Consent and informed consent. *Principles of Health Care Ethics, Second Edition*, 297-303.
[341] Norton, M. L. (1975). Contract Law as a Viable Alternative to Problems of Informed Consent. *Cath. Law.*, 21, 122.
[342] Hohfeld, W. N. (1920). Fundamental legal conceptions as applied in judicial reasoning: and other legal essays. Yale University Press, at 51-52.
[343] Hohfeld, W. N. (1913). Some fundamental legal conceptions as applied in judicial reasoning. The Yale Law Journal, 23(1), 16-59 at 54.

> contractual obligations on P, the power to discharge a debt, owing to P, the power to 'receive' title to property so that it shall vest in P, and so forth'.[344]

This explains how the power/liability relationship pans into consent based (contractual) relationship.

> 'Suppose A mails a letter to B offering to sell the former's land, White acre, to the latter for ten thousand dollars, such letter being duly received. The operative facts thus far mentioned have created a power as regards B and a correlative liability as regards A. B, by dropping a letter of acceptance in the box, has the power to impose a potential or inchoate obligation *ex contractu* on A and himself'.[345]

It would seem that Hohfeld is suggesting that the paradigm example of contracts by post is applicable in principle to all forms of contracts. Even though there is no specific mention of consent, consent is the implicit base line of the exercise of power by the owner in the example above. Consent is integral to the exercise of power under the Hohfeldian scheme. Consent is an exercise of will, choice, or volition by the power holder. It is essential to consensual action that the various parties involved in a consent transaction know certain things just as parties entering into a contract ought to know the terms of that contract. A person who proposes or intends to perform a consent-dependent action such as enrolling in research, needs to know the kind of research that their sample or data will be used for in the future.[346] In stored tissue research the tissue source, having given broad consent for a consent dependent action of the initial research, would not know the terms of the new research. The tissue source can therefore not be said to have consented or exercised their right of choice in relation to the secondary use of the sample or data.

2.10 Informed consent

Consent is considered fully informed when a competent research subject to whom full disclosure has been made and who fully understands all that has been disclosed, voluntarily consents to participation. In its most important role in bioethics, informed consent is a legitimacy requirement for certain actions. In the United States informed

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[344] Ibid.

[345] Ibid

[346] Manson, N. C. (2007), *Consent and Informed Consent'*, in R. E. Ashcroft, A. Dawson, H. Draper & J. R. McMillan, eds, *Principles of Health Care Ethics*, 2nd edn, John Wiley & Sons, Ltd, Chichester.

consent is perceived from the angle of risks of personal injury from medical treatment, and from exposure to dangerous products. In these contexts, informed consent does not only pursue the goals of individual autonomy found in contract law, but it also advances two related ideas of fault and injury that pervade the law of torts that a person should not be exposed to a risk of harm unless he has agreed to the risk.[347] The ethical and legal legitimacy of consent sought and obtained is the starting point of the consent process. The idea of legitimacy of consent in torts holds that as long as the one who suffers harm consents to it, then the injurer is deemed not to be at fault. In such situations, the injurer is relieved of their duty to the victim and in effect this negates the injurer's fault. In research, informed consent authorises the otherwise unlawful access that the researcher is able to have to the samples or data of an individual.

Trespass to the person protects the inviolability of the person, and in *Freeman v Home Office* it was held that tortious battery is the unconsented to intrusion of another's bodily integrity.[348] In other words, mere touching or the unconsented to removal of a specimen from a person may suffice as grounds for a claim of battery. A similar concern for the psychological integrity of the individual has its historical origin in tort law as well. This is evidenced in the tort of intentional and negligent infliction of nervous shock.[349] This tort protects an individual from negligent or intentional infliction of emotional distress.

In spite of the capacity of the tort of battery to protect against physical invasion and autonomy of patients, the relationship between healthcare personnel and patients or research subjects does not fit well into the mould of battery because of the prior consent to treatment. In most common law jurisdictions, the appropriate action where it is alleged that the right of the patient to know has been infringed, and that this has vitiated the patient's choice, has been to bring an action in negligence rather than battery or assault.[350] This was further clarified in the case of *Montgomery v Lanarkshire Health Board* [351] where the Supreme Court held that the law of negligence 'entails a duty on the part of doctors to take reasonable care to ensure that a patient is aware of material risks

[347] Schuck, H. (1994). Rethinking informed consent. *Yale Law Journal*, 899-959 at 902.
[348] *Freeman v Home Office* [1983] All E.R.3 589.
[349] *Wilkinson v. Downton* (1897) LR, 2 Q.B. 57.
[350] McLean, S. A. (2009). *Autonomy, Consent and the Law*. Routledge at 70-73.
[351] *Montgomery v Lanarkshire Health Board* [2015] UKSC 11. At para 82

of injury that are inherent in treatment'.[352] This, their Lordships held, can be understood within the traditional frame work of the law on negligence. The Court also held that in order not to vitiate the reality of consent there must be a greater level of communication and disclosure of risk from the doctor to the patient (or, in biobank research, from the researcher to the tissue source) that would enable a patient make a voluntary decision after being aware of 'material risks'.

> 'An adult person of sound mind is entitled to decide which, if any, of the available forms of treatment to undergo, and her consent must be obtained before treatment interfering with her bodily integrity is undertaken. The doctor is therefore under a duty to take reasonable care to ensure that the patient is aware of any material risks involved in any recommended treatment, and of any reasonable alternative or variant treatments. The test of materiality is whether, in the circumstances of the particular case, a reasonable person in the patient's position would be likely to attach significance to the risk, or the doctor is or should reasonably be aware that the particular patient would be likely to attach significance to it'.[353]

In *Moore v University of California*,[354] the claimant brought an action against the defendant (his physician) and others for using his cells in potentially lucrative research without his permission. The claimant alleged that his physician failed to disclose pre-existing research and economic interests in the cells before obtaining consent to the medical procedure in which the cells were extracted. The court held that the defendant breached the physician's duty of disclosure; that for the patient's consent to be effective, it must be an informed consent; and that the physician was under a fiduciary duty to disclose all information material to the patient's decision. In deciding what was material information, the Court expounded two principles: that a physician must disclose personal interest unrelated to the patient's health, whether research or economic, which may affect the physician's professional judgement; and that a physician's failure to disclose such interests may give rise to a cause of action for performing medical procedures without informed consent or in breach of fiduciary duty.

In the United Kingdom, *Montgomery v Lanarkshire Health Board* considered explicitly the issue of non-disclosure by a physician and its effect on consent obtained from the

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[352] Ibid at 82.
[353] Ibid at 87.
[354] *Moore v Regents of the University of California*, (1988) 249 Cal. Rptr. 494, 249 Cal. 494, 202 Cal. 3d 1230.

patient. The Court was categorical that it was incumbent on the doctor to advise the patient of all material risks, especially if it was likely to affect the decision of the patient. More fundamentally the court reiterated that holding out on disclosing material risk was a breach of duty to advise the patient.[355] This decision, although one on medical negligence as opposed to research ethics, gives clear guidelines on the significance of disclosure of material risk and the effect that non-disclosure has on consent of the patient. In transposing this relationship to that of the researcher in a biobank and the tissue source in biobank research, consent obtained without disclosure of material risks is no consent at all. The Supreme Court in *Montgomery* also confirmed that assessment of materiality of the risk should not be based on statistics but rather on the nature of the risk, the effect that the occurrence of the risk would have on the patient, the importance to the patient of the benefits of the treatment, the alternatives to the treatment, and the risks involved in those alternatives. The implication of judgement is that the assessment should be patient-centric. In other words it should be up to the patient (or in biobank research, the tissue source) to weigh the risks and alternatives before making a decision on whether to consent to the treatment (or allow the secondary use of his tissue in future research).

2.11 Informed consent in biological research

Within the context of biobank research, it has been argued that it is not possible, as it is with other types of research, to obtain conventional and traditional consent and in turn give adequate disclosure of information at the point of recruitment[356] and broad consent has become the preferred solution,[357] although it remains controversial.[358] The ability of this type of consent to enable participant choice and autonomy has been questioned,[359] the reason being that broad consent is not informed consent. Informed consent presupposes that the research subject is not only competent, but also understands the

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[355] *Montgomery v Lanarkshire Health Board* [2015] UKSC 11 at 103.

[356] Maschke, K. J. (2006). Alternative consent approaches for biobank research. *The Lancet Oncology*, 7(3), 193-194.

[357] UK Biobank, (2007), Ethics & Governance Framework V.3. Available at http://www.ukbiobank.ac.uk/wp-content/ uploads/2011/05/EGF20082.pdf.

[358] Caulfield, T., & Kaye, J. (2009). Broad Consent in Biobanking: Reflections on Seemingly Insurmountable Dilemmas. *Medical Law International*, 10, 85-100.

[359] Simon, C. M., L'Heureux, J., Murray, J. C., Winokur, Weiner, G., Newbury, E., & Zimmerman, B. (2011). Active choice but not too active: public perspectives on biobank consent models. *Genetics in Medicine*, 13(9), 821-831 at 822.

scope and consequences of the research to be undertaken. In the context of biobank research, by giving broad consent the subjects give consent to research of which they do not know the scope nor its risks or benefits, if any. In this regard, it would appear that the law is precise in its position on the need for full information to be provided to the tissue source in order to ensure that the ethical and legal imperative of autonomous decision making in research is upheld. More precisely it is arguably the position that the right of the tissue source to exercise individual autonomy based on full disclosure of risks in research is discounted through the mechanism of broad consent, especially in the light of the ruling in *Montgomery v Lanarkshire Health Board.* Four out of five of their Lordships appear to have recognised that 'the doctor's duty arises out of the patient's right to make his own decision and not vice versa'.[360] Lady Hale stressed this to an even greater extent, confirming that 'the issue is not whether enough information was given to ensure-consent to the procedure, but whether there was enough information given so that the doctor was not acting and giving due protection to the patient's right to autonomy'[361] Although *Montgomery* was primarily concerned with medical treatment as opposed to research, the case would serve as guide for postulating the position the Court might take in relation to biobank research.

In the Canadian case of *Halushka v University of Saskatchewan,*[362] it was held that even where research is a therapeutic experiment, the ordinary standards of disclosure should be observed and that the subject of medical experimentation is entitled to full and frank disclosure of all facts, probabilities and opinions which a reasonable man might be expected to consider before giving consent. It follows that even in non-invasive research such as biobanking research, full disclosure of information should be given prior to obtaining consent. Broad consent which does away with the need for full disclosure of information in future unspecified research can be said to flout the requirements of a valid consent.

In African communities these issues of consent in biobank research are exacerbated by factors such as high rates of illiteracy, and by stigmatisation from sharing information

[360] *Montgomery v Lanarkshire Health Board* [2015] UKSC 11 at 73.
[361] Ibid at 108.
[362] *Halushka v. University of Saskatchewan* (1965), 53 DLR (2d) 436, 52 WWR 608.

on disease leading to ostracisation within communities. In Nigeria, for example, the controversy that trailed Pfizer[363] and its clinical trial on Trovan illustrates the challenges that African countries have with consent and disclosure of risk. In the Trovan trial, the parents of the children that took part were largely illiterate and did not understand that they were enrolling in research; they believed that they were-consenting to treatment. If informed consent to specific research can pose the number of problems it posed in the Pfizer trial, there can be little doubt that broad consent as a regime of consent to future unspecified studies will pose greater challenges to the African states. Broad consent as regime of consenting to future research will open the door to claims of the violation of the rights of members of the community to privacy and choice. Also in the light of *Montgomery,* a persuasive authority for the Nigerian courts (see Section 2.2), non-disclosure of these risks and possible harm would be a basis for a cause of action for the tissue source even in the context of biobank research. It would be possible for the tissue source to bring an action against a biobank for non-disclosure of risk (as long as it was deemed material) where they had suffered harm such as stigmatisation.[364]

2.11.1 Possible approaches to consenting to biobank research

There are several proposals to consent options for biobank research ranging from the individual-oriented model of specific consent, to the more communal and open ended broad consent and blanket consent, through to the more extreme option of the total waiver of consent for the use of identifiable data.[365]

2.11.1.1 Implied or presumed consent and consent waivers

This is used in the absence of specific consent in circumstances where the samples are already in existence. In such situations, agreement can be implied or it can be presumed that the person would most likely be willing to give consent. This approach, although

[363] *Abdullahi v. Pfizer, Inc.*, (2009) 562 F.3d 163 (2d Cir).

[364] Ramsay, M., de Vries, J., Soodyall, H., Norris, S. A., & Sankoh, O. (2014). Ethical issues in genomic research on the African continent: experiences and challenges to ethics review committees. *Hum Genomics*, 8, 15.

[365] Otlowski, M. F. (2012). Tackling legal challenges posed by population biobanks: reconceptualising consent requirements. *Medical Law Review*, 20(2), 191-226.

efficient, is problematic because it does not protect the right of individuals to make informed choices in matters involving them.[366]

Consent waivers have been proposed in which research subjects entrust their consent to an independent third party who decides whether subsequent research using the biobank is consistent with the original consent provided by the subject.[367] Consent can also be waived by human research ethics committees. This is done in circumstances where it is impracticable to obtain consent and where there is a strong public interest in the research.[368] An advantage of this approach is that it is convenient for research participants, but drawbacks include high costs and the risk that the proxy may not make decisions that accurately align with the source's desires.

One of the justifications for a consent waiver and indeed for implied or presumed consent is that the right of an individual to consent can be waived for reasons of impracticability rather than it not being possible to contact the tissue source. This is not acceptable given that consent as a concept should enable the tissue source to make a choice. Hansson[369] and others have also argued that it is not acceptable for research ethics committees to permit biobank research or indeed any research without some form of consent, although the basis of their objection was to justify broad consent as the lesser of two evils.

2.12 Group consent

Another alternative is group consent. The shift from studying genetic variations within families with high rates of disease to studying genetic variations within communities has often forced researchers to deal with some kind of collective group consent.[370] The pragmatic argument for group consent is that research in the midst of a population will

[366] Sheremeta L., (2005) *Population Biobanking in Canada: Ethical and Legal Issues* in Protecting Privacy in the age of Genetic information (Canadian Biotechnology Advisory Committee) available at http://publications.gc.ca/collections/Collection/Iu44-19-2004E.pdf last accessed 3/12/2015

[367] Skene, L. Patients' Rights or Family Responsibilities? Two Approaches to Genetic Testing'(1998). *Medical Law Review*, 6, 1., Winickoff, D. E., & Winickoff, R. N. (2003). The charitable trust as a model for genomic biobanks. *New England Journal of Medicine*, 349(12), 1180-1184.

[368] NHMRC, 2010, *National Health And Medical Research Council Biobanks Information Paper*, Available at https://www.nhmrc.gov.au/guidelines/publications/e110 last accessed May 2014

[369] Petrini, C. (2010). 'Broad' consent, exceptions to consent and the question of using biological samples for research purposes different from the initial collection purpose. *Social Science & Medicine*, 70(2), 217-220.

[370] Greely, H. T. (2001). Informed consent and other ethical issues in human population genetics. *Annual Review of Genetics*, 35(1), 785-800.

often require the approval of the population's governance structure or leadership. One of the issues driving the debate about group consent is the concern over the possible harm that such research may do, not only to the group but also to the individual tissue source. Group consent may violate the rights of an individual within the group, and where that happens it is unclear what options of withdrawal or opt out are feasibly available to the individual tissue source in cases of group consent.

One of the objections against group consent is that it favours group rights over individual rights. If, as Greely puts it, 'a mentally competent adult wishes to participate in research, why should her right to do so be overruled by a collective decision, particularly where the group definition or the identification of culturally appropriate authorities is uncertain?'[371] It has also been opined that group consent may result in a paternalism which undermines the autonomy of the individual.[372] In the discussions of the ethics of biobank research, it has been argued that the core protection of individual dignity, autonomy and privacy is informed consent. However the concept of group consent cannot address these ethical challenges in the field of biobanking research.[373]

In a bid to justify participation in biobank research within the limits of broad or blanket consent, an analogy between conscription into the military and conscription into the biobank has been drawn. The argument put forward has been that because there are certain activities that are perceived to be necessary and important to society, it is sometimes acceptable to oblige people to participate in such activities. Most societies have had to conscript male adult citizens into the army for the defence of the nation at some point in their history. It has been argued that participation in biobank research can be just as important to society as peace and security, and that conscription can be a justifiable option in enrolling tissue sources into biobanking research. The preservation of the population as well as the moral obligation of reciprocity have also been considered as justifications for possible conscription into biobanking research.[374] It has been argued that just as persons can be conscripted for reasons of necessity without their

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[371] Greely, H. T. (2001). Informed consent and other ethical issues in human population genetics. *Annual Review of Genetics*, 35(1), 785-800.

[372] Juengst, E. T. (1998). Groups as gatekeepers to genomic research: conceptually confusing, morally hazardous, and practically useless. Kennedy Institute of Ethics Journal, 8(2), 183-200.

[373] Solbakk, J. H., Holm, S., & Hofmann, B. (eds)(2009). *The ethics of research biobanking*. Springer. 23.

[374] Ibid 259.

consent, persons can be enrolled into biobanking research without specific consent for reasons of necessity of preservation of life. This view raises issues, one of which is the question of the value or importance of biobank research to society. Biobanks of course have the potential to improve the health of people, but where a tissue source is conscripted and his tissue sample is used in further studies unconnected with any pressing, important health activity, the arguments for conscription would not justify overriding the autonomy of the tissue source.[375] Biobanking research does not entail the necessity that generally underpins military conscription and should therefore not be the basis of an argument for legitimising implied or presumed consent.

2.13 Conclusion

Express consent has come to be recognised as the acceptable standard for inclusion in health care research, as the best means of protecting research subjects from abuse, and for ensuring that the research subject exercises autonomy by voluntarily making their decision in relation to the proposed research. This traditional mode of obtaining consent has been said to be better adapted to clinical research. Proponents of this view also argue that insistence on specific consent and re-consenting for secondary uses is expensive, impracticable and will hinder the advancement of research. The European Council[376] has also, in a draft memorandum, taken the view that broad consent to future research use is acceptable. This view is shared by several writers who think that this is an emerging trend in biobank ethics.[377] The move towards broad or general consent is also supported both by empirical surveys and by philosophical arguments.[378] However, this position has been contested. Greely,[379] for instance, argues that if we are to preserve a meaningful notion of informed consent for participation in research, it should only be used for specified research where the participants are informed about the aims and

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[375] Ibid 260.

[376] Council of Europe (2006) *Draft explanatory memorandum to the draft recommendation on research on biological materials of human origin*, Strasbourg: Council of Europe Steering Committee on Bioethics, https://wcd.coe.int/ViewDoc.jsp?id=961137

[377] Cambon-Thomsen, A., Rial-Sebbag, E., & Knoppers, B. M. (2007). Trends in ethical and legal frameworks for the use of human biobanks. *European Respiratory Journal*, 30(2), 373-382; Haga, S. B., & Beskow, L. M. (2008). Ethical, legal, and social implications of biobanks for genetics research. *Advances in Genetics*, 60, 505-544.

[378] Hansson, M. G., Dillner, J., Bartram, C. R., Carlson, J. A., & Helgesson, G. (2006). Should donors be allowed to give broad consent to future biobank research? *The Lancet Oncology*, 7(3), 266-269.

[379] Greely, H. T. (2007). The uneasy ethical and legal underpinnings of large-scale genomic biobanks. *Annu. Rev. Genomics Hum. Genet.*, 8, 343-364.

methods of a particular research proposal; there is no such thing as 'general informed consent'.[380] The more general the consent is, he says, the less informed it becomes. He argues that it is misleading to use the notion of informed consent for participation in research that is unforeseen and has not been specified in a research protocol.[381] The various pitfalls and criticisms of broad consent cannot be overlooked in this era of digitization and advanced information technology.

The notion and practice of broad consent in biobank research ought to be re-evaluated in light of the ethical and legal dimensions of biobank research and the protection of the tissue source.[382] There is a need to be mindful of and to protect the source from discrimination that may be cultural, ethnic or environmental. For instance, associations in developing economies such as Nigeria with diseases such as epilepsy may lead to stigmatisation of individuals, groups or even entire lineages. Discussions on biobank research need to be sensitive towards the socio cultural and economic context of the tissue source. Given the nature of biobank research, in that samples and data will be shared across borders, attention must also be given to respecting the sensitivities of the source, and this can be achieved with the strong participation of the research participant through a dynamic consent process.

Dynamic consent creates a platform for ongoing communication between the biobank, the tissue source and the researchers.[383] Ongoing communication fosters respect and allows for a more streamlined way of re-consenting. A patient-oriented system of consent in biobank research could have the effect of reducing the cost of recruitment.[384] It has been deployed in the Encore project and many writers are of the opinion that the benefits are considerable. Kaye et al have noted that:

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[380] Árnason, V. (2004). Coding and consent: moral challenges of the database project in Iceland. *Bioethics*, 18(1) 27-49 at 41; Caulfield, T. (2007). Biobanks and blanket consent: the proper place of the public good and public perception rationales. *KLJ*, 18, 209.

[381] Greely, H. T. (1999). Breaking the stalemate: a prospective regulatory framework for unforeseen research uses of human tissue samples and health information. *Wake Forest L. Rev.*, 34, 737.

[382] Kettis-lindblad et al. (2006) Genetic Research and Donation of Tissue Samples to Bio banks What do potential sample donors in the Swedish general public think? *European Journal of Public Health* 16: 433-440

[383] Stein, D. T., & Terry, S. F. (2013). Reforming biobank consent policy: a necessary move away from broad consent toward dynamic consent. *Genetic Testing and Molecular Biomarkers*, 17(12), 855-856.

[384] Kaye, J. (2012). Embedding biobanks as tools for personalised medicine. *Journal of Management & Public Policy*

> '[t]he benefit of this interface is that it enables individuals to exercise their autonomy by giving informed consent for new types of research in real time rather than being asked to give a broad consent at the beginning of the research process when they are recruited into a biobank. The benefits for the research process are that recruitment is easier, less costly and more efficient; the legal and ethical requirements of consent can be met with ease; there is greater transparency and accountability in the research process and research findings can be returned to research participants as part of a personalised medicine approach'.[385]

Respect for personal autonomy requires informed consent prior to the collection and processing of biological specimens or personal data, be it genetic, medical or concerning lifestyle.

The information to be given prior to consent ought to state, and state clearly, the purpose or purposes served by the processing of data in the biobank. The donor's consent should be express and specific; in other words, it should be given for a particular use especially in regard to named data. It is appreciated that this information may affect elements of a more general interest such as the importance of research to public health. Therefore, it would not be unthinkable to present views which would include an option between specific or broad consent. Such an approach is encapsulated within the dynamic consent model.

The argument of the notion that there is minimal risk associated with biobank research may not be completely true today.[386] It is possible for information to be traced to an individual using other databases.[387] Depositing a sample may not have the same risks as physically participating in a clinical trial, but the informational risk is real and can have unknown future adverse effects. In biobank research, it is in many cases envisioned that samples will be networked and shared with other research institutions and databanks. This can be complicated by the fact that possibilities of data storing and the technological tools for analysis are improving rapidly. Generally, it will be difficult to secure informed consent for the successive uses of data and samples. However, a

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[385] Kaye, J., Whitley, E. A., Kanellopoulou, N., Creese, S., Hughes, K. J., & Lund, D. (2011). Dynamic consent: a solution to a perennial problem? *BMJ*, 343 (Nov 01).

[386] Stein, D. T., & Terry, S. F. (2013). Reforming biobank consent policy: a necessary move away from broad consent toward dynamic consent. *Genetic testing and molecular biomarkers*, 17(12), 855-856.

[387] Gymrek, M., McGuire, A. L., Golan, D., Halperin, E., & Erlich, Y. (2013). Identifying personal genomes by surname inference. *Science*, 339(6117), 321-324.

solution to this issue should be one requiring re-consent and adaptive governance mechanisms that allow for representative decision making on behalf of tissue sources in biobank research, such as the process of dynamic consent.

3. The Privacy Conundrum with Broad Consent in Biobank Research

3.1 Introduction

Privacy has emerged in bioethics and in particular in biobanking research as a yardstick for measuring the adequacy of rules and practices. Privacy concerns over the adequacy of rules feature in debates on how to collect, use, store and share samples and data in biobank research. Biobank research challenges traditional expectations of confidentiality and anonymity of information about the tissue source, and the traditional methods for protecting research subjects' confidentiality and anonymity, such as anonymisation and broad consent, are not able to fully protect the tissue source from future unspecified use of their samples and data in a way that does not breach their privacy rights.

Although there is enormous benefit in the promise of breakthroughs in medicine that will come from biobank research, individual interests should be respected and secured alongside the quest for breakthroughs in biomedical research. A person's interest can be affected not only by the time and effort taken in participating in biobank research, but more significantly by the use of their genetic information in future unspecified research because the use of bio information makes it possible to identify and relate the results of the research to the tissue source.[388]

In harnessing real research value, biobank research requires not only biological samples, but also the use of medical, environmental as well as personal data. The genetic information that the samples reveal is not limited to the tissue source alone. This is because the very nature of DNA, for example, has implications for others who are related to the tissue source. UNESCO notes, in Article 4 of its declaration, [389] that

[388] Mullen, C. (2009). Decisions, consent and expectations of the individual. *The Governance of Genetic Information: Who Decides*, 51-72 at 55.

[389] UN Educational, Scientific and Cultural Organisation (UNESCO), *International Declaration on Human Genetic Data*, 16 October 2003, available at: http://www.refworld.org/docid/4042241f4.html accessed 24 March 2015.

genetic information can be predictive of genetic dispositions concerning the tissue source, and that such predictions can be relevant not only to the source but also to their family. Assessing how the tissue source's interest will be affected is further complicated by the fact that these samples may contain information 'the significance of which may not be known at the time of collection'.[390] The extent to which the predictive nature of genetic information will affect the interest of the tissue source depends on a number of factors which include whether the tissue source is informed of the types of research in which his information will be used, and also whether the information will be simply anonymised or irreversibly anonymised.[391] As the Advisory Committee on World Health has noted,[392] that genetic information could be used by insurers or employers in making decisions relating to individuals, and that could result in discriminatory practices. Thus it is possible that excised samples and data that produce predictive genetic information in biobank research could lead to discrimination or stigmatisation if the information is not properly protected or irreversibly anonymised. That is not to suggest that the risk of discrimination is a necessary consequence of enrolling in biobank research, but rather that the risk is a consequence of failure to protect against the future use of genetic information in ways that could enable discriminatory practices.[393] These concerns raise questions on how best to protect the tissue sources' and their families' privacy without hindering research.

The fruits of biobank research promise possibilities in drug breakthroughs and tailored drug therapies, but at the same time they also allow for use of samples and data in future research studies. Some of these studies focus on a particular scientific or medical problem while others are used broadly.[394] Some of these future studies may be undertaken locally and some will be international collaborative studies. This inevitably means that the ultimate destination and uses of these samples and the possible incursions on the confidentiality of data of the tissue source are simply unascertainable

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[390] Ibid, Art 4.

[391] Harris, J., & Keywood, K. (2001). Ignorance, information and autonomy. *Theoretical medicine and bioethics*, 22(5), 415-436.

[392] World Health Organisation. (2002). *Genomics and world health: Report of the Advisory Committee on Health Research* 157-160

[393] Mullen, C. (2009). Decisions, consent and expectations of the individual. *The Governance of Genetic Information: Who Decides*, 51-72 at 56

[394] Greely, H. T. (2007). The uneasy ethical and legal underpinnings of large-scale genomic biobanks. *Annu. Rev. Genomics Hum. Genet.*, 8, 343-364.

at the point of enrolment. It also illustrates how the individuals who contribute to these biobanks are rarely acknowledged even though there is rarely any personal benefit to them, because their contribution rarely leads to an improvement in their individual circumstance, and neither does it lead to a treatment for their own peculiar medical issues but it may lead to commercial or academic benefits for the researcher. Individuals who make tissue and data available for research purposes are concerned about the downstream process of commercialising technological advances arising from their research, as was evident in the Greenberg case. In Nigeria, however, a recent study[395] revealed that the concerns of Nigerians relate more to transfer and future uses of samples. In the words of one of the participants, 'my consent has to be obtained before you share my specimen with other researchers'. The participants' concern about commercialisation of the fruit of research appears to be low in the hierarchy of concerns discussed in the findings of the study. The concerns expressed revolved mainly around return of incidental findings and risk of infringement of confidentiality of information through sharing of this information. According to this study, when the focus group participants were asked to choose between broad, tiered, or restricted consent, half of the respondents chose broad consent, while others chose restricted or tiered consent. The main reason advanced for choosing tiered consent was a desire to maintain control over the types of research conducted with donated samples. From this study it would appear that Nigerians, unlike people in more developed countries, are more concerned about privacy issues and discrimination that may arise from sharing their data.[396] What this suggests is that the relevant choice of appropriate consent measures and privacy entitlement protection may differ for Nigeria.

This chapter then argues that the rights of the tissue sources who contribute to biobanks to have a say and to decide whether they want their data shared in furtherance of the purpose of a particular study should be respected. It also argues that broad consent, although convenient for biobanks, does not enable adequate protection of the tissue source. It will discuss the concerns of privacy arising from biobank research, explore

[395] Igbe, M. A., & Adebamowo, C. A. (2012). Qualitative study of knowledge and attitudes to biobanking among lay persons in Nigeria. *BMC medical ethics*, *13*(1), 27.
[396] Ibid at 28

the concept of privacy and its existing regulatory frameworks, and the implications for protecting the privacy of the tissue source in biobank research.

As this chapter deals with the privacy infractions of the tissue source in biobank research, it may be useful to begin by outlining the importance of privacy in order to appreciate privacy concerns in relation to biobank research.

3.2 The importance of privacy

There is ample evidence that human beings require privacy. This need for privacy is manifested in varying degrees and in different ways from culture to culture. This section does not address the degrees of privacy, rather it is interested in the significance of privacy in biobank research as a basis to have it protected by law. The privacy paradigm rests on a conception that individuals have autonomy[397] in the sense that they can make decisions for themselves. In *Evans v Amicus Healthcare Ltd,* Arden LJ observed that the fact that each person has a right to be protected against interference with their private life is an aspect of the principle of self-determination or personal autonomy.[398] If the position of Arden LJ is correct, then it is possible to argue that a right to be protected against interference with one's private life justifies the person making decisions about who has access to. A person's entitlement to privacy evinces the notion that that he may justifiably make decisions in whether or not to allow access to his medical information. Privacy is also based on a notion of there being a boundary between individuals. In the context of biobank research, the notion of privacy would arise by setting a boundary between the tissue source and the downstream researcher with whom the tissue source has no relationship. According to Westin, privacy is important because it distinguishes a liberal democratic society from a totalitarian society, it creates a balance that ensures strong citadels for individual and group privacy, and it limits unfettered disclosure of private information and surveillance.[399]

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[397] Henkin, L. (1974). Privacy and autonomy. *Columbia Law Review*, 1410-1433.
[398] *Evans v. Amicus Healthcare Ltd*, 2004 E.W.C.A. Civ 727.
[399] Westin, A. F. (1970*).* Privacy and freedom. Athenum at 24.

Rachels describes the first element of the theory of privacy as 'a characterisation of the special interest in being able to be free from certain kinds of intrusion'.[400] Since people have a number of interests that can be harmed by invasions of their privacy, including in the use of their samples and data in future unspecified research, the protection of this interest is significant in biobank research. In some cases a person may want to keep certain aspects of their life, behaviour or health private simply because it may be embarrassing for other people to know, or because it may prejudice their chances in competitive situations such as employment or politics. In biobank research incidental findings on venereal diseases could wreck a marriage just as research that reveals a pattern of alcoholism or incidence of a stigmatising disease could result in discrimination in the community or possible loss of employment. More than the protection of an unfaithful spouse from being embarrassed by the revelation of their infidelity, privacy is important because it protects the right of a person to decide what they want to share with others. In biobank research, the significance of privacy becomes more apparent because of the control the tissue source loses when prevented from deciding whether or not to have tissue and data used in future research. There is a close connection between the ability to control who has access to us and our information and our ability to determine relationships with others.[401] The individual tissue source has a right to decide how their samples and data are used. The following paragraphs outline the concerns of the tissue source in relation to use of tissue in biobank research

3.2.1 Risk of unauthorised access

In the recent past, the advances in genetic data processing technology have significantly reduced the cost of genome sequencing which has dropped from the six figure price tag it had a decade ago to one in the region of $5,000.[402] This fall in price will make sequencing available to more people and possibly usher in a situation where genome scanning of a person will be a routine procedure in medical research and clinical medicine. This will also increase the volume of data available to biobanks for

[400] Rachels, J. (1975). Why privacy is important. *Philosophy & Public Affairs*, 323-333.
[401] Ibid.
[402] The $1,000 genome: the revolution in DNA sequencing and the new era of personalized medicine. SimonandSchuster.com.

linkages,[403] as well as eventually increase the risk of unauthorised access to personal health information, including genetic information. It also increases the possibility of linking to other anonymised sources of data and making it possible to identify the tissue source.

3.2.2 Identifiability

Another privacy concern of data use and data sharing is the possibility of identifiability and disclosure of sensitive information leading to discrimination or even ostracism. These people may also fear other consequences of involuntary disclosure of their information. A person may be apprehensive about the consequences amongst friends, family or others of disclosure of a past sexually transmitted disease, the illegal use of drugs, an elective abortion, or the presence of a harmful or socially undesirable genetic trait.

3.2.3 Concern over access

In biobank research, biobanks collect a substantial amount of information on children that might be stored and used for prolonged periods – or indefinitely. Access to data and samples by third parties such as the government, law enforcement agencies, employers, insurers and educational institutions raises particular privacy concerns since the information could be incorporated in a decision affecting a child's future employment, insurance coverage, marriage prospects or education. The increasing use of banked biological materials and data augments the prospect of a breach of privacy by virtue of its wide availability and distribution.[404]

The move to global data sharing has been facilitated by international collaborative research funded by funders who have supported open access policies to enable global data sharing among the scientific community.[405] This has made information more accessible to researchers. The Human Genome Project, which started in 1990 and was completed in 2001, laid the foundation for open access and data sharing among

[403] Aldhous, (2009). Genome sequencing falls to $5000. New Scientist. http://www. newscientist.com/article/dn16552-company-will-sequence-your-dnafor-5000. html; Davies, K. (2010). The $1,000 genome: the revolution in DNA sequencing and the new era of personalized medicine. SimonandSchuster. com.

[404] Dove, E. S., Black, L., Avard, D., & Knoppers, B. M. (2013). Charting the Privacy Landscape in Canadian Paediatric Biobanks. *Health LJ*, 20, 1.

[405] For example, the Encode project: www.genome.gov/Encode.

researchers.[406] The arguments for the efficient use of resources underpin the policy of open access and data sharing. These policies can be traced to the Bermuda principles of 1996.[407] Although these policies have been in use for less than a decade they have had tremendous impact on the way results of research are disseminated. In addition to sequence reference libraries such as the one provided by the Hap Map project online, repositories, have been established to organise the storage and sharing of data derived from genome wide studies. (GWAS)[408] The problem with this powerful breakthrough in scientific research is that the privacy of the individual becomes vulnerable to increased intrusion.[409] In population studies for instance, there may be cases where only a particular group that is directly affected by the results of the study in which case, there may be a potential harm of stigmatisation associated with the study protocol. Through biobank research a linkage can be established between the medical information of the group and that of individual without much difficulty, after the results of the research are published[410]. Thus, the information generated by DNA sequencing can potentially reveal sensitive data that increases the potential for genetic discrimination by government, insurers, employers, schools, banks and others.[411] Furthermore, despite the assumption that genetic data in databases of biobanks, can be rendered anonymous, it is possible that individuals could be identified, with all of the aforementioned associated consequences.

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[406] Since the completion of the Hap map project other data generating projects have been initiated. They include: ENCODE; http://www.genome.gov/10005107); the Human Epigenome Project (http://www.epigenome.org); the International HapMap Project(http://www.hapmap.org); and, more recently, the 1000 Genomes Project (http://www.1000genomes.org). These projects have provided unrestricted access to sequence references on the internet.

[407] These are principles that were drafted for the Human Genome Project freedom of data access at a 1996 summit in Bermuda, leaders of the Human Genome Project agreed that all human genomic sequence information generated by centres funded for large-scale human sequencing should be made freely available and in the public domain within 24 hours after generation. Available at http://www.casimir.org.uk/storyfiles/64.0.summary_of_bermuda_principles.pdf

[408] A genome-wide association study is an approach that compare the genomes of healthy controls with those of people who exhibit a disease or a specific trait in order to identify the genetic variants associated with that disease or trait Once new genetic associations are identified, researchers can use the information to develop better strategies to detect, treat and prevent the disease. Such studies are particularly useful in finding genetic variations that contribute to common, complex diseases, such as asthma, cancer, diabetes, heart disease and mental illnesses.(http://www.genome.gov/)

[409] Makdisi, J. M. Z. (2000). Genetic Privacy: New Intrusion a New Tort. *Creighton L. Rev.*, 34, 965.

[410] Hansson, M. G. (2005). Building on relationships of trust in biobank research. *Journal of Medical Ethics*, 31(7), 415-418.

[411] Curren, L., Boddington, Gowans, H., Hawkins, N., Kanellopoulou, N., Kaye, J., & Melham, K. (2010). Identifiability, genomics and UK data protection law. *European Journal of Health Law*, 17(4), 329-344.

The need to link existing biobanks through a common data sharing infrastructure increases the potential for privacy incursion on research participants. This is further compounded by the fact that many of the secondary research uses of data were not anticipated at the time of obtaining consent for the collection of samples and data. Biobanking research or research involving stored tissue thus raises issues of privacy and confidentiality in relation to the use of research findings, access to and control of information, data protection of research subjects and family relations during and after research, as well as the protection of their identities when research findings are being disseminated.

In spite of the concerns relating to privacy incursions in biobank research, there are arguments in support of using existing research collections and data for future unspecified research purposes which include the cost and the volume of data generated by biobank researchers. The argument is that recruiting into large studies is expensive and time consuming, and that large samples sizes in research yield better and more accurate results. However, for developing countries such as Nigeria and Ghana where these biobanks are beginning to spring up, governance systems and procedures to promote scientific advancements as well as to protect the tissue sources are yet to be developed, leaving room for unmitigated privacy incursions.

The concept of informed consent is classically individualistic in form and intent; it is unable to take into account the interests of relatives of the tissue source when engaging the tissue samples and data of the tissue source in future research. However, because the interests of relatives may be affected by possible disclosure through data sharing in some future research, the privacy interests of these relations – who essentially become involuntary research participants – should be considered and accommodated within the consent process. The information revealed through biobank research may be relevant and stigmatising to others, and so the assessment of the interests at stake must also take into account these other parties. For instance, a carrier of a disease should not have the exclusive right to this information since the health and welfare of others are affected.

3.3 The concept of privacy

To further explore the protection of the tissue source, it is necessary to consider whether they are protected under the existing law on privacy by examining the meanings and

understandings of the concept of privacy. It would be difficult to assess the claim of a tissue source to privacy protection against the future unspecified use of his sample and data in biobank research without having a clear understanding of what privacy is. This section will set out the theoretical definitions and understandings of the concept.

There appears to be no consensus on the definition of privacy.[412] The Merriam Webster dictionary defines privacy as the quality or state of being apart from company or observation, seclusion; freedom from unauthorised intrusion. Privacy, according to Parent, is a concept in a state of confusion which he compares to a haystack in a hurricane. He then defines privacy from the angle of control as 'a condition of not having undocumented personal information about oneself known by others'.[413] Privacy is a broad and largely difficult concept to define; one writer has compared describing privacy to netting fog.[414] It is recognised as a complex multifaceted, fluid and evolving concept, which is open to a number of potential interpretations.[415] It is also a concept based on the principles of human dignity and respect for the freedom of an individual[416] which has been used to protect various interests ranging from bodily privacy, to genetic privacy, to confidentiality of communication between people, and right to privacy in the home.[417] The notion finds backing in various international instruments which recognise the entitlement of a person to privacy as a fundamental human right.[418] Privacy is also valued in different ways, under different circumstances; some writers describe its value in terms of its importance for the promotion of dignity, some in terms of its preservation of autonomy,[419] and some for the preservation of self through control of information.

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[412] Carolan, E. (2011). *The Concept of a Right to Privacy*. Available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1889243 last accessed 03/12/2015. The writer reviews the literature on the difficulties of defining a right to privacy and provides a summary of the work of authors such as Judith Jarvis Thomson, Russell Brown, Warren and Brandeis, Ruth Gavison, Beate Rossler, Nicole Moreham and Daniel Solove.

[413] Parent, W. A. (1983). A new definition of privacy for the law. *Law and Philosophy*, 2(3), 305-338 at p.306-307.

[414] Taylor, M. (2012). *Genetic data and the law: a critical perspective on privacy protection (Vol. 16)*. Cambridge University Press, 14.

[415] Otlowski, M. (2002). Protecting genetic privacy in the research context: Where to from here. *Macquarie LJ*, 2, 87.

[416] Le Bris, S., & Knoppers, B. M. (1997). *International and comparative concepts of privacy*. *Genetic secrets.* Yale University Press, New Haven, 418-448.

[417] S.37 of The Constitution of the Federal Republic of Nigeria 1990, provides that 'The privacy of citizens, their homes, correspondence, telephone conversations and telegraphic communications is hereby guaranteed and protected'.

[418] International Covenant on Civil and Political Rights Art. 17 and the OECD Guidelines on the protection of privacy and Transborder flows of Personal Data.

[419] Henkin, L. (1974). Privacy and autonomy. *Columbia Law Review*, 74, 1410.

Others have described the value and rationale for privacy in terms of its preservation of health and wellbeing. Many express privacy as a cluster of rights.

Having said this, there are two main perspectives on privacy: a dignitarian view and a libertarian one.[420] According to Whitman, '… privacy protections are, at their core, a form of protection of a right to *respect* and *personal dignity'*. This position can also be gleaned from the decisions in *Campbell v MGN*[421] and *Roe v Wade.*[422] In the latter case Justice Black, reiterating the libertarian view, stated that the right of privacy is broad enough to encompass a woman's decision whether or not to terminate her pregnancy. Also in the U.S. case of *Lawrence v Texas,*[423] Justice Kennedy, delivering the opinion of the Court, stated that liberty protects the person from unwarranted government intrusions into dwellings or other private places. Art. 8(1) of the European Convention on Human Rights (ECHR) also provides for the right to respect for a person's private and family life, his home and his correspondence, and Section 37 of the Constitution of the Federal Republic of Nigeria 1990, provides that '[t]he privacy of citizens, their homes, correspondence, telephone conversations and telegraphic communications is hereby guaranteed and protected'.

The Naomi Campbell case evinces the dignitarian and libertarian perspectives to privacy. In that case, the House of Lords noted that human rights had identified private information as something worth protecting as an aspect of autonomy and dignity. Dignity, in the traditional sense, has at its core honour, respectability and status. In Campbell's case, her respectability was affected by the article in the Daily Mirror which said that she lied about drug addiction. According to Baroness Hale, the core business of privacy is what she referred to as the protection of the individual's informational autonomy.[424]

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[420] Whitman, J. Q. (2004). The two western cultures of privacy: dignity versus liberty. *Yale Law Journal*, 1151-1221. At 1161

[421] *Campbell v. MGN Ltd* [2004] UKHL 22.

[422] *Roe v. Wade*, (1973) 410 U.S. 113,.

[423] *Lawrence v. Texas* (2003), 539 U.S. 558.

[424] *Campbell v. MGN Ltd* [2004] UKHL 22 at 134.

These different views emphasise the difficulty in defining privacy. Though Daniel Solove[425] calls it a concept in disarray, he defines it thus:

> 'Privacy is a sweeping concept, encompassing (among other things) freedom of thought, control over one's body, solitude in one's home, control over personal information, freedom from surveillance, protection of one's reputation, and protection from searches and seizures'.

Alan Westin also famously defined privacy as a prerogative over the flow of information:

> 'the claim of individuals, groups and institutions to determine for themselves when, how, and to what extent information about them is communicated to others. Viewed in terms of the relation of the individual to social participation, privacy is the voluntary and temporary withdrawal of a person from the general society through physical or psychological means, either in a state of solitude or small group intimacy or, when among large groups, in a condition of anonymity or reserve'.[426]

This chapter will consider privacy from the point of view of the entitlement of individuals to determine when, how, and to what extent information about them self is communicated to others in biobank research.

Within the field of research and bioethics privacy consists of various interrelated dimensions, which come into play in four different ways, according to the description by Allen:[427]

- Informational privacy concerns about access to personal information;
- Physical privacy concerns about access to persons and personal spaces;
- Decisional privacy concerns about governmental and other third-party interference with personal choices; and
- Proprietary privacy concerns about the appropriation and ownership of interests in human property.

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[425] Solove, D. (2008). *Understanding privacy*, 1

[426] Westin, A. F. (1967). *Privacy and freedom New York: Atheneum at p.7* .

[427] Allen, A. L. (1997). Genetic privacy: emerging concepts and values in *Genetic secrets: Protecting privacy and confidentiality in the genetic era*, 31-59.

These four heads can be subsumed in academic literature into the two dominant paradigms in which the concept of privacy is understood; spatial and informational privacy. The claim of entitlement of the tissue will be examined within this paradigm using Allen's description.

3.3.1 Informational privacy

According to Allen,[428] a claim of entitlement to privacy can arise to determine how and to what extent information about an individual is communicated. In the context of biobanks, informational privacy protects the interest of the tissue source from undesired access to their data. Informational privacy has been said to:

> 'imply that the denial of access implies the denial to personal health information to those whom the information does not relate, to recognise the interest of patients or research subjects in maintaining information in a state of non-access and preventing the unauthorised use or disclosure of that information to others'.[429]

It can also be seen as a state in which personal information about an individual is protected from unwanted access by others. In relation to biobank research, 'health informational privacy is the basis for an individual's claim to control the circumstances in which personal health information is collected, used, stored, and transmitted'.[430] It protects against unwanted access and dissemination of private information about a person and is our ability to control who has access to us and to information about us. This view of privacy that focuses on control over information about oneself was advocated by Warren and Brandeis[431] and by Prosser,[432] and has also been advanced by more recent commentators such as Fried and Parent.[433] Kupfer, in discussing the relationship between privacy, autonomy and the concept of self, also states that privacy enables control over personal information and control over personal choices and self.[434]

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[428] Ibid at 36.

[429] Laurie, G. (2002). *Genetic privacy: a challenge to medico-legal norms*. Cambridge University Press, 64.

[430] Gostin, L. O. (2009). *Public health law: power, duty, restraint (Vol. 3)*. University of California, 316.

[431] Warren, S. D., & Brandeis, L. D. (1890). The right to privacy. *Harvard Law Review*, 4(5), 193-220. He called for the recognition of a right to be left alone, stressing the point that individuals needed to keep certain personal information from the world.

[432] Prosser, W. (1960). *Privacy*, 48 Cal. L. Rev. 383.

[433] Kaye, J. (2012). The tension between data sharing and the protection of privacy in genomics research. *Annual review of genomics and human genetics*, 13, 415-431 at 416.

[434] Kupfer, J. (1987). Privacy, autonomy, and self-concept. *American Philosophical Quarterly*, 24(1), 81-89.

Privacy, to him, involves the control over who can have access to personal information. Some writers emphasise the intimate nature of information as a basis for privacy protection and the need to be able to make decisions about one's actions.[435] Others define the notion of control over access to information to include control over access to the body. Moore argues that bodily privacy 'is a right to control access to one's body, capacity and powers'. [436] Schoemann[437] focuses on privacy norms that enable a personal expression of relationships. All said, privacy provides a haven from intrusion and access to information by others. It also prevents others from controlling the individual through their access to personal information.

Spatial privacy can be viewed as a state of non-access from others. It is the notion that persons have an enforceable entitlement of respect for their privacy which can be viewed as a state of separateness or non-access to an individual's physical or psychological self.[438] Informational privacy is a state in which private information about an individual is protected from unwanted access by others,[439] and this is the definition that is adopted in this thesis. For the rest of the chapter, privacy in the context of biobank research should be taken to refer to a state in which an individual (and thus their samples) are apart from others either in a physical sense or a psychological sense by reference to the inaccessibility of intimate adjuncts to the individual such as personal information.

In the context of biobank research and future unspecified use of samples and data, the concept of informational privacy appears to be more relevant than that of spatial privacy. The possible future use of samples and data has increased the challenges of dealing with questions and issues relating to confidentiality of information in the context of biobank research. Genetic information has the potential to reveal secrets within the family; for instance, a study may reveal that paternity is different from what had been supposed. This may cause conflicts over access and control of such information. Traditionally, in a doctor patient relationship a duty of confidentiality is

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[435] Inness, J. C. (1996). *Privacy, intimacy, and isolation*. Oxford University Press.
[436] Moore, A. D. (2003). Privacy: its meaning and value. *American Philosophical Quarterly*, 40(3), 215-227.
[437] Schoeman, F. D. (Ed (1984). *Philosophical dimensions of privacy: An anthology*. Cambridge University Press.
[438] Laurie, G. (2002). *Genetic privacy: a challenge to medico-legal norms*. Cambridge University Press 6-8
[439] Ibid.

owed by a doctor to his patient. This duty and the protection it provides, is being challenged by the issues surrounding biobank research. Primarily, the duty of the doctor to the patient, and by extension of the researcher to the tissue source, is to protect the confidentiality of information; it does not elaborate on whether that duty extends to others who are affected by this confidential information and who may not be their patient or research participant. In biobank research, the significance of people knowing that relevant decision making processes are respectful of their privacy interests goes beyond the superficial. If people perceive that their interests are not duly considered, it may discourage voluntary participation in biobank research.[440] Respect for the personal information of the patient and or research subject is a way to demonstrate respect for the individual. Failure to account for the privacy interests of the tissue source in future research may undermine trust in the governance arrangements of biobank research.

3.3.2 Privacy and control over information

Privacy has been identified as a state or condition of control over information, as 'a limitation of others' access to an individual',[441] 'freedom from unwanted access',[442] 'selective control of access to the self or one's group'[443] or as 'the claim of individuals, groups, and institutions to determine for themselves when, and how, and to what extent information about them is communicated to others'.[444] It is our ability to control who has access to us and to information about us. This view of privacy focusing on control over information about oneself was advocated by Feldman,[445] Westin,[446] Warren and Brandeis[447] and by Prosser,[448] but has also been criticised by more recent commentators

[440] Taylor, M. (2012). *Genetic data and the law: a critical perspective on privacy protection*. Cambridge University Press at 14.
[441] Gavison, R. (1979*).* Privacy and the Limits of Law. *Yale LJ*, 89, 421.
[442] Moreham, N. (2005*).* Privacy in the Common Law: A Doctrinal and Theoretical Analysis'. *Law Quarterly Review*, 121, 628-630.
[443] Altman, I. (1975). The environment and social behaviour: privacy, personal space, territory, and crowding. Brooks/Cole Publishing Company, Monterey, California
[444] Westin, A. F. (1970). *Privacy and freedom*. New York: Atheneum.
[445] Feldman, D. Secrecy, Dignity or Autonomy? Views of Privacy as a Civil Liberty'(1994). *Current Legal Problems*, 47, 41.
[446] Westin, A. F. (1970). *Privacy and freedom*. New York: Atheneum.
[447] Warren, S. D., & Brandeis, L. D. (1890). The right to privacy. *Harvard Law Review*, 4(5), 193-220.
[448] Prosser, W. (1960). 48 C*alif. L. Rev*, 383, 389-92. Available at: *www.californialawreview.org/assets/pdfs/misc/prosser_privacy.pdf*

such as Fried and Parent.[449] Parent has argued that control based theories fail because they are both conceptually and empirically broad: 'to define privacy as control over all information about oneself implies that every time I walk or eat in public my privacy is compromised'.[450] Parent would still challenge this definition as unacceptable even if it were restricted to control over personal information. He discredits this definition using the comatose patient example;[451] that if in situations such as that of the comatose patient who cannot exercise control, control based theories offer no other option but to conclude that privacy has been compromised which Parent maintains is not always the case. His criticism seems to assume that a control based conception of privacy is one that depicts absolute control over all forms of personal information. Privacy being defined in terms of control over information is a general overriding right that an individual exercises to determine when access can be given to personal information, not absolute control. Absolute control based definitions cannot distinguish between private information being accessed on a familial level and that which is not. It does not accommodate nor adequately reflect the possibilities of issues presented by new technologies in genomics. The protection of privacy should not be based on absolute control. Rather, 'the question raised by privacy claim is not whether the individual retains exclusive control over the subject matter in question but rather, he ought to be able to control another's access to, or use of that subject matter'.[452] Privacy claims should not be an assertion of exclusive control and absolute access, but an assertion of the right to control current and future access to information.

To adequately protect the privacy of research participants, there ought to be a system in place capable of acknowledging and enforcing an individual's desire not to allow 'unwelcomed access' to their information or samples by 'unwelcomed others'.

The current mode of consent for biobank research, does not provide such a system, and neither does it enforce the tissue source's desire to have a say in future uses of their sample and data. Consent forms are the only current means whereby the tissue source

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[449] Parent, W. A. (1983). Recent work on the concept of privacy. *American Philosophical Quarterly*, *20*(4), 341-355. At p.344 citted in aye, J. (2012). The tension between data sharing and the protection of privacy in genomics research. *Annual review of genomics and human genetics*, 13, 415-431 at 416.

[450] Laurie, G. T. (2002). *Genetic privacy: a challenge to medico-legal norms*. Cambridge University Press, 53.

[451] Parent, W. A. (1983). Recent work on the concept of privacy. *American Philosophical Quarterly*, 341-355 at 344.

[452] Carolan, E. (2011). The Concept of a Right to Privacy. Available at *SSRN* 1889243, at 21.

can register their wishes and exercise autonomy in relation to the research. In principle, consent forms, if perceived as a contractual agreement, present potential tissue sources an opportunity to negotiate terms of re using their data and samples in future research. However in low and middle income countries such as Nigeria, this may be unrealistic as the balance of power between the researcher and the tissue source is more likely to be tilted towards the researcher. Consequently, future research on samples needs to be explained and may be announced by deploying a dynamic mode of consent using locally accessible communication methods such as SMS and radio jingles. Informed consent should be seen as an ongoing process that would enhance the entailment of the tissue source to make decisions and not a once and for all decision.

. This can only be achieved if privacy is conceived as the power to control not access as such, but access of *particular* others to *particular* materials or *particular* information. Kupfer,[453] in discussing the relationship between privacy, autonomy and the concept of self, states that privacy enables control over personal information and over personal choices and self. Privacy, to him, involves control over who can have access to personal information. Some writers such as Schoemann,[454] Kupfer,[455] and Moore[456] emphasise the intimate nature of information as a basis for privacy protection and the need to be able to make decisions about one's actions.[457]

In relation to biobank research, the intimate nature of 'health informational privacy is the basis for an individual's claim to control the circumstances in which personal health information is collected, shared, used, stored, and transmitted'.[458] In *Campbell v MGN*[459] one of the three tests developed for determining what information is termed private is the 'reasonable expectation' test for determining private life which is based on whether, in relation to a set of disclosed facts, the individual in question had an expectation of privacy. In determining what information is private and therefore inaccessible to others, the test should be whether the individual and, in the context of research, the tissue

[453] Kupfer, J. (1987). Privacy, autonomy, and self-concept. *American Philosophical Quarterly*, 24(1), 81-89.
[454] Schoeman, F. D. (Ed (1984). *Philosophical dimensions of privacy: An anthology*. Cambridge University Press, 3.
[455] Kupfer, J. (1987). Privacy, autonomy, and self-concept. *American Philosophical Quarterly*, 24(1), 81.
[456] Moore, A. D. (2003). Privacy: its meaning and value. *American Philosophical Quarterly*, 40(3), 215-227.
[457] Inness, J. C. (1996). *Privacy, Intimacy, and Isolation*. Oxford University Press.
[458] Gostin, L. O. (2009). *Public Health Law: Power, Duty, Restraint (Vol. 3)*. University of California, 316.
[459] *Campbell v. MGN Ltd*, 2004 A.C.2 457; [2004] UKHL 22.

source, had a reasonable expectation of privacy from the researcher. In the context of biobank research, the tissue source can be said to be in a researcher/participant relationship of confidence with the biobank. It therefore follows that this relationship creates a duty of care[460] which imputes a duty of confidentiality between the researcher, the biobank and the tissue source. The source can thus have a reasonable expectation that their private and personal information will be kept confidential.

Personal information refers to information about identifiable subjects. In the context of biobank research, it includes information contained within genes that can be acquired and accessed through research or genetic testing.[461] According to Lord Hope in *Campbell v MGN*,[462] the underlying question where it is alleged that there has been a breach of the duty of confidence is whether the information that was disclosed was private and not public. In *A v B plc*,[463] the Court of Appeal opined that the answer usually will be obvious. Where it is not, the broad test is whether disclosure of the information about the individual ('A') would give substantial offence to A, assuming that A was placed in similar circumstances and was a person of ordinary sensibilities and that there must be some interest of a private nature that the claimant wishes to protect.

In *S and Marper v UK*[464] the Court stated that the concept of 'private life' is a broad term not susceptible to exhaustive definition. It covers the physical and psychological integrity of a person. It can also embrace multiple aspects of the person's physical and social identity.[465] Beyond a person's name, his or her private and family life may also include other means of personal identification and of linking to a family.[466] Information about the person's health is an important element of private life.[467] Even though not specifically in relation to biobanking, the courts have found that the mere storing of data

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[460] *Grimes v. Kennedy Krieger Institute, Inc*., (2001) 782 A.2d 807, 366 Md. 29.

[461] Manson, N. (2009). The Medium and the Message: Tissue Samples, Genetic Information and Data Protection.in Widdows, H., & Mullen, C. (Eds.). The governance of genetic information: who decides? Cambridge University Press. at 21.

[462] *Campbell v. MGN Ltd*,2004 A.C. 2 para 92

[463] *A v B plc* [2003] QB 195, 206 at 11.

[464] *S and Marper v UK* [2009] 48 EHRR 50 at 66-67

[465] *Mikulić v. Croatia*, 99 ECHR 2002 (2002).

[466] *Ünal Tekeli v. Turkey*, 42 EHRR 53 (2006).

[467] *Z v. Finland*, 25 EHRR 371 (1998).

relating to the private life of an individual amounts to an interference within the meaning of Art. 8 of the HRA.[468] However, in determining whether the personal information stored and shared in future unspecified research involves any of the aspects of private-life mentioned above, the Court should have regard to the specific context in which the bio information at stake has been stored, the way in which these information are used and processed, the results that may be obtained, as well as the effect of these results on the tissue source and his biological relations.

Open Access policies developed by leading funders of genomics research have been applied to most forms of data and these policies though contain statements requiring the protection of individual privacy yet encourages wide scale data sharing.[469]Open access principles have been found to be in conflict with privacy concerns. In 2008, genetic data placed on the web by researchers for GWAS use had to be withdrawn when it was realised that individual participants could be distinguished from open shared data.[470]

Genetic information can affect families.[471] This dimension to informational privacy underscores the desire for individuals to view privacy from the angle of a claim or notion of control. The fact that private information should be accorded some protection seems uncontested,[472] but the issue in relation to research is how this should be achieved. There are several legal devices that can be employed to protect the privacy interest of the tissue source in biobank research. It is possible for judicial systems to recognise property rights in biological material gathered for biobanking purposes by allowing this right to remain with the tissue source (see Chapter 4). The right to privacy can also be protected through the consent process. Control of secondary use can be

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[468] *Leander v. Sweden*, 9 EHRR 433 (1987).

[469] Trust, W. (2003, January). Sharing data from large-scale biological research projects: a system of tripartite responsibility. Available from http://www.wellcome.ac.uk/stellent/groups/corporatesite/@policy_communications/documents/web_document/wtd003207.pdf. Last accessed 3/12/2015.

[470] Kaye, J. (2012). The tension between data sharing and the protection of privacy in genomics research. *Annual review of genomics and human genetics*, 13, 415-431; Homer N, Szelinger S, Redman M, Duggan D, Tembe W, et al. 2008. Resolving individuals contributing trace amounts of DNA to highly complex mixtures using high-density SNP genotyping microarrays. *PLoS Genet.* 4(8)

[471] Gostin, L. (1991). Genetic discrimination: the use of genetically based diagnostic and prognostic tests by employers and insurers. *Am. JL & Med.*, 17, 109.

[472] Moreham, N. (2006). Privacy Rights. In Tugendhat, M., & Christie, I. (eds). *The Law of Privacy and the Media: Main Work and Second Cumulative Supplement*. Oxford University Press.

exercised through the use of consent which would set the parameters for future use of the resource.

3.4 Spatial privacy: physical privacy concerns about access to persons and personal spaces

3.4 1 Privacy and restricted access

This concept of physical privacy is viewed as a concern for the quantum of access another party has over one's territory. Spatial privacy covers claims in relation to a specific geographical space, as well an individual's own personal space; which may also relate to his person.[473] This aspect of privacy protects the right to be free from unwanted physical access or from intrusion into one's physical space; it reflects the idea of protection of a private zone, space, or sphere. This notion of privacy is founded in norms regulating access to individuals; it protects a private sphere into which one can retreat to escape from unwanted incursion or prying. At common law, this idea was expressed by Knight-Bruce V-C in the case of *Prince Albert v Strange,*[474] where he described the unauthorised publication of the Prince's etchings as 'an intrusion- an unbecoming and unseemly intrusion'. This position of protecting from intrusion or invasion an intimate personal or private sphere was echoed in *R v Broadcasting Standards Commission, ex parte BBC.*[475] In that case, the BBC had successfully sought judicial review of the decision by the Commission upholding a complaint by the electronics retailer Dixons that covert filming of their over-the-counter transactions amounted to an unwarranted infringement of its privacy under section 110(1)(b) of the Broadcasting Act 1996. The Crown Court had upheld the BBC's arguments that the expression 'privacy' in the English statute, as construed in accordance with Art. 8 ECHR, was restricted to natural persons and did not extend to corporations. That Court also ruled that there could be no infringement of privacy by the mere fact of secret

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[473] *R v Dyment* (1988) 55 DLR (4th) 505 : [473] R *v. Dyment*, 1988 S.C.R.2 417 (1988). The Supreme Court upheld the lower court decision that the seizing of blood taken for medical purposes was a violation of privacy rights. The court, examined the scope of protection provided by section 8 and found that underlying section 8 is a right to privacy, which was described as a constitutionally protected value, stating that:
privacy is at the heart of liberty in a modern state...[g]rounded in man's physical and moral autonomy, privacy is essential for the well-being of the individual. For this reason alone, it is worthy of constitutional protection, but it also has profound of the citizen go to the essence of a democratic state significance for the public order. The restraints imposed on government to pry into the lives

[474] *Prince Albert v Strange* (1849) 18 LJ Ch 120. 64 ER at 293.

[475] *R v Broadcasting Standards Commission ex parte BBC* [2000] 3 WLR 1327

filming of an event in public, since that event did not have the requisite 'quality of seclusion' about it. On appeal, however, it was held, that there was no need for an activity subject to covert filming to have a 'quality of seclusion about it' in order to warrant the protection of Art. 8. On the issue of whether the expression 'privacy', in the Broadcasting Act, when construed in accordance with the ECHR, extended to corporations, it was held that a company could clearly have private activities which needed protection from unwarranted intrusion. Once it had been established to the satisfaction of the Court that the Commission had rightly found an intrusion of privacy, that was the end of the matter. Lord Mustill[476] said that privacy denotes the personal space in which the individual is free to be himself. In other words, spatial privacy protects from incursion the physical space of an individual and a corporate entity, and it enforces his claim to it.

The legal recognition of the protection of physical space is backed up by the opinion of scholars and commentators. Commentators have described this notion of the concept of privacy in terms of access or accessibility[477]. For instance, privacy has been defined as 'a limitation of another's' access to an individual'[478] 'freedom from unwanted access or as 'our ability to control who has access to us and to information about us'.[479] Gavison[480] argues further that interests in privacy are intertwined with our concerns over what others know about us, the extent to which they have physical access to us, and the extent to which we are the subject of their attention. Thus, the concept of privacy is best understood as a concern for limited accessibility and one has perfect privacy when one is completely inaccessible to others. According to Gavison, privacy can be gained in three independent but interrelated ways: through secrecy, when no one has information about one; through anonymity, when no one pays attention to one; and through solitude, when no one has physical access to one. Gavison's view is that the concept of privacy is a combination of all three ways, all being a part of the notion of accessibility. Furthermore, Gavison argues that the concept is also coherent because of the related

[476] *R v Broadcasting Standards Commission ex parte BBC* [2000] 3 WLR 1327 at para 48

[477] Tugendhat, M., & Christie, I. (eds)(2004). *The law of privacy and the media: first cumulative updating supplement*. Oxford University Press at p 62., Warren, S. D., & Brandeis, L. D. (1890). The right to privacy. *Harvard Law Review*, 4(5), 193-220

[478] Gavison, R. (1979). Privacy and the Limits of Law. *Yale LJ*, 89, 421.

[479] Rachels, J. (1975). Why privacy is important. *Philosophy & Public Affairs*, 4(4), 323-333.

[480] Gavison, R. (1979). Privacy and the Limits of Law. *Yale LJ*, 89, 421.

functions privacy has, namely 'the promotion of liberty, autonomy, selfhood, human relations, and furthering the existence of a free society'.[481] Also that the unauthorised access to the person and his space is breach of privacy.[482]

The issue of access to samples and data for future unspecified use in biobank research touches upon the spatial and informational dimensions of privacy outlined above. For instance, large prospective cohort studies that use DNA samples combined with medical, lifestyle, and environmental information are becoming standard research tools for examining the effects of genetic and other factors on disease.[483] The use of both samples and data, by downstream researchers' in future unspecified research can have implications for the informational privacy of the tissue source. Emerging forensic methods have shown that a third party with access to a sample of an individual's DNA could use the DNA sequence data of the type collected and shared by genetic biobanks to determine that the sample belongs to a biobank participant.[484] Most studies and biobanks research like the one outlined above do not involve experimental treatments and therefore have very little impact on the tissue source personally. Tissue sources generally undergo minimally invasive sample collection with little risk of physical harm but provide personal information through biological samples, medical records, or surveys. As with most biobank research, participants would initially sign a consent form that outlines the data-sharing policies of the biobank. The issue is whether access to samples and data should necessarily justify and compromise the privacy interest of the tissue source or whether it would allow tissue sources the opportunity to provide separate consents for each particular study using dynamic consent, or whether another model of consent such as approval for broad disease categories or categories of research would be used.

There are two main ways in which the law ameliorates the infraction of privacy caused by data sharing: consent and anonymisation. Each has value in protecting the tissue

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[481] DeCew, Judith, 'Privacy', *The Stanford Encyclopaedia of Philosophy* (Fall 2013 Edition), Edward N. Zalta (ed.), Available at <http://plato.stanford.edu/archives/fall2013/entries/privacy/>. Last accessed 3/10/2013

[482] Tugendhat, M., & Christie, I. (eds)(2004). *The law of privacy and the media: first cumulative updating supplement*. Oxford University Press at 62; Warren, S. D., & Brandeis, L. D. (1890). The right to privacy. *Harvard Law Review*, 4(5), 193-220; Westin, A. F. (1968). Privacy and freedom. *Washington and Lee Law Review*, 25(1), 166.

[483] Biobank, U.K. (2008). UK Biobank Homepage. http://www.ukbiobank.ac.uk/.

[484] Kaufman, D. J., Murphy-Bollinger, J., Scott, J., & Hudson, K. L. (2009). Public opinion about the importance of privacy in biobank research. *The American Journal of Human Genetics*, 85(5), 643-654.

source and each has limitations. Consent allows for a research participant to make a choice of whether or not to participate in a study after being told the risks.[485] It also allows the participant to withdraw from the research at any time. However, in biobank research, the control over access to data is very limited. The right to withdraw from biobank research is limited because it does not allow the tissue source to withdraw their samples or data it only allows withdrawal of participation.

The common thread from these different views is that privacy is a concept of broad application with deep roots extending along different dimensions of law, as well as other facets of life. Some of these dimensions are traceable and form the basis of expectations of claims regarding access to, and exclusivity of use of samples and data. Privacy as a concept preserves the right of a person to be left alone and to decide who has access to the individual and when. In relation to biobank research it is argued that the current legal framework inadequately protects the privacy of the tissue source from invasion when their sample or data is used in future unspecified research, especially if assessed according to the dimensions of privacy outlined above. The foregoing analysis describes the current patterns of privacy which mirrors its relationship to biobank research and in turn the tissue source. Mirroring the definition of privacy along the lines of the four dimensions of privacy proposed by Allen, the claim of the tissue source to privacy has emergent informational, decisional, and physical dimensions. The concerns of confidentiality and access to data through sharing in future research remains a major concern the protection of which will be further examined in subsequent sections.

While privacy may be a universal necessity and right, its form and rules of engagement are culturally dependent. Individual expectations of privacy are context specific, and they can vary depending on religion, culture, climate and other circumstances.[486]

3.4.2 Decisional privacy

The concept of privacy under this head, relates to the individual's entitlement to make their own decisions. It restricts the actions or interference of the state and others in that

[485] Laurie, G. T. (2002). *Genetic privacy: a challenge to medico-legal norms*. Cambridge University Press.

[486] Spiro, H. J. (1971). 'Privacy in Comparative Perspective,' in Pennock and Chapman, *Privacy: Nomas XIII*, 121-148; cited in Moore, A. D. (2003). Privacy: its meaning and value. *American Philosophical Quarterly*, 40(3), 215-227.

regard. A research participant or patient's active participation in research and health decisions without interference from unauthorised persons is an aspect of decisional privacy.[487] According to Allen, decisional privacy concerns are heard in calls for autonomous decision making by individuals.[488] A degree of choice with regard to participation in genetic counselling, genetic testing and abortion have been said to be requirements of respect for decisional privacy.[489] The recruitment of participants and an individual's decision to accept or decline an invitation to participate in future research may be an interest in decisional privacy. When an individual has chosen to participate, there may also be physical privacy interests that arise during the acquisition of genetic material which relate to decisional privacy. Where a person voluntarily consents to a study and sample and data are used in subsequent studies based on the broad consent to the initial research, his right to make a decision relating to the new research has been compromised by not giving him an opportunity to decide one way or another.

In the context of biobanking research, changes in the way research is conducted (especially the use of data sharing models) raise issues of decisional privacy that go beyond the tissue source to the possibility of identifying other members of the community especially in population studies without their consent. This is because secondary research or future unspecified research is conducted with the aid of broad consent outside the control of the tissue source.[490] The use of tissue and data in future unspecified research reinforces the concern of infringing the decisional privacy of the tissue source to make an autonomous decision about whether or not to enrol in future research activities. This is because a person's active participation in decisions and control of their body without the interference of government or unauthorised persons is a decisional variant of privacy.[491] Non-consensual use of these samples and data is capable of resulting in incursions of privacy. As biobanks collect increasingly larger amounts of genomic and other data and grant access to more diverse groups of

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[487] DeCew, J. W. (1997). In pursuit of privacy: Law, ethics, and the rise of technology. Cornell University Press.
[488] Allen, Anita L. 'Genetic privacy: emerging concepts and values.' *Genetic secrets: Protecting privacy and confidentiality in the genetic era* (1997): 31-59 at 34
[489] Ibid.
[490] Kaye J, Gibbons SMC, Heeney C, Parker M, Smart A. 2012. *Governing Biobanks: Understanding the Interplay Between Law and Practice*. Oxford, UK: Hart.
[491] Allen, A. L. (1997). Genetic privacy: emerging concepts and values. *Genetic secrets: Protecting privacy and confidentiality in the genetic era*, 31-59.

researchers and others for a broader range of purposes, the risk to research participants of significant privacy breaches and confidentiality infringement may increase.

In research contexts, under rubrics of privacy, individuals are sometimes ascribed rights of self-determination and autonomy over parts and products of their bodies. This right, though contested, does not imply a right to commodify the body or the parts as would be possible with real property.[492] However, proprietary understandings of privacy will continue to find expression in biobank research contexts because tissue sources have privacy interests in their bio-banked samples/data. These are sources of health information that reflect what individuals and their biological families are like, and what will become of them.

3.4.3 Proprietary privacy

Proprietary privacy is concerned with the appropriation and ownership interest in human personality[493]. Moral and legal theorists have offered accounts of the relationship between 'property' and 'privacy' 'property rights' and 'privacy rights'.[494] Some have considered there to be a property right in the self, which encompasses both the body (physical) and the soul (nonphysical).[495] Locke,[496] for instance, characterised the relationship between a person and their body as self-ownership. Annas also posits that the self is worthy of self-love by its owner, the person.[497] Proprietary privacy is that aspect of privacy that is considered to protect proprietary interest in the self.[498] In biomedical research contexts, under rubrics of privacy, individuals are sometimes ascribed rights of self-ownership and the ownership of parts and products of their bodies, as was done in the case *of Moore v. Regents of the University of California,*[499] where a novel philosophical argument on privacy was advanced that in taking his DNA-laden tissue for unrevealed research and development purposes unrelated to Moore's

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[492] *Moore v. Regents of the University of California*, (1988) 249 Cal. Rptr. 494.

[493] Rothstein, M. A. (Ed (1997). *Genetic secrets: protecting privacy and confidentiality in the genetic era*. Yale University Press.

[494] May, L., 1988, 'Privacy and Property,' *Philosophy in Context*, 10(40): 40–53.

[495] Lackoff, G. and Mark Johnson, 1999, *Philosophy in the Flesh: The Embodied Mind and its Challenge to Western Thought*, New York: Basic Books.

[496] Machan, T. R. (2008). Self-Ownership and the Lockean Proviso. *Philosophy of the Social Sciences*.

[497] Annas, J. (1989). Self-Love in Aristotle. *The Southern Journal of Philosophy*, 27(S1), 1-18.

[498] Thomson, J. J. (1975). The right to privacy. *Philosophy & Public Affairs*, 4(4), 295-314.

[499] *Moore v. Regents of the University of California*, 249 Cal. Rptr. 494, (1988). Para 138

cancer treatment, UCLA doctors had appropriated his identity in a manner analogous to advertisers using a person's photograph without consent for commercial gain. At the time, Moore's privacy claim was novel but the claims of celebrities to control the attributes of their personal identities, likenesses, voices, and names have been commonly styled as privacy rights. Moore argument drew an analogy between the privacy rights accorded celebrities to protect their identities from being used without their consent and the use of his tissue without proper disclosure. On appeal to the Supreme Court of California, the Court did not accept Moore's argument and neither did it agree that the injury Moore suffered fitted the traditional types of privacy invasions. The Court ruled:

> 'Lacking direct authority for importing the law of conversion into this context, Moore relies, as did the Court of Appeal, primarily on decisions addressing privacy rights. One line of cases involves unwanted publicity. [interpreting Cal. law].) These opinions hold that every person has a proprietary interest in his own likeness and that unauthorised, business use of a likeness is redressible as a tort. But in neither opinion did the authoring court expressly base its holding on property law'.[500]

They went on further to state that 'For purposes of determining whether the tort of conversion lies, however, the characterisation of the right in question is far from pointless. Only property can be converted'. Indeed Moore's argument may not have swayed the California Supreme Court at the time, but the case and the arguments put forward reinforces the need to acknowledge the entitlement and expectation of the tissue source to privacy protection. In a related case that did not result in tort litigation in her lifetime, cells taken from Baltimore resident Henrietta Lacks[501] were the basis of an important immortal cell line, HeLa. Lacks died in 1951, but the cell line created using her cervical cancer cells without her knowledge or consent lives on. It has been used in the treatment and eradication of numerous conditions and illnesses, including polio, without any financial reward to her or her heirs.

Proprietary understandings of privacy have continued to find expression in health research contexts. This includes protecting the sources of health information that reflect

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[500] Ibid 138 -139

[501] Skloot, R., & Turpin, B. (2010). *The immortal life of Henrietta Lacks* (369). New York: Crown Publishers.

what individuals and their biological families are like and what will become of them. Individuals have asserted what they describe as privacy and proprietary interest in controlling what becomes of the samples and data excised at the point of enrolling for biobank research. In the UK, the most recent evolution of the common law approach to finding property in human gametes was established in *Yearworth v North Bristol NHS Trust*[502] where the Court of Appeal recognised a property right belonging to the claimant over his sperm, even though this is not the type of proprietary interest in one's person that that proprietary privacy seeks to protect.

Writers have identified several forms of privacy – informational, spatial, proprietary and decisional – as an ideal of biomedical ethics for the conduct of research and administrative practices relating to biobanking research. Even though there is ample disagreement about the scope of the privacy entitlement of the tissue source, there is consensus on the significance of confidentiality, and privacy of the tissue source in relation to his sample or data in biobank research. In spite of this consensus, there is substantial disagreement about the limits of personal autonomy or individual choice of the tissue source in stored tissue research. As the use of electronic data management technologies and genome-wide association studies expand, the range and complexity of important privacy questions in research are likely also to expand. In the previous sections, the various definitions and understandings of privacy were examined to assess the scope of the tissue source's legitimate expectation of privacy protection which is accommodated within these definitions and understanding of the concept of privacy. The definitions relate to a state of separateness from others which are reflected under four heads, which can be subsumed under two main interests of privacy – informational and spatial. From these definitions, privacy places a considerable emphasis on the protection of rights and interests of the individual and presupposes respect for autonomy and dignity.

3.4.4 Privacy within the context of African communitarian values

In African traditional ethics, communitarian values are evident in the belief in the fundamental unity between the different people in the community. This is evident in the

extended family relationship and the communal living that encourage a unity of human relationships. The extended family setting, for instance, reflects an ethic of mutual help, survival and care for each other.[503] African ethic of communitarianism places considerable value on conformity of the individual to the social group in order to preserve the unity of human relationships. It could be said that, in a way, African thought is more concerned with the relationship than with the different entities which constitute the relationship.[504] According to Mbiti,[505] 'I am because we are, and since we are, therefore I am.' In other words, it is only in terms of other people that the individual is conscious of their own being, duties, privileges and responsibilities towards themselves or towards other people:

> This is a morality of conduct rather than a morality of being, or of personal morality. 'It is a morality of conduct in the sense that it is one's relationships and, therefore, his conduct in the social sphere that dictates one's sense of morality. This morality occurs in contrast to emphasising an individual's sense of self, autonomy or being, that is, of the self which does not place much value on the social relationships'.[506]

In African communities, there is a strong awareness of one's existence and relationship with others in the community, a strong sense of 'social self'. The support of others is more important than one's capacities to achieve one's existential ends, hence the value of corporate existence. According to Menkiti, a crucial distinction thus exists between the African view of man and the view of man found in Western thought: in the African view it is the community which defines the person as a person, not some isolated static quality of rationality, will, or memory.[507]

This African social ethic is expressed in many maxims or proverbs that emphasise the importance of the values of mutual helpfulness, collective responsibility, cooperation, interdependence, and reciprocal obligations. One of the proverbs on the importance of

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[503] Elza Vetner (2004).The notion of Ubuntu and communalism in Africa. *Studies in Philosophy and Education* 23: 149–160.

[504] Kigongo, J. K. (2002). The relevance of African ethics to contemporary African society. *Ethics, human rights and development in Africa*, 8, 51-65.

[505] John S. Mbiti, (1969), *African Religions and Philosophy*, Nairobi: East African Educational Publishers Ltd. 108-109.

[506] Kigongo, J. K. (2002). The relevance of African ethics to contemporary African society. *Ethics, human rights and development in Africa*, 8, 51-65.

[507] Menkiti, I. A. (1984). Person and community in African traditional thought. *African philosophy: An introduction*, 3, 171-182.

family and social relations is found in the Yoruba repertoire: human beings (kith and kin) are my clothes *(Eniyan laso mi*). The lesson of this proverb is not that a person should always look to another (or others) for their well-being and the attainment of their goals, but that there are occasions when the solidarity of the community and the demonstration by others of goodwill, sympathy, compassion and willingness to help can be a great boost to a person's attempts to achieve their goals, and to fulfil their life.[508] The dependency noted in the foregoing proverb is a reflection of the overriding importance attached to social and communal bond in the Yoruba African setting. The social, communal or relational character of the African prescribes a social ethic, rather than an ethic of individualism.[509] Individualistic ethics that focus on the welfare and interests of the individual are hardly regarded in African moral thought. In African cultures, such as in Nigeria, the boundaries of personal privacy are narrower. Extended family and communal living tend to blur demarcations of personal and spatial privacy within the family setting. The extended family setting is essentially a communal setting in which everyone looks out for the other even in matters relating to health and welfare.

According to Jegede:

> 'genetic screening in Africa requires that issues of confidentiality go beyond the individual participant and other family members who are living but also importantly the interest of departed souls and those yet unborn are even more critical'.[510]

In the traditional setting, the interest of the community or extended family may be more important than the interest of the individual. This is because communities may bear risks that are not simply aggregates of the risks to individuals and, in the African culture, community participation is a fundamental aspect of individual decisions.[511] Thus, the decision to participate in future unspecified research may be that of the community in conjunction with the tissue source. In spite of the fact that the margin of privacy is narrower in African communities they do not discount the concept of privacy

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[508] Gyekye, Kwame, 'African Ethics', The Stanford Encyclopaedia of Philosophy (Fall 2011 Edition), Edward N. Zalta (ed.), http://plato.stanford.edu/archives/fall2011/entries/african-ethics/.

[509] Teffo, L.J. (1998). Both *ubuntu* as a way forward for contemporary South Africa. *Word and Action*, 38*(*365*)*, 3–5.

[510] Jegede, A. S. (2009). Culture and genetic screening in Africa. *Developing world bioethics*, 9(3), 128-137.

[511] Diallo, D. A., Doumbo, O. K., Plowe, C. V., Wellems, T. E., Emanuel, E. J., & Hurst, S. A. (2005). Community permission for medical research in developing countries. *Clinical Infectious Diseases*, 41(2), 255-259.

within their communities. Privacy, as a concept of being left alone to make choices best suited to an individual, remains the norm in these communities. The application of privacy to the individual, as opposed to a corporate norm, is the point of digression in African communities. Community involvement should be as important as individual consent in cultural settings, yet it should not override or substitute for an individual's refusal to participate in future unspecified research.[512]

3.4.5 Privacy and related concepts

3.4.5.1 Privacy and dignity

The concept of privacy has been recognised as based on principles of human dignity and respect for individual freedom.[513] Commentators[514] have also recognised this relationship between privacy and dignity: Warren and Brandeis in their seminal work referred to the interest protected by privacy as spiritual and closely linked it with the 'inviolate personality' of the individual.[515] and Bloustein [516] argues that there is a common thread in the diverse legal cases protecting privacy. According to Bloustein, all the coherence of privacy as a legal concept lies in the fact that all privacy interferences are an affront to dignity. According to Bloustein, when one person interferes with the privacy of another:[517]

> 'The injury is to our individuality, to our dignity as individuals, and the legal remedy represents a social vindication of the human spirit thus threatened rather than a recompense for the loss suffered'.

This relationship was judicially recognised in the case of *Campbell v MGN* where Lord Hoffmann observed, '[w]hat human rights law has done is to identify private information as something worth protecting as an aspect of human autonomy and

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[512] Hall, A. J. (1989). Public health trials in West Africa: logistics and ethics. *IRB*, 8-10.

[513] Rosen, J. (2011). *The unwanted gaze: The destruction of privacy in America*. Random House LLC at 12-17, Post, R. C. (2000). Three concepts of privacy. *Geo. LJ*, 89, 2087.

[514] Prosser (1960), Privacy, 48 Calif. L. Rev. 383; Warren, S. D., & Brandeis, L. D. (1890). The right to privacy. *Harvard Law Review*, 4(5), 193-220.

[515] Cane, (1997). *The anatomy of tort law*. Hart Publishing.

[516] Bloustein, E. J. (1964). Privacy as an aspect of human dignity: An answer to Dean Prosser. *NYUL Rev.*, 39, 962.

[517] Bloustein, E. J. Privacy as an Aspect of Human Dignity: An Answer to Dean Prosser'(1964) 39. *New York University Law Review*, 6, 962.

dignity'.[518] He went on to refer to Lord Sedley in *Douglas v Hello! Ltd*,[519] that protection of confidentiality of individuals in law is based on the high principle of respect for human dignity- the right to control the dissemination of information about one's private life and the right to the esteem and respect of other people. This decision has been followed in the case of *Mosley v News Group Newspapers Ltd*,[520] where Eady J noted that, in the prevention of misuse of private information, the law is 'concerned to prevent the violation of a citizen's autonomy, dignity and self-esteem'. Dignity in itself, has been described in terms of respect. Immanuel Kant in his discussion of the rights of the individual to be treated with respect said:

> Man, and in general every rational being, exists as an end in himself and not merely as a means to be arbitrarily used by this or that will. He must in all his actions, whether directed to himself or to other rational beings, always be regarded at the same time as an end.… Persons are, therefore, not merely subjective ends, whose existence as an effect of our actions has a value for us; but such beings are objective ends, i.e., exist as ends in themselves'.[521]

According to Kant, one should respect the intrinsic value of all human beings and thereby seek as much as possible to further their ends by not using a human being simply as a means to an end. It is this entitlement not to be treated as a means to an end that is the basis of privacy interests. For example, Stanley Benn argues that the 'general principle of privacy' is grounded upon a more general 'principle … of respect for persons'.[522] Privacy invasions may represent lack of respect for a person's dignity in the sense that the incursions show no respect for the person's rights, neither does the injurer care about the effect that such incursions may have on the individual.

Bloustein defends the view that each of these privacy rights is important because it protects against intrusions demeaning to personality and against affronts to human dignity. His argument is that respect for values such as dignity, personal autonomy and integrity, grounds and unifies, but leaves as separate concepts, our conception of

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[518] *Campbell v. MGN* [2004] UKHL 22 at para 51

[519] *Douglas v. Hello! Ltd [2001] Q.B.961 at 1001*.

[520] *Mosley v. News Group Newspapers Ltd* [2008] EWHC 1777 at para7 .

[521] Kant, I., & Ellington, J. W. (1994). *Ethical philosophy: the complete texts of Grounding for the metaphysics of morals, and Metaphysical principles of virtue, part II*. Hackett Publishing. 35

[522] Benn, S. I. (1988). *A theory of freedom*. Cambridge University Press. Cited in N. Moreham (2008) *Why is Privacy Important? Privacy, Dignity and Development of the New Zealand Breach of Privacy tort*. Available at *www.victoria.ac.nz/law/pdf/nm-law-liberty-legislation.pdf*

privacy. The idea of dignity referred to in the foregoing works describes an inherent value worthy of protection in people which is contained in the Universal Declaration of Human Rights Preamble as follows:[523]

> 'Whereas recognition of the inherent dignity and of the equal and inalienable rights of all members of the human family is the foundation of freedom, justice and peace in the world'.

The idea that the respect for dignity demands a protection of privacy can be reflected in the context of biobank research. Failure to maintain the privacy of the tissue source may affect the feeling of self-worth of the individual which may prevent others from enrolling in research. For example the case of the Havasupai tribe where bio samples collected for diabetes study were used in further unspecified studies which included studies on schizophrenia affected the members of the tribe. The ability to control who knows what about us leads us to alter our behaviour with different people. Losing this control can erode personal autonomy and the dignity and worth of individuals.[524] Biobanking research deals with mainly human tissue, human genetic material and bio information. A tissue source may consider their genes to be an extremely intimate and integral part of their identity and dignity and so would like to know the types of research his samples and data are used for in the future. For example, one may hold a religious belief that all human beings have dignity because they are created in the image of God and that, therefore, genes – as containing that image – are sacred and should not be tampered with. This of course is not the only position that a belief in divine creation necessarily supports. For such people, genetic research in general will always be an offence to dignity.

Given that the focus in the preceding sections is on how the law establishes expectations, and entitlements to privacy of the tissue source, and the background right to informational privacy continues to be articulated through a human rights framework, the following section will examine privacy and more particularly in the articulation of

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[523] Assembly, U. N. (1948). Universal declaration of human rights. *Resolution adopted by the General Assembly*, 10(12).

[524] Kirchhoffer, D. G., & Dierickx, K. (2012). Human dignity and consent in research biobanking. *South African Journal of Bioethics and Law*, 5(2), 74-77.

the protection of informational privacy through a number of important legal instruments.

3.5 Privacy as a fundamental human right

'Human rights are norms that help to protect all people everywhere from severe political, legal, and social abuses'.[525] Examples of human rights are the right to freedom of religion, the right to a fair trial when charged with a crime, the right not to be tortured, the right to privacy and the right to engage in political activity. These rights exist in morality and in law at the national and international level. Historical sources for bills of rights include the Magna Carta (1215), the English Bill of Rights (1689), the French Declaration of the Rights of Man and the Citizen (1789), and the Bill of Rights in the United States Constitution (1791). Early philosophical sources of the idea of human rights include Francisco Suarez (1548–1617), Hugo Grotius (1583–1645), John Locke (1632–1704), and Immanuel Kant (1724–1804). In the UK, the Human Rights Act 1998 came into force in the United Kingdom in October 2000. It is composed of a series of sections that aim to give further effect to the protections in the European Convention on Human Rights within UK law. The Act makes available in the UK courts a remedy for breach of a Convention right, without the need to go to the European Court of Human Rights in Strasbourg.[526] Art. 8 of the European Convention on Human Rights protects everyone's right to respect for his private and family life. In Nigeria, s. 37 of the Nigerian Constitution protects the right to privacy and states: 'The privacy of citizens, their homes, correspondence, telephone conversations and telegraphic communications is hereby guaranteed and protected'.[527]

Asserted as a fundamental right, privacy provides an enclave within which individuals and groups are entitled to be free from the unauthorised scrutiny of others.[528] The right to privacy has also found expression in the Universal Declaration of Human Rights

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[525] Nickel, J., 'Human Rights', *The Stanford Encyclopaedia of Philosophy* (Spring 2014 Edition), Edward N. Zalta (ed.), http://plato.stanford.edu/archives/spr2014/entries/rights-human/.

[526] Arnheim, M. T. (2004). *The handbook of human rights law: an accessible approach to the issues and principles.* Kogan Page Publishers.

[527] Laws of the Federation 2002

[528] *National Statement on Ethical Conduct in Human research* accessed on 8/10/2013 from www.nhmrc.gov.au/_files_nhmrc/publications/attachments/e35.pdf 52, Anderson, W. (2011), 2007 National Statement on Ethical Conduct in Human Research. Internal Medicine Journal, 41: 581–582. doi: 10.1111/j.1445-5994.2011.02528.x

(UDHR) as well as the European Convention for the protection of Human Rights and Fundamental Freedoms (ECHR).[529] The UDHR, represented a land mark in the international recognition of the right of an individual to enjoy privacy without unjustified interference. The UDHR however does not explain the term privacy or its relationship to family, correspondence or health and health research. The UDHR also fails to show how an interference with privacy was to be evaluated. Art. 12 states in no uncertain terms that:

> 'No one shall be subjected to arbitrary interference with his privacy, family, home or correspondence, nor to attacks upon his honour and reputation. Everyone has the right to the protection of the law against such interference or attacks'.

It however fails to explain what privacy is, nor does it explain how privacy relates to family, home and correspondence, neither does it indicate how any interference was to be judged. However, Art. 29(2),[530] explains what may constitute a justifiable interference with a protected right such as privacy. The provision does not state in clear terms when precisely it would be permissible by law to allow for privacy interferences for the purposes of 'just requirements of morality, public order and the general welfare in a democratic society'. It does not state precisely when it would be permissible for the law to allow interference for the purposes of securing the rights and freedom of others and general welfare in a democratic society. If these just requirements are to be entirely determined by the state using the instrumentality of the legislature, then the right to privacy would be seriously compromised. There should be other parameters outside of statute that should influence curtailing the right to privacy. Even though the UDHR does not answer questions relating to specificity of the interests of privacy, it has gone a long way in recognising that privacy must be accounted for by a regulatory system, and that there must be justification for any interference with a privacy right.[531] In Europe, for instance the requirements of the UDHR have been re-enacted albeit in a filtered form

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[529] Council of Europe, *European Convention for the Protection of Human Rights and Fundamental Freedoms, as amended by Protocols Nos.* 11 *and* 14, 4 November 1950, ETS 5, available at: http://www.refworld.org/docid/3ae6b3b04.html [accessed 8 October 2013]

[530] Art 29(2) In the exercise of his rights and freedoms, everyone shall be subject only to such limitations as are determined by law solely for the purpose of securing due recognition and respect for the rights and freedoms of others and of meeting the just requirements of morality, public order and the general welfare in a democratic society.

[531] Taylor, M. (2012). Genetic data and the law: a critical perspective on privacy protection (Vol. 16). Cambridge University Press.

within a regional commitment of some considerable significance, namely the European Convention for the Protection of Human Rights and Fundamental Freedoms (ECHR). The ECHR, although cast like the UDHR, provides clearer insights into how the rights and freedoms identified by the UDHR can be better understood.

In 1950, members of the Council of Europe (CoE) resolved in their preamble to take steps for the collective enforcement of certain rights stated in the UDHR. It was agreed that the obligation to secure these rights will be defined within the ECHR. The European Convention for the protection of Human Rights and Fundamental Freedoms, (ECHR) based on Art. 12 of the Universal Declaration of Human Rights,[532] states, that

> 'No one shall be subjected to arbitrary interference with his privacy, family, home or correspondence, nor to attacks upon his honour and reputation. Everyone has the right to the protection of the law against such interference or attacks'.

Art. 8 of the ECHR states:

> 1. Everyone has the right to respect for his private and family life, his home and his correspondence.
>
> 2. There shall be no interference by a public authority with the exercise of this right except such as is in accordance with the law and is necessary in a democratic society in the interests of national security, public safety or the economic well-being of the country, for the prevention of disorder or crime, for the protection of health or morals, or for the protection of the rights and freedoms of others.

In comparison to Art 12 of the UDHR on the same matter, Art 8 appears to be more limited in scope. Art. 8 refers to a right to private life and family life, while Art. 12 refers to privacy; also Art 8 does not explicitly include within its scope attacks upon honour or reputation. However the qualification on the right established in Art. 8(1), found in Art. 8(2), can be seen as an improvement on the more general qualification found in Art. 29(2) of the UDHR. For instance, the courts have interpreted the terms private and family life in a very broad fashion. Indeed the Court in *Niemietz's*[533] case

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[532] No one shall be subjected to arbitrary interference with his privacy, family, home or correspondence, nor to attacks upon his honour and reputation. Everyone has the right to the protection of the law against such interference or attacks. www.un.org/en/documents/udhr/

[533] *Niemietz v Germany* (1992) 16 EHRR 97.

suggested that there should be no exhaustive definition of the notion of private life and would not limit the scope of what might potentially be privacy infringing.[534]

From the point of view of protection of the tissue source in future unspecified research, the inclusive approach to determining the scope of relevant issues that are covered by Art. 8 gives reason to suppose that access to genetic data do fall within the scope of Art, 8 of ECHR[535] and presumably Art, 12 of the UDHR. In *M.S. v. Sweden,*[536] although the court noted that the confidentiality of health data is a vital principle in the legal systems of all contracting parties to the convention. it remains unclear how Art. 8 will engage the privacy of the tissue source in future unspecified research.

In spite of this uncertainty, there are a number of relatively specific circumstances that the court would find Art. 8 engaged in relation to data. In *S. and Marper v The United Kingdom*[537] the Court found that the retention of both biological materials and DNA profiles might infringe an individual's right to private life. The retention of biological materials was considered significant in part because of the potential future uses of that material. Similarly *in Z v Finland,*[538] it was the interpretative potential of DNA profiles and its capacity to provide a means of identifying genetic relationships between individuals and the possibility of allowing inferences to be drawn on ethnic origins that was considered significant. Although the courts have shown an appreciation of the sensitivity of genetic data for individuals, presumably including tissue sources, what remains unclear is the reasoning behind how the acquisition and retention of data or in the case of biobank research secondary use of data and samples might engage Art. 8(1). In *S and Marper,*[539] the Court agreed that the retention of DNA samples constituted an interference with the individual right to private life because of the interpretative potential of DNA and therefore would engage Art. 8 (1).[540] It would appear that the interpretative potential of the material was key to engaging Art. 8. Familial interests

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[534] Ibid.

[535] The list of things recognised by Art 8 as engaging private life are described in the briefing note issued by the Council of Europe. They include the physical and psychological integrity of a person.

[536] *MS v. Sweden*, 28 EHRR 313 (1999).

[537] *S and Marper v. United Kingdom* [2009] 48 EHRR 50, 2008 ECHR 1581.

[538] *Z v Finland* 25 EHRR 371 (1998) 69-71.

[539] *S and Marper v. United Kingdom* [2008] 48 EHRR 50; [2009] ECHR 1581 at 3223-3224.

[540] Ibid at 71-72.

were also identified as an interest that could be affected by interpretative potential of DNA in the case. In relation to biobank research, using the interpretative potential of genetic information as a basis, the right of a tissue source to private life may be infringed by future use of their data or sample in unspecified research because the data has the potential to give information that the source may not be willing to share, and that information may be interpreted in a way that it could infringe the right to private life of the tissue source's family.

On the other hand, while there appears not to be an instance yet where the court has ruled that an interference with the private life of the tissue source can be defended on grounds of research access to genetic data, being a necessary and proportionate interference with the private life of the tissue source, one can imagine that an argument may be made that biobank research being a legitimate aim to be pursued in a democratic society for the protection of health under Art8 Based on the argument, that biobank research is crucial to the advancement of cures of diseases and formulation of more effective drugs. it is submitted that inspite of such arguments interference of privacy of information through non-consensual secondary use of data in biobank research should be rejected. Even though there is a dearth of case law on the precise formula for deciding when an interference with the right to private life of the tissue source would be justified by access to data/sample for future unspecified research, it can be surmised that a blanket policy permitting the use of samples/data without consent for future use would be in violation of a right to private life. This Convention has been ratified by all the members of the Council of Europe. In UK, s.1 of the Human Rights Act[541] states that courts should consider decisions, judgements, declarations or advisory opinions relating to Art. 8 when determining a question which has arisen in connection with a Convention right.

3.5.1 Limitations of privacy protection

The protection of privacy is enshrined in various legal instruments[542] but in spite of these, privacy is not an absolute right. Interference must however be justified in the

[541] http://www.legislation.gov.uk/ukpga/1998/42/schedule/1.

[542] European Union, *Charter of Fundamental Rights of the European Union*, 7 December 2000, Official Journal of the European Communities, 18 December 2000 (364/01), at:http://www.refworld.org/docid/3ae6b3b70.html

public interest and by law. There are certain circumstances where an individual's right to privacy may be overridden and confidential information be legitimately disclosed. Where a person gives consent to disclosure of otherwise private information such consent will operate to absolve the defendant of any liability. An individual's right to privacy may also be infringed by operation of law, for instance, where the law requires disclosure of information or situations in which it is in the public interest for confidential information to be disclosed. Art. 8 of the ECHR para 2 limits the right to respect to private and family life by operation of law, and where it is necessary in the interest of public health, public safety, public moral or protection of public order.

In *Silver v UK*,[543] the applicants, who were prisoners, complained of the interception of their mail by the prison authorities. These prisoners had written various letters to broadcasting associations, newspapers, journalists, solicitors and relatives complaining, amongst other things, about maltreatment in prison. A number of their letters had been intercepted by prison authorities either because the prisoners had not first raised their complaints with the proper authorities, or because the letters contained improper language, discussed criminal offences, were not addressed to an approved relative or friend, or because they contained statements that were prejudicial to prison security. It was held that the interception of mail constituted an interference with the applicants' right to respect for private life as well as their right to freedom of expression. At issue was whether the interference was 'prescribed by law' and 'necessary in a democratic society'. In this case, the prisoners' rights to respect to private and family was deemed to have been infringed although the court acknowledged that the prison authorities could limit the right to private life in accordance with the law. It follows that the Court may in specific cases find that the right to respect for private life has been infringed, but the general rule that the right to private life will be limited in accordance with para 2 of Art. 8 of the ECHR holds true.

[accessed 8 October 2013]. Art 12 of the Universal Declaration of Human Rights asserts that 'no one shall be subjected to arbitrary interference with his privacy, family, home or correspondence, nor to attacks on his honour and reputation'. Art. 8 of the European Convention on Human Rights provides a right to respect for one's 'private and family life, his home and his correspondence', subject to certain restrictions that are 'in accordance with law' and 'necessary in a democratic society'.

[543] *Silver v. United Kingdom* [1983] 5 EHRR 347.

The right to respect for private and family life, home and correspondence may be restricted as contained in para 2 of Art 8 of the ECHR for the protection of health and morals.[544] Public health laws of various jurisdictions require that statistics on the incidence of infectious diseases are recorded and reported and that information on births and deaths are recorded.[545] It is possible for a great deal of anonymous data to be gathered from these applications and this information, although anonymous on the face of it, may contain pointers that can make the individuals traceable thereby raising confidentiality and privacy questions. The main focus of the Art. 8 obligations is to assess whether any interference by a public authority is lawful by reference to the tests posited by Art. 8(2).The decisions in relation to health do not explicitly give guidance on the role of public authorities in relation, for instance, to tissue in national biobanks. Courts have mainly upheld the obligation of soldiers to have their hair cut,[546] participation by prisoners in having their prison cells cleaned out,[547] and the criminalisation of consensual adult sado-masochistic homosexual practices where the harm inflicted was deemed severe.[548] In *S. and Marper v. the United Kingdom*[549] the failure to remove the profiles of individuals who were arrested but later acquitted or not charged from the National DNA database was challenged on the grounds that it constituted an invasion of privacy. Even though the Court of Appeal had previously held that the indefinite retention of such profiles was lawful because it was easy to distinguish between those who were innocent and those who were guilty; the European Court unanimously ruled that Art. 8 had been breached, as the policy was disproportionate and unnecessary. In considering the possible grounds for limiting privacy protection of the tissue source within the context of biobank research, the question of determining whether an interference with the right to private life is defensible on grounds that it was necessary and proportionate for the sake of research is yet to be answered by the courts. It is my suggestion that in the event of dispute on this, the court should rule on the merits of each case based on the fact that not all research is

[544] *X v. United Kingdom* [1981] 4 EHRR 188.
[545] Births and Deaths Registration Act 1953
[546] *Peter Stutter v. Switzerland*, DR 16 (1979) 166 Appl. No
[547] *X v. United Kingdom* [1981] 4 EHRR 188.
[548] *Laskey, Jaggard and Brown v. United Kingdom* [1997] 24 EHRR 39.
[549] *S and Marper v. United Kingdom* [208] 48 EHRR 50.

equally valuable, and that some research methods such as biobank research will necessarily use data more than others. Also the question of whether the reasons given for intruding on the privacy of the tissue source is relevant, sufficient and proportionate to the proposed compromise of privacy should be considered.

The right to know and right to control genetic information brings to the fore the peculiarity of the shared nature of genetic information and its attendant challenges for privacy. The disclosure to the tissue source of results of incidental findings of a genetic predisposition to disease which has implications for the health of a family member may raise questions of whether the other members of the family have a right to be informed of their own genetic status, or at least alerted to the potential risk. This situation places otherwise private information of the second person into the hands of the first and vice versa. This has been said to mirror the conflicts between Arts. 8 and 10 of the ECHR.[550] Art. 10 contains provisions on the right to freedom of expression, whilst Art. 8 protects the right to private and family life.[551] Some people may feel the need to inform the relatives concerned if the disease or condition indicated is severe.[552] Some others would share with blood relatives as a matter of course the results of genetic tests. This is neither here nor there. A more definitive structure should be put in place for the governance of this part of the law which would determine whether or not researchers should be permitted to breach their duty of confidentiality and the right to respect to private life in order to warn third parties of genetic risks only as a last resort to avert serious harm.

Article 7 of the Charter of Fundamental Rights of the European Union[553] largely repeats the provisions of Art. 8 of the ECHR which establishes a right to private and family life, and also seems to be limited only to private life, not to privacy under any other

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[550] Kaye, J., & Stranger, M. (eds)(2009). *Principles and practice in biobank governance*. Ashgate Publishing, Ltd 174.

[551] Under Art 8(1). In *Rotaru v Romania*,(2000) 8 BHRC 43 the Court held that the collection, storage and use by a public authority of personal data interfered with the right to privacy under Art. 8(1). In addition, see *Peck v UK* [2003] 36 EHRR 41.

[552] Morren, M., Rijken, M., Baanders, A. N., & Bensing, J. (2007). Perceived genetic knowledge, attitudes towards genetic testing, and the relationship between these among patients with a chronic disease. *Patient Education and Counselling*, 65(2), 197-204.

[553] European Union, *Charter of Fundamental Rights of the European Union*, 7 December 2000, Official Journal of the European Communities, 18 December 2000 (OJ C 364/01), available at: http://www.refworld.org/docid/3ae6b3b70.html [accessed 8 October 2013]

circumstances and in any place. The Charter makes reference to data protection by specifically stating in its Art. 8 that everyone has a right to the protection of personal data concerning him or her. The provision of Art. 8 on the right to protection of personal data has a stronger meaning and scope, which seems to connote active legal intervention. However, the reference to data in this section is wide as it refers to personal and not private data. Art. 8(2) lays down conditions for processing data which includes fairness and consent of the individual. It would appear that the provision gives a right of access to data collected, by establishing an independent agency to control compliance with the rules protecting personal data. These rights are cast at a level of abstraction and it is within the Data Protection Directive and, in turn, the Data Protection Act that they are more explicitly protected. These protections will be examined via the discussion on confidentiality of data of the tissue source in subsequent sections of the thesis.

One of the challenges in asserting the right to privacy is its controversially broad nature which is evidenced in the difficulty of definition. The very scope and borders of privacy are difficult to define. This difficulty is heightened by the tendency of privacy to merge into the ideas of liberty and autonomy.[554] Commenting on the relationship between privacy and autonomy, Gross noted that an offence is an offence of autonomy, not every curtailment of autonomy is a compromise of privacy.[555] The following section will examine autonomy and its relationship with privacy as a vehicle for justifying the claim of entitlement of the tissue source to having a say on how his data/sample are used in future unspecified research in biobank research.

In *Douglas v Hello!*, Sedley LJ, further identified the relationship between autonomy and privacy when he defined privacy as being 'a legal principle drawn from the fundamental value of personal autonomy'.[556] Lord Nicholls, in *Campbell v MGN* also held that privacy lies at the heart of liberty in a modern state.[557] In *Goodwin v UK*,[558] the

[554] Feldman, D. (1994) Secrecy, Dignity or Autonomy? Views of Privacy as a Civil Liberty'. *Current Legal Problems*, 47, 41 at 49
[555] Gross, H. (1971). Privacy and autonomy. *Nomos XIII: Privacy*, 169, 81.
[556] *Douglas v Hello! No 1* [2001] 2 WLR 992.
[557] *Campbell v. MGN Ltd* [2004] UKHL 22, 2004 A.C.2 457.
[558] *Goodwin v. United Kingdom* [2002] 35 EHRR 18.

European Court of Human Rights held that the notion of personal autonomy is an important one and underlies the interpretation of the Convention, which also confers on individuals the ability to conduct their life as they please. The same position was echoed in *Pretty v DPP* where it was held that the provisions of Art. 8 prohibits interference with the way an individual chooses to lead their life:

> 'There is no question, then, that personal autonomy, at least with respect to the right to make choices concerning one's own body, control over one's physical and psychological integrity, and basic human dignity are encompassed within security of the person, at least to the extent of freedom from criminal prohibitions which interfere with these.'[559]

In the context of biobank research, this section has examined the nature of the consent and how it impinges on the privacy interest of the tissue source. It argued that broad consent to future unspecified research does not represent the autonomous act of an autonomous person. Since the goal of consent is to enable tissue sources to perform autonomous acts, broad consent does not adequately enable the source to make substantially autonomous choices about authorising future research uses of their samples and data.[560]

Autonomy enables the tissue source to protect their privacy at least in the broad sense of self determination and choice. The exercise of autonomy in this regard would be to protect the right to determine who and under what circumstances someone can have access to one's personal affairs. Informed consent has been a vehicle used to enable research participants to exercise their autonomy in medical research, but the policy of open access and wide scale data sharing are challenging the traditional role of enabling the autonomy of the tissue source that informed consent performs as outlined in the Declaration of Helsinki.

3.5.2 Privacy and confidentiality in biobank research

Privacy and confidentiality have been used interchangeably, but this belies the important distinction between the two concepts: that something can be private, known or felt exclusively by an individual or intimate associate(s), but may yet be extended

[559] *Pretty v. United Kingdom*, 35 [2002] EHRR 1 at 175.

[560] Eyal, Nir, 'Informed Consent', *The Stanford Encyclopaedia of Philosophy* (Fall 2012 Edition), Edward N. Zalta (ed.), URL http://plato.stanford.edu/archives/fall2012/entries/informed-consent.

into the realms of confidentiality if revealed with restraints on use and disclosure to third parties. Biggs[561] describes the distinction in terms of the duty of disclosure or non-disclosure. According to her, a piece of information is private as long as it is kept to one's self. Once that information is shared with others who are required or expected to limit its disclosure, then it becomes confidential. For example, as soon as a woman discovers that she is pregnant, that information is private to her as long as it is known just to her and her partner. Once she shares it with her doctor, the information becomes confidential. In this situation the nature of the doctor patient relationship imposes a professional and legal duty of confidentiality wherein personal information can only be disclosed under prescribed circumstances to prescribed people. In England under the NHS, maintaining patient confidentiality is considered vital. According to the Caldicott report,[562] maintaining the confidentiality of patient information is fundamental to the relationship between patients and healthcare professionals. The report stated that confidentiality is an integral part of the ethics of the healthcare professions, and that both common law and statute impose relevant obligations of confidentiality and require the protection of information.

Research in the NHS must comply with basic principles of confidentiality and data protection as contained in several NHS policy documents such as The NHS Confidentiality Code of Practice,[563] and the NHS Protection and use of Patient Information.[564] Both of these documents are based on the principles developed by the Caldicott committee which are designed to ensure that the transfer of identifiable patient information is done for justified purposes only, and that only the minimum necessary information is transferred. The Report also requires that health service providers establish a framework of individual responsibility. National frameworks have been

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[561] Biggs, H. (2009). *Healthcare Research Ethics and Law: Regulation, Review and Responsibility*. Routledge. 99.

[562] The Caldicott report is a review commissioned in 1997 by the Chief Medical Officer of England owing to increasing concern about the ways in which patient information is being used in the NHS in England and Wales and the need to ensure that confidentiality is not undermined. Such concern was largely due to the development of information technology in the service, and its capacity to disseminate information about patients rapidly and extensively.

[563] England, N. H. S. (2014). NHS Code of Practice on Protecting Patient Confidentiality. https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/200146/Confidentiality_-_NHS_Code_of_Practice.pdf last accessed 09/04/2015

[564] Executive, N. H. S. (1996). *The protection and use of patient information*. NHS Executive. http://www.dhsspsni.gov.uk/the_protection_and_use_of_patient_and_client_information_.pdf last accessed 09/04/2015.

developed to facilitate this, and NHS organisations are accountable for the preservation of confidentiality through clinical governance.

The Caldicott principles are theoretically for clinical purposes as opposed to research, but since they 'adhere to fundamental ethical beliefs and standards that are enshrined in the majority of ethical codes, they reflect the stance adopted by IRBs and they are relevant for that reason'.[565] to a discussion on research. Also, the Caldicott principles are generally an invaluable resource of advice for researchers and could therefore serve as a guide in formulating governance principles for maintaining privacy and confidentiality of the tissue source in future unspecified biobank research. In the response of the government to the revised Caldicott principles in 2013, the Health Minister Jeremy Hunt admitted that the principles were applicable to research. In his response to the report on the revised Caldicott principles he said:

> 'Our response sets out how individuals and organisations should improve the way that information is used for research, commissioning and above all good care'.[566]

Confidentiality is the respectful handling of information disclosed within relationships of trust, especially as it relates to further disclosure.[567] Confidentiality can be implied even if the relationship is not a formal relationship of trust:

> 'A confidential relationship arises not out of the legal association between the parties but out of a longstanding personal or social relationship which has resulted in one party placing a high degree of trust, faith, and confidence in the other'.[568]

In the context of biobank research, the obligation of confidentiality is relevant to protecting informational privacy interests. This obligation can be based in contract, tort, or upon equitable principles that may give rise to legally enforceable obligations to maintain confidentiality in all but exceptional circumstances.[569] One established

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[565] Biggs, H. (2009). *Healthcare Research Ethics and Law: Regulation, Review and Responsibility*. Routledge. 104.

[566] Caldicott, F. (2013). *Information: To share or not to share*. Available at https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/251750/9731-2901141-TSO-Caldicott-Government_Response_ACCESSIBLE.PDF last accessed 09/04/2015

[567] Lowrance, W. W. (2012). *Privacy, Confidentiality, and Health Research*. Cambridge University Press. 33.

[568] Melnick, N. (1961) *The Confidential Relationship Theory of Constructive Trusts-An Exception to the Statute of Frauds*, 29 Fordham L. Rev. 561 at 562 Available at: http://ir.lawnet.fordham.edu/flr/vol29/iss3/6

[569] Otlowski, M. (2002). Protecting genetic privacy in the research context: Where to from here. *Macquarie LJ*, 2, 87.

example of a relationship giving rise to obligations of confidentiality is found in health care, where professionals owe a duty of confidentiality to their patients and only in rare circumstances should they disclose information about them. The relationship between the researcher and the tissue source should fall within this category thereby creating a duty of confidentiality on the part of the researcher not to disclose personal information about the source without consent. However, in biobank research, the answer to the question of whether a legal duty of care exists between the biobank or researchers and the tissue source remains unclear. This situation is further complicated by the absence of clarity in the jurisprudence relevant to the issue.[570] There are a number of legal regimes that may govern the relationship between biobanks and the source.[571] The first is the statute or regulation establishing the biobank. The second is a contract between the participants and the biobank. The third is the law of tort under which a duty of care may be owed to research participants and possibly relatives by the biobanks and the researchers who use the samples and data. Finally property law may be relevant in advancing a duty of care to the tissue source.[572]

Some biobanks are governed by statutory provisions that require them to report results of tests for cancer to a cancer council or registry.[573] In *Grimes v Kennedy Krieger Institute*,[574] the majority held that a special relationship of proximity giving rise to a duty of care could be established under U.S. 45 Code of Federal Regulations (CFR) part 46 (2000). However in jurisdictions outside of the United States where this rule does not apply, the court said this duty of care can be implied from the Nuremberg Code and the Declaration of Helsinki which are intended to be applied internationally. This position of the court in *Grimes* strongly acknowledges the existence of special relationship between a researcher and the tissue source which imposes a legal duty of care on the researcher or biobank. The Court also accepted that a duty of care exists between an investigator and the research subjects which imposes a duty of care on the researcher for the benefit of a research subject. The Court went on to establish that the duty of care can

[570] Nwabueze, R. N. (2013). *Legal and Ethical Regulation of Biomedical Research in Developing Countries.* Ashgate. 234.
[571] Kaye, J., & Stranger, M. (eds)(2012). *Principles and Practice in Biobank Governance*. Ashgate Publishing, Ltd.
[572] Wolf, S. M., Paradise, J., & Caga-anan, C. (2008). The law of incidental findings in human subjects research: establishing researchers' duties. *The Journal of Law, Medicine & Ethics*, 36(2), 361-383.
[573] Australian Cancer Act 1958; Cancer Reporting Regulations 2002
[574] *Grimes v. Kennedy Krieger Institute, Inc*., (2001) 782 A.2d 807, 366 Md. 29.

be imposed by contract through the consent form signed by the research subject. The consent form in the opinion of the court constituted a bilateral contract. The legal relationship between a biobank and participants may be contractual, and the terms will generally be implied and evidenced by the consent form. Under this contract, tissue sources will authorise the use of their samples or data for the purpose of the research described in the consent form. In most cases where a broad consent is employed, it would be for a range of research. In spite of the general nature of the authorisation, the arrangement remains an authorisation to use the samples or data for the stated purposes, and this gives the research participant a limited proprietary right in the tissue.

Commentators have argued for and against the recognition of a property right in tissue or an ongoing control in relation to excised tissue,[575] and this yet to be accepted as a general principle of law. In *Yearworth v North Bristol NHS Trust*[576] a limited exception was recognised in which the Court of Appeal held that appellants who deposited their sperm for freezing before undergoing cancer treatment had property rights in the sperm at least for the sake of a claim in negligence.[577] The Court of Appeal also said that the unit in which the sperm was deposited was liable in bailment as a gratuitous bailee[578] and that the circumstances were closely related to contract.

If the relationship between the biobank and the tissue source is contractual, it is conceivable that there would be specific terms relating to privacy of the tissue source and those terms should then be enforceable. Whether the relationship is contractual or not, there are rights and duties that the law of torts may impute into the relationship. These rights may be imputed independently or in addition to contractual obligations of the researcher as contained in the consent form which may also impose a duty of care. For instance, the biobank and possibly third parties who acquire tissue or information for research would seem to be sufficiently proximate to the tissue source[579] to meet Lord Bridge's 3 stage test for ascertaining a duty of care in *Caparo Industries Plc v*

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[575] Gibbons, S., Kaye, J., Smart, A., Heeney, C., & Parker, M. (2007). Governing genetic databases: Challenges facing research regulation and practice. *Journal of Law and Society*, 34(2), 163-189.
[576] *Yearworth v. North Bristol NHS Trust* [2009] E.W.C.A. Civ 37.
[577] Ibid at 45 para f.
[578] Ibid at 51.
[579] Kaye, J., & Stranger, M. (eds)(2012). *Principles and PracticeiIn Biobank Governance*. Ashgate Publishing, Ltd at 167

Dickman[580] so as to give rise to a duty to take reasonable care not to injure the source. In *Greenberg v Miami Children's Hospital*,[581] Moreno J observed that in certain circumstances, a medical researcher has a duty of informed consent. Also in the *Creutzfeldt Jakob Disease Litigation*[582] it was established that researchers owe a duty of care to research participants akin to that of the doctor and patient relationship. Even though the duty of care acknowledged in the *Jakob* case was found in a clinical trial, it does not detract from the fact that the law is beginning to recognise that researchers owe a duty of care to the research participant[583] or tissue source which can imply a duty of confidentiality between the biobank and the source. Much of the information collected in health research is done under the protection of the duty of confidentiality.[584] The duty to protect confidence yields to overriding public interest, such as disclosure in the interest of public health or personal security.[585] The CIOMS[586] guidelines require researchers to tell research subjects the limits of confidentiality that the researcher can offer the research subject.

3.5.3 Confidentiality in the context of Biobank research

At common law, a general duty is imposed on a doctor to respect the confidences of his patient. This duty applies to all confidential information which may not be medical in nature. In the case of *Stephens v Avery*,[587] the Court cited classic examples of the priest and penitent relationship as one of the examples of relationships of confidentiality, and in *AG v Guardian Newspapers Ltd (No. 2)*,[588] the House of Lords affirmed that there is a public interest in the protection of confidences received in a relationship of confidenceor in circumstances where it is reasonable to expect the information to be

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[580] *Caparo Industries Plc v. Dickman*, 1990 A.C.2 605..

[581] Greenberg v. Miami Children's Hospital Res. Inst., Inc., 264 F. Su2d 1064 (S.D. Fla. 2003).

[582] *Creutzfeldt-Jakob Disease Litigation, Claimants v. United Kingdom Medical Research Council* [1996] 54 BMLR 8.

[583] *Halushka v. University of Saskatchewan* [1965] 53 DLR (2d) 436, 52 WWR 608.

[584] Council for International Organisations of Medical Sciences. (2007). *International ethical guidelines for biomedical research involving human subjects*. Geneva: CIOMS, 2002. Guideline 18

[585] *Tarasoff v. Board of Regents of the University of California* [1974] 529 2d 553, 118 Cal. Rptr. 129, 13 Cal. 3d 177.

[586] Council for International Organisations of Medical Sciences. (2007). *International ethical guidelines for biomedical research involving human subjects*. Geneva: CIOMS.

[587] *Stephens v. Avery* [1988] 1988 Ch 449.

[588] *Attorney General v. Guardian Newspapers (No 2)* [1988] 3 WLR 776.

treated as confidential. Following the decision in *Coco v. AN Clark (Engineers) Ltd*,[589] there are four criteria that must be met for a breach of confidence to be established under common law:

- The information must be of a private and personal or intimate nature in order to possess the necessary quality of confidence.
- The Information must have been imparted in circumstances that import an obligation to maintain confidence.
- The alleged improper disclosure must have been made to a person who was not authorised to have access to the information.
- It must be shown that the subject of the information would suffer some harm from the disclosure.

In *Campbell v Mirror Group Newspaper Ltd*[590] it was held that the details of one's medical circumstances were obviously private and deserving of protection by the law. In that case, Naomi Campbell, a celebrated fashion model, was photographed by the *Daily Mirror* coming out of a Narcotics Anonymous (NA) meeting. The *Daily Mirror* published these photographs with the headline: 'Naomi: I'm a drug addict'. The article itself contained in very general terms information relating to Ms. Campbell's treatment for drug addiction, which, included the number of NA meetings she had attended. The claimant admitted that there was a public interest justifying publication of the fact that she was a drug addict and was having therapy, but claimed damages for breach of confidentiality and compensation under s.13 of the Data Protection Act 1998 for the publication of further details. The House of Lords, reversing the Court of Appeal by a 3-2 majority, held that the additional information in the publication was confidential as its publication would have caused substantial offence to a person of ordinary sensibilities in the claimant's position. It was also held that the claimant's Art. 8 rights outweighed the defendant's Art. 10 rights, so publication of the additional information was an infringement of the claimant's Art. 8 rights for which she was entitled to damages. The case appears to have expanded the scope of an obligation of confidence on private information actions to include non-information based intrusions. Lord Hoffman said

[589] Coco v. AN Clark (Engineers) Ltd [1969] RPC 41.
[590] *Campbell v. MGN Ltd* [2004] AC2 457, UKHL 22.

that the abandonment of the of the existence of a confidential relationship requirement and the influence of Art.8 ECHR meant that:

> '…these developments [represented] a shift in the centre of gravity of the action for breach of confidence when it is used as a remedy for the unjustified publication of personal information. It recognises that the incremental changes to which I have referred do not merely extend the duties arising traditionally from a relationship of trust and confidence to a wider range of people'. [591]

As Sedley LJ observed in a perceptive passage in his judgment in *Douglas v Hello Ltd* [592] the new approach takes a different view of the underlying value which the law protects. Instead of the cause of action being based upon the duty of good faith applicable to confidential personal information and trade secrets alike, it focuses upon the protection of human autonomy and dignity – the right to control the dissemination of information about one's private life and the right to the esteem and respect of other people.

In other words, the test of reasonable expectation put forward by Lord Nicholls attests to the change in values to the effect that Arts. 8 and 10 of the ECHR are not limited to actions between the state and the individual, but are applicable to actions between private individuals as well. The crux of the breach lies in the claimant having a reasonable expectation that the information would be kept confidential and the person publishing the information knows or ought to know that there was an expectation of confidentiality concerning the information. This aspect of the test reflects the subjective nature of a privacy interest.[593] For example, it would enable the court to make findings on claims of expectation of privacy of a tissue source who gave samples for a malaria test and possibly malaria research, but discovers that their sample is being use to evaluate the incidence of epilepsy, a highly stigmatising ailment in their community. It should be noted that the test still has an objective test of reasonableness to it. Even though the expectation of the individual is crucial, such an expectation would be put to an objective test of reasonableness. According to Lord Hope,[594] the reasonableness

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[591] *Campbell v. MGN Ltd (No 2)*, 2005 U.K.H.L. 61, At para 51
[592] [2001] QB 967, 1001,
[593] Moreham, N. (2005). Privacy in the Common Law: A Doctrinal and Theoretical Analysis. *LQR*, 121, 628.
[594] *Campbell v. MGN Ltd* [2004] AC2 457, UKHL 2 at 99.

requirement will be assessed from the perspective of the claimant using the test of what is highly offensive to a reasonable man.

In biobank research, the magnitude of harm occasioned by a violation of privacy may depend on the types and clinical relevance of the disclosed data and findings, the likelihood that the individual could be identified from the data, and the additional harm that could occur as a result. Harm in this regard is difficult to define as it is by its nature intangible. Judicial pronouncements have sometimes taken the position that harm may be construed in broad terms. In *Stone v South East Strategic Health Authority,*[595] the possibility of damaging public trust in the sanctity of the doctor-patient relationship through the publication of a report containing the medical records of the defendant was regarded as a public harm. On the other hand, in *R v Department of Health ex parte Source Informatics*[596] it was held that no breach of confidence occurred on the disclosure of anonymous data. Ethics require that the use of identifiable patient information be governed by the overriding principle of respect for autonomy manifested through the process of informed consent. This would seem to imply that no data should be disclosed for research purposes without the explicit consent of the individual concerned. In practice however judicial decisions seem to provide for circumstances whereby public interest has been held to outweigh the right of an individual to confidentiality and non-disclosure of information. In the case of *AG V Guardian Newspapers*[597] Lord Goff explains the limitations to the principle of confidentiality as follows:

> 'The first limiting principle … It is that the principle of confidentiality only applies to information to the extent that it is confidential. In particular, once it has entered what is usually called the public domain … then, as a general rule, the principle of confidentiality can have no application to it. … The second limiting principle is that the duty of confidence applies neither to useless information, nor to trivia. …'The third limiting principle is of far greater importance. It is that, although the basis of the law's protection of confidence is that there is a public interest that confidences should be preserved and protected by the law, nevertheless that public interest may be outweighed by some other countervailing public interest which favours disclosure. This limitation may apply, as the learned judge pointed out, to all types of confidential information.

[595] *Stone v South East Strategic Health Authority* [2006] EWHC 1668 at 44.
[596] *R v. Department of Health, Ex Parte Source Informatics* [1999] All E.R. 185.
[597] *Attorney General v. Guardian Newspapers (No 2)* [*1990*] 1 AC 109 at 282.

> It is this limiting principle which may require a court to carry out a balancing operation, weighing the public interest in maintaining confidence against a countervailing public interest favouring disclosure.'

Whilst there may be an understandable public interest in the disclosure of personal information with regard to epidemics for disease protection, breaches of confidence to facilitate research should not be encouraged. In using biobank samples and data in research relating to HIV/AIDS, especially in Africa where keeping confidential the very fact of participation is important for the protection of the research subject, sharing of data of the tissue source or research subjects should be discouraged. In biobank research the magnitude of harm occasioned by breach of confidentiality may depend on the types of the disclosed data, the likelihood of being identified, and the additional harm of stigma, and the ostracisation that could accrue.[598] Even when an individual cannot be identified, the perception by the individual of loss of control of a part of them or loss of control of what they consider private, such as genetic information, may constitute harm.[599] According to the Campbell test, a piece of information would be recognised as private when the tissue source has a reasonable expectation that it would be treated as confidential and also when its disclosure is highly offensive to a reasonable person of ordinary sensibilities. The social consequences of identification would be highly offensive to anyone in the shoes of the tissue source. Consent processes that are less than specific rob the tissue source of the ability to control who knows what.[600]

Although it is arguable that a researcher can disclose anonymised data of a research subject's participation in research,[601] competing interests of the public and that of individuals whose privacy is invaded should be carefully weighed and an acceptable position reached on whether only anonymised data should be shared except in circumstances where the tissue source specifically consents otherwise. The balance should not be based solely on the subjective view of the aggrieved party. Rather it should be expressed in clear and objective terms. Privacy and confidentiality invasions

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[598] Beskow L.M., Burke W., Merz J.F., Barr A., Terry S., Penchaszadeh V.B., Gostin L.O., Gwinn M., Khoury M.J. (2001) Informed consent for population-based research involving genetics. *JAMA*,18, 2315–2321.

[599] Nass, S.J., Levit, L.A., and Gostin, L.O. (2009). *Beyond the HIPAA privacy rule: enhancing privacy, improving health through research*. Available at http://www.nap.edu/catalog/12458.html

[600] Institute of Medicine. (2009). *Beyond the HIPAA Privacy Rule: Enhancing Privacy, Improving Health Through Research*., 320

[601] *R v. Department of Health, Ex Parte Source Informatics* [1999] All E.R. 185.

breed offence and a lack of trust on the part of research subjects; as such, researchers and research ethics committees should protect the confidentiality and privacy of the tissue source, more overtly.

Regardless of the actual risk or magnitude of additional harms, some people will forgo participating in medical research and avoid seeking medical care and genetic testing in order to prevent unwanted disclosures of their medical and genetic information.[602]

In the context of informational privacy, unwanted access and unauthorised use of information are some of the concerns that secondary use of tissue and data, especially in stored tissue research, raise. The question of unwanted access is subject to a variable number of conditions which may change with the times, information, technology and possibly the environment. Until the courts consider and give a more precise ruling on acquisition of samples and data for biobank research purposes, it may be difficult to precisely draw the line on what constitutes interference of privacy of the tissue source in biobank research. The Data Protection Act 1998[603] defines the law on the processing and protection of the personal data of identifiable people. The Act was introduced to bring UK law in line with the EU Data Protection Directive of 1995 which required Member States to protect people's fundamental rights and freedoms and in particular their right to privacy with respect to the processing of personal data. The purpose of the EU Data Protection Directive (DPC) is to secure respect for the fundamental freedoms of each individual in particular the right to privacy with regard to personal data.[604] The idea of personal data is a key concept emerging as a gateway to the application of the data protection principles. Personal data as a concept articulates more clearly when data will be personal to the individual and therefore capable of engaging the individual's right to privacy as recognised by law. In practice it provides a way for individuals to control information about themselves; it also protects the privacy rights of individuals in respect of their personal data. Personal data is defined as any data that can be used to identify an

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[602] Baruch, S., Kaufman, D., and Hudson, K. (2007). U.S. *public opinion on uses of genetic information and genetic discrimination*. Available at http://www.dnapolicy.org/resources/GINAPublic_Opinion_Genetic_Information_Discrimination.pdf.

[603] http://www.legislation.gov.uk/ukpga/1998/29/contents

[604] Taylor, M. (2012). *Genetic data and the law: a critical perspective on privacy protection* (Vol. 16). Cambridge University Press at 76-77

identifiable living individual.[605] An identifiable living person is one who can be identified directly or indirectly in particular by reference to an identification number or one or more factors specific to his physiological, cultural, economic, mental or social identity.[606]

From the provisions of Art. 2, it can be said with a level of certainty that when genetic data satisfies this definition, it falls within the scope of personal data protected by the directive. Furthermore, before genetic data could be considered to be personal data (from the provisions of Art. 2), it must relate to an identifiable individual. Working Party 29 stated that,[607] information would be considered to relate to an individual in a number of ways. There are situations where the data is clearly about an individual, and this can be context dependent.[608] For instance in biobank research, the same data might provide information that relates to other people such as relations.

The Working Party also identified other ways in which data might relate to a person aside from being obviously about them. They identified that data might relate to an individual if a relevant purpose or result element could be demonstrated.[609] They suggested that the relevant purpose element might be said to exist when the use of data was likely to have a particular impact on the fundamental rights and freedoms of the person. In relation to genetic data and biobank research, this element may create difficulties because it would be difficult to limit scope of personal data in relation to the tissue source. There are a number of circumstances in which genetic data may relate to a person in terms of content purpose or result. If that happens, then any processing of data that satisfies these elements would be subject to the data protection directive according to the concept of personal data of the Working Party. Only when genetic data is considered to relate to an identifiable individual can the protection and principles of data processing be applied to it. Where data cannot be associated with a particular identifiable tissue source, then the implication is that privacy is adequately protected by

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[605] Art 2(a) Data Protection Directive

[606] Data Protection Directive Art. 2

[607] This is an independent European Advisory board on data protection and privacy with tasks as stated in Art 30 of the Directive 95/94/EC

[608] *Niemietz v. Germany* [1992] 16 EHRR 97.

[609] Art 29 Data Working party, Opinion 4/2007 on the concept of personal data 10.

that lack of identifiable association. This position reflects a very limited privacy protection for the tissue source in biobank research. It appears that only individuals are held to have privacy expectations, and that those individuals must relate to the processing of the genetic data in an identifiable way.

3.5.4 Data sharing

One of the characteristics of genomic research is the concept of data sharing through databases to allow secondary use of the data. In spite of the significance of science in health delivery, the importance of protecting privacy in the context of research cannot be overemphasised. Data sharing has been employed in the field of human genomics since the advent of Genome Wide Association Studies (GWAS).[610] This relaxed stance has increased data access and allowed more groups without data generating capacity an opportunity to conduct research on these data. These benefits to public health have led funding agencies to require researchers to deposit genomic data and anonymised information in public databases.[611] This attitude of unrestricted access to data is uncertain in the light of a study carried out by Homer which revealed that it is possible to determine whether a certain individual participated in a study from interpreting genomic information[612] and, although personal identifiers are removed from genomic data, it does not protect the research participant from being identified. The ability to infer the identity of research participants enables them to be linked to other genetic data that might be stigmatising or discriminatory.[613] The standard modes of protection of data such as encryption and anonymisation are not able to protect research participants in the face of new sequencing technology. The traditional mode of privacy protection is not capable of addressing the concerns raised by data sharing and genome sequencing. New technology on sequencing as well as wide scale data sharing is challenging the existing privacy protection available for research participants within the current framework and

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[610] Wright, G. E., Koornhof, G., Adeyemo, A. A., & Tiffin, N. (2013). Ethical and legal implications of whole genome and whole exome sequencing in African populations. *BMC medical ethics*, 14(1), 21.

[611] For example, the federally-funded NIH expects research resources generated by NIH projects to be shared with the scientific community unless there are reasons that justify that exemption (e.g. data sharing not covered in the original consent documents, institutional policies, etc

[612] Heeney, C., Hawkins, N., De Vries, J., Boddington, & Kaye, J. (2010). Assessing the privacy risks of data sharing in geno Data Protection Directive Art 2 (1), 17-25.

[613] Tabor, H. K., Berkman, B. E., Hull, S. C., & Bamshad, M. J. (2011). Genomics really gets personal: how exome and whole genome sequencing challenge the ethical framework of human genetics research. *American Journal of Medical Genetics Part A*, 155(12), 2916-2924.

consent of research participants in biobanking research is not always sought prior to sharing their data. This prevents participants from making a decision on whether or not to assume any privacy risk associated with new research using stored tissue samples or data. When data is made available on the internet, there are no oversight or governance mechanisms in place for secondary research using these data online. As sequencing technology advances and data becomes more widely shared and accessible, it would be desirable for there to be a move to change the current practice of research oversight to one that encourages more research participant participation in decision making. The concerns of privacy incursions should be addressed while at the same time striking a balance with scientific advancement. It is suggested that if data should be shared at all, such plans should be explained to the research participant from the outset and that it should form part of the informed consent process.

3.6 Conclusion

There are various issues in the discussion on protection of the privacy of the tissue source in biobank research that may sometimes conflict, and have raised discussions among writers. The autonomy of the tissue source should be exercised to make autonomous choices on how and when his genetic information or samples should be used. While acknowledging that the claim and right to autonomous choice is not absolute and that it is desirable in the context of biobank research for autonomy to be balanced against the need to conduct research, using information about a person without explicit consent remains a violation of autonomy.[614] The rights of the tissue source may be implicated if biobanks continue to exclude the need for a more specific consent and if they continue to rely on checks and balances such as the technical security of anonymisation[615] and the bureaucratic check of IRB.[616] Arnason criticises this position and argues that technical security cannot and should not replace the need for consent to ensure privacy protection of the tissue source.

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[614] Etzioni, Amitai. (1999) *The Limits of Privacy.* Basic Books, New York.

[615] In the context of the Icelandic database the question of consent was excluded by emphasising coding of the data.

[616] Wright, G. E., Koornhof, G., Adeyemo, A. A., & Tiffin, N. (2013). Ethical and legal implications of whole genome and whole exome sequencing in African populations. *BMC medical ethics*, 14(1), 21.

Since there is no absolute protection of privacy of coded data, the risk of identification is always there and when healthcare data is linked to other types of data and to genetic information, there is a considerable risk that individuals can be identified. The information that biobanks hold is not, on its own, a threat to anyone; however, it is the potential of such information that makes the issue of privacy important. The information may be the kind which holds is of little or no significance in terms of the the donor's privacy; for instance, if genetic information reveals the source's eye colour, most likely that piece of information would not generally be of threat to the right to privacy of the source in normal circumstances, even if it was accessed by an unauthorised agent. Information is not sensitive all the time and everywhere, but there are pieces of information that can cause violations of the donor's privacy if they are misused in some way.

It has been argued that the possible violations to the tissue source in biobank research are minimal. This is because most of the envisaged violations in biobank research are mainly informational, and that the informational risks are taken care of by anonymisation and securing the data. However, the threat to the privacy of the tissue source and the loss of control over personal data cannot be taken care of by IRB oversight, anonymisation, or right to withdrawal.

4. Property Rights Issues in Biobanking Research

4.1 Introduction

The application of property law to subject matter such as excised tissue has been the subject of debate. While some commentators are divided, much of this division is along the lines of those in favour of property rights over and above the narrower scope that in personam rights through the law of torts and contract have to offer and those against property rights because of the harms of commodification or full rights of ownership. This chapter argues for the recognition of property rights over excised tissue, that the recognition of such rights is the more appropriate category for ensuring that rights of control of the tissue source in biobanking research are protected, and that the recognition of property in tissue does not necessarily entail the right to alienate.

Commerce and economic transactions in the area of health in general, and the buying and selling of human biological material in particular, are among the most controversial issues in health policy. Issues regarding commodification and commercialisation of tissues stored in biobanks, and information extracted from sequencing human DNA is part of the ongoing debate.[617] An underlying issue in this is self-ownership and the concept of ownership in tissue and whether its acceptance might open the door for morally objectionable practices such as sale of organs and body parts and even the right to engage in prostitution or self-slavery.[618] Self-ownership it is said could also encourage the idea that we own our bodies, sperm, foetuses and, by extension, our children and hence we can do as we please in relation to them.[619] n the light of this, courts are reluctant to attach proprietary interests to biological materials.[620] This

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[617] Moore v Regents of the University of California Supreme Court of California 51 cal 3d 120, 793 P 2d 479, 271 Cal Rptr 146 (1990), Ashcroft, R. (2000). The ethics of reusing archived tissue for research. *Neuropathology and Applied Neurobiology*, *26*(5), 408-411.

[618] Quigley, M. (2007). Property and the body: Applying Honoré. *Journal of Medical Ethics*, 33(11), 631-634.

[619] Brazier, M. (2003). Organ retention and return: problems of consent. *Journal of Medical Ethics*, 29(1), 30-33.

[620] In *Moore v. Regents of University of California*, 793 P.2d 479, 51 Cal. 3d 120, 271 Cal. Rptr. 146 (1990). the court found that granting ownership rights to tissue source would hinder research but the court had no objection to the researchers obtaining a patent on the tissue samples.

reluctance, has in some cases, been based on a policy of not wanting to hinder the growth of research.[621] It is perhaps because of these reasons that some might want to dismiss the recognition of property in tissue and body parts. Even though the idea of commodifying the human body is repugnant, considering the body within a property framework may be an effective method of dealing with the effects of the changing conceptions of the tissue and its value as a property approach does not necessarily entail buying and selling of body parts. This is because in because recognising property rights in tissue within is not tantamount to embracing a full spectrum of alienable property rights.[622] Indeed a property rights approach to tissue has the advantage of giving tissue source the a continuing control over excised tissue and a possible cause of action in tort. A bundle of rights approach to property makes it possible to exercise this right on body. The inappropriateness of traditional (full) property rights to bodily parts was also emphasised by Honoré, who wrote:

> In other cases again, we speak not of having a thing but a right in or to something. Thus, a person does not either own or have his body or liberty, though perhaps he owns dead parts of his body such as his hair and nails. In general he has, instead, a right to bodily security or liberty, and a right to determine how parts of his body, such as his kidneys, are to be used during his lifetime if he chooses to forego their use or, being dead, no longer has use for them. Here the analogy with the ownership of a thing is tenuous. These rights are either inalienable or can be dealt with only by something in the nature of a gift'.[623]

In other words, it can be argued that recognising property rights in tissue need not encourage commercialisation of the body and its parts as feared in some quarters. Non alienable rights or non-tradable rights if recognised in tissue will enable the tissue source to have a say in future unspecified research, but still not be allowed to sell. From a practical point of view, realising the recognition of property rights in tissue without the baggage of commodifying the human body can be achieved through a charitable trust model.(A proposal that will be discussed in the following chapter.)

As Winickoff and Neuman puts it

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[621] *Washington University v. Catalona*, 400 F.3d 667, 2007 W.L. 1758268 (Court of Appeals 2007) per Limburg J at 1002

[622] Winickoff, D. E., & Neumann, L. B. (2005). Towards a social contract for genomics: property and the public in the'Biotrust'Model. *Life Sciences Society and Policy*, *1*(3), 8.at p.13

[623] Honoré T. Ownership. In: Guest AG, ed. Oxford essays on jurisprudence. Oxford: Oxford University Press, 1961 at p.52

> The creation of a charitable trust would not require a general property right in *the* body, but something much narrower: the recognition that personal rights of control, and use, and access in pieces that can be extracted without harm (indisputably held by the person prior to donation) may form the basis of a legal trust. In fact, the charitable trust is a legal tool for effecting this norm of non-commodification. The structure relies on the recognition of a property-like interest in donated materials only for the narrow purposes of creating an enforceable trust relationship, one that embeds control of tissue in a managed network of noncommodity exchange: samples must be used according to the terms of the trust, and the trustee enforces this use. Furthermore, the donor retains some control over the use of the donation because she can withdraw according to the trust agreement.[624]

The trust model may not grant full ownership rights to the tissue source, but it protects them by recognising them as beneficiaries in the same as beneficiaries of a trust. They also have the added protection under the law that limit what trustees can do with the trust property. This model will limit the rights of the biobank to unmetered quest for profit and possibly relieve the apprehensions of unfettered commercialisation of tissue.

Indeed, property is not the only framework that can be used to explore the rights of the tissue source; other non-proprietary ways include notions of battery, trespass to the person, contract, or even imputing a fiduciary duty.[625] However implicit in some of these approaches is the question of damage. The recognition of the right of the tissue source to determine what future research his sample or data are used for may not always be predicated on damage. The recognition of a proprietary right within the property framework does not require proof of damage, and therefore proves more useful than non-property frameworks.

This chapter examines the concept of property from two perspectives, one being the layman's perspective and the other being the bundle of rights perspective. The chapter will also examine property from the lens of Honoré to determine whether tissue can be the object of a property claim by the tissue source. The chapter also examines the common law rule of no property right in tissue with a view to arguing for a review of the rule and also a streamlining of the work and skill exception to accommodate the claim of the tissue source in biobanking research. The chapter recognises the general

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[624] Winickoff, D. E., & Neumann, L. B. (2005). Towards a social contract for genomics: property and the public in the'Biotrust'Model. *Life Sciences Society and Policy*, *1*(3), 8. At p.14

[625] Quigley, M. (2007). Property and the body: Applying Honoré. *Journal of Medical Ethics*, 33(11), 631-634.

debate about whether the tissue source should be a partaker of the fruits of research but does not enter into it. It seeks to advance a legal basis for an entitlement claim of the tissue source. By analysing and defining the concept of property, the chapter aims to determine whether tissue, as well as the claim of the tissue source, has hallmarks of what the law can protect.

4.1.1 Significance of property rights to the claim of the tissue source in biobanked samples and data

The law on property is a mechanism whereby access to and control of resources are regulated. It is a tool that organises finite resources. The law of property has been used as a system for resolving disputes between parties who have different interests in a thing. Where, for instance, a party wishes to use or possess a thing, property law operates to determine who has a better claim. These rights are protected by rules based on designation of control and the protection of that designation.[626] The ability of a property framework to grant access and control over the thing in question is one of the reasons why the idea of locating the claim of the tissue source within the property framework is being suggested. When relating to a thing, property law may relate to it as the property or more importantly as a system that identifies and recognises which thing can have property rights exercised over it.[627] The ability of property to accommodate the various rights regardless of whether the thing is tangible or not makes it a framework with flexibility that can accommodate excised tissue.[628] According to Gray and Gray[629] the definition of property is constantly on the move. Grubb also believes that the categories of property are never closed or static and that they shift with societal norms.[630]

A legal conception of property as rights gives it flexibility and, in turn, makes it useful in analysing legal issues arising from technological advancement.[631] Flexibility is an

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[626] Goold, I. (2005) Sounds Suspiciously like Property Treatment: Does Human Tissue Fit within the Common Law Concept of Property? *University of Technology Sydney Law Review*, 7, 62.

[627] Munzer, Stephen R. (1990) *A Theory Of Property*. Cambridge University Press.

[628] Ibid at 105.

[629] Gray, K. J., & Gray, S. F. (1987). *Elements of Land Law at p.14*. London: Butterworths.

[630] Grubb, A. (1998). 'I, me, mine': bodies, parts and property. *Medical Law International*, 3(4), 299-317.

[631] Nwabueze, R. N. (2007). Biotechnology and the challenge of property: property rights in dead bodies, body parts, and genetic information. Ashgate Publishing, Ltd, 31-32

important feature of the property concept which makes its framework suitable for analysis of claims such as that of the tissue source to control of excised tissue in biobank research. Is this flexibility achievable only through the property rights approach?

4.1.1.1 Property rights and personal rights

A personal right is a right against another person for the performance of an obligation, i.e.: the other person must either do or refrain from doing something. These rights are usually created by contract. In relation to tissue, there appears to be a preference and a leaning toward personal rights in the form of informed consent. For instance, in Moore's case, it was held that Moore had given proper informed consent for the extraction of further tissue taken from him after the initial splenectomy but his claim to property rights in the same tissue was rejected. A common law preference for recognising personal rights in tissue over and above property rights is also reflected in the emphasis on consent in the UK Human Tissue Act 2004.[632] Also the regulatory framework suggested by the Retained Organs Commission[633] is based on an informed consent model. The report emphasises the personal rights of the donor and their families to give or withhold consent to secondary uses of organs and tissues removed from bodies. This position was reflected in the Human Tissue Act that was passed after this report. The pattern of preferring personal rights over property rights is in spite of new frontiers such as biobanking research that are challenging the sufficiency of consent to protect the rights of tissue sources in secondary uses. Personal rights alone do not possess the flexibility required by tissue sources in terms of being able to have a say in future unspecified research. Since the tissue source in not aware of the future uses of their tissue and data, the broad consent obtained would only amount to giving up further proprietary interest in the tissue. Recognising property in tissue will permit the tissue source to grant permission or withhold consent as the case may be.. One of the issues that the retained organ commission was faced with was the idea of taking organ and

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[632] Human Tissue Act 2004 (Chapter 30). *London, UK: Office of Public Sector Information. URL: http://www. opsi. gov. uk/ACTS/acts2004/ukpga_20040030_en_1 [accessed 21 February 2016]*.

[633] NHS Retained Organs Commission. (2004). *Remembering the Past, Looking to the Future: the Final Report of the Retained Organs Commission Including the Summary Accountability Report for 2003/2004*. Department of Health.para5;8 at p.45

parts without permission, more so when the families identified the tissue, organs and parts as being part of a person and not being mere tissue blocks. The idea of tissue being an object as well as a person presents difficulty in legal terms. The law sees something as being a person or an object, but not both. However, human tissue and genetic material possesses both properties. From the report of the Retained Organs Commission,[634] the families saw tissue as elements of their dead babies whilst the pathologist saw only blocks. In spite of recognising the sentiments and the pain of bereaved parents, the reluctance of the law to treat the human aspect of tissue under property law but rather under personal rights framework is reflected in the legal framework of consent and the subsequent legislation of the Human Tissue Act 2004 that the Commission suggested. In the light of continued renunciation of recognising rights of tissue sources.

4.1.2 What is property?

The term property can be used to describe aspects of the relationship between people and things and also to describe the thing itself. Property can be used to describe the nature of things such as a car. This is the popular sense of the term property, often referred to as the layman's understanding of property. This view of property perceives it as something physical and essentially tangible. However, it can be used to describe the nature of a relationship, such as a bailment. This is the conception of property that lawyers have. In other words, rather than view property as the thing itself, property consists of the legal relations with the thing or bundle of rights exercised with respect to the thing. According to Nwabueze:

> the dephysicalization of property resulting from the perspective of the bundle of rights theory imbues it with some flexibility that is amenable to judicial and analytical creativity, and also creates an opportunity for the propertization of rights and interests on the fringes of property law,s uch as dead bodies and body parts'.[635]

[634] NHS Retained Organs Commission. (2004). *Remembering the Past, Looking to the Future: the Final Report of the Retained Organs Commission Including the Summary Accountability Report for 2003/2004*. Department of Health.para5;28-5.29 at p.53

[635] Ibid at 8.

In *Yanner v Eaton*, [636] the Australian court observed that property does not refer to a thing, but that it is a description of the legal relationship with a thing. This relationship can exist between a person and a thing, between persons with respect to things, and between persons without reference to things. The implication of these different forms of property relationship is that they refer more to rights than to things. The abstraction of property as rights bodes well for legal analysis since it gives more freedom to characterise new things as property, or to accord property protection in new situations as necessitated by circumstances.[637] The flexibility and malleability of property makes it a useful tool of analysis for the right of the tissue source to control the use of samples or data in future research. Property has been described as being a dynamic concept which implies that it is not static but rather it is a constantly evolving.[638]

The meaning of property is not, according to Macpherson,[639] the actual institution of property; he observed that property was perceived by people to consist of rights over things up until the seventeenth century when the conception of property as material objects emerged. This change in the meaning of property was due to the spread of capitalism, and the dependence on land as a source of capital changed. Mathews states that:

> **...**the ambit of 'property' had broken its bounds, and there was no stopping it. Debts… became 'property', governed by the same principles. So did rights of action. Intellectual property was invented, and subsumed into the property framework. Shares in companies, confidential information and goodwill, all were taken under the property wing. In the twentieth century we see energy as property, and other forms of information, and maybe personality and image as well'.[640]

The changes in the meaning of property are therefore related to purposes which society wants the concept to serve. This flexible feature of the concept of property right makes it generally applicable to situations of new forms of wealth.[641] Technological and social

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[636] *Yanner v. Eaton* [1999] CLR 201, 351.

[637] Nwabueze, R. N. (2007). Biotechnology and the challenge of property: property rights in dead bodies, body parts, and genetic information. Ashgate Publishing, Ltd 12- 13

[638] Ibid.

[639] Macpherson, C. B. (1978). The meaning of property. *Property: Mainstream and critical positions*, 1(2).

[640] Matthews, (1983). Whose body? People as property. *Current legal problems*, 36, 193.

[641]Nwabueze, R. N. (2007). Biotechnology and the challenge of property: property rights in dead bodies, body parts, and genetic information. Ashgate Publishing, Ltd at 67-70

changes can bring changes to forms of wealth and the perception of property. Developments in science and medicine have also impacted on the use of the concept of property in the context of the human body. For instance, biological samples can contain genetic information relating to a particular individual and their relations, and this information could be used in a wide variety of research. These samples and data are held in biobanks which hold prospects for profit in some cases where they are commercial.[642] This has generated a debate on the justification of taking tissue samples from tissue sources without compensation and also using and sharing samples and data in secondary studies without reference to the tissue source.[643] However, the legal basis for claiming remuneration or control over excised tissue is unclear.

4.2 The reified perspective

The reified theory of property conceptualises it as things or physical entities. In other words it objectifies property. This perception of property dates back to the nineteenth century, when William Blackstone described property rights as comprising:

> 'that sole or despotic dominion which one man claims and exercises over the external things of the world, in total exclusion of the right of any other individual in the universe'.[644]

This view has changed and few, if any, would argue that property confers absolute despotic dominion. Property rights are not absolute; the law through statute does place limitations on the exercise of property rights by property owners.[645] Blackstone's reference to 'despotic dominion' can thus be interpreted to mean the right of the property owner to exclude others from using his property. Strahan,[646] a century later, also affirmed that property must be a physical object and further stated that debts and copyright were not property. This position echoes the concerns that property rights objectify the human body. In spite of this, reified theory of property does have the advantage of simplicity and certainty, even though it does not cater for the intangible

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[642] Hoeyer, K. (2005). The role of ethics in commercial genetic research: notes on the notion of commodification. *Medical Anthropology*, 24(1), 45-70.
[643] Bear, J. C. (2004). ' What's my DNA worth, anyway?' A response to the commercialization of individuals' DNA information. *Perspectives in biology and medicine*, 47(2), 273-289.
[644]Blackstone, W. (1879). *Commentaries on the laws of England: In four books* (Vol. 2). Callaghan.
[645] Rose, C. M. (1998). Canons of Property Talk, or, Blackstone's Anxiety. *Yale Law Journal*, 601-632.
[646] Strahan, J.A., and Baxter. J.S., (1908) *A General View of the Law of Property*. Stevens.

property rights such as intellectual property rights. In the context of biobank research, using the reified perspective, tissue samples may be recognised as property because of their physical nature. However, it may not recognise information as property nor the right of the tissue source to control of the data. This limitation of the reified theory appears to be out of touch with the times. The growth of information technology has endowed certain pieces of information and data with greater value than was previously attributed to them; as a result some classes of information have attained the status of property.[647] The increased significance of information and its effect on the concept of property plays out in the field of biobank research.[648] A gene contains genetic information about the tissue source and this could be shared and used in a number of ways, including future unspecified research, which are totally different from the one the tissue source enrolled for. This has generated a debate on the legal status of human genetic information and whether genetic information can be owned.[649]

Writers have argued for the ownership of information, and have also warned that failure to recognise information as capable of being stolen and therefore property is unrealistic.[650] In the context of biobank research, the emergence of population biobanks has heightened the debate on the legal status of samples and data. The advancement in technology has dictated a change in property and its forms. These new forms of property that have emerged in the wake of biotechnology and biobank research, challenge traditional forms of property law regimes, although the issue of whether a tissue sample is recognised as property remains a question to be clearly answered even though the reified perspective of property appears to suggest that it is.

In *Roche v Douglas,*[651] the claimant applied for a DNA analysis of the deceased's tissue sample. For the application to succeed, it must be established that the body tissue qualified as property in the eyes of the Court. It was held that, in addition to the

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[647] Weinrib, A. S. (1988). Information and property. *University of Toronto Law Journal*, 117-150.

[648] Human Genetics Commission, & Human Genetics Commission. (2002). Inside information: balancing interests in the use of personal genetic data. *HGC*, 167.

[649] Ontario report genetic testing and gene patenting charting new territory in health care available at http://www.health.gov.on.ca/en/common/ministry/publications/reports/geneticsrep02/report_e.pdf last accessed 6/11/2014

[650] Weinrib, A. S. (1988). Information and property. *University of Toronto Law Journal*, 117-150; Barrad, C. M. V. (1992). Genetic information and property theory. *Nw. UL Rev.*, 87, 1037.

[651] *Roche v. Douglas*, (2000) WASC 146.

procedural benefits of identifying a property right in the deceased's tissue sample, it defies reason not to regard tissue samples as property, and that such samples have real physical existence. The Court in *U.S. v Arora*[652] also found the reified perspective useful. In that case, personal animosity between two scientists employed by the National Institute of Health reached its peak when one of them maliciously destroyed the cultured human cells produced by the other. The United States brought an action in conversion against the offending researcher. The Court, using a pure property analysis, held that the cell, although a product of a living body, was property. In spite of these decisions and other decisions applying the reified perspective to ascertain property in tissue, there is little consensus on the application of the reified perspective to human tissue.[653] There are writers such as Strahan writing in 1895 who argue that only things are capable of ownership; therefore, we cannot in this sense own a debt or any property right in human tissue.[654] However, it is arguable that tissue samples in the context of biobank research can be considered as property under the reified approach.[655]

4.3 Bundle of rights theory of property

Another approach to the theory of property is to consider property as a right over a thing and not the thing itself. These are rights exercisable over the thing which are often intangible and may include intellectual property rights, rights of way, and rights of access. Property in this sense encompasses a great variety of intangible rights, the greatest exercise of which is ownership.[656] These rights are legal in so far as the legal system in which they exist provides rules to safeguard the holder's interest in them from undue interference.[657] Also each of these rights is capable of qualifying as property. It is not necessary for a person to exercise all the rights in the bundle over a thing.

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[652] *U.S. v. Arora*, 860 F. Su1091 (D. Md. 1994).

[653] *Janicki v. Hospital of St. Raphael* [1997] 744 A.2d 963, 46 Conn. Su204 (1999), Cornelio v. Stamford Hospital, 1997 W.L. 430619.

[654] Strahan, J. A. (1901). *Law of Property*. Stevens.

[655] Nwabueze, R. N. (2011). *Legal paradigms of human tissues. Human Tissue Research: A European Perspective on the Ethical and Legal Challenges*, 87.

[656] Nwabueze, R. N. (2013). Body parts in property theory: an integrated framework. *Journal of Medical Ethics*, 2012.

[657] Calabresi, Guido, and A. Douglas Melamed. 'Property rules, liability rules, and inalienability: one view of the cathedral.' *Harvard Law Review* (1972): 1089-1128.

In relation to biobank research, the right of the tissue source to have a say in the use of his sample or data in future unspecified research is arguably one of the rights in the bundle because it supports the claim of the source to have a say in future unspecified use of their data based on a claim of entitlement to privacy as an autonomous person. It also supports claims for the intangible and more importantly for data and sample to be recognised as having the qualities of property. The bundle of rights approach as rights over the tangible has sufficient rights in its bundle to qualify a thing as property. In line with the argument advocated in this discussion for a say in future research, the discussion proceeds in the following section on the basis that property rights are a collection or an accumulation[658] of ownership entitlements and that each individual right in the bundle is capable of qualifying as property. This position played out in *Catalona*[659] where patients sought to assert their right to determine downstream use of their tissue. The case, in the opinion of Dickenson,[660] was framed in terms of the right to possess one of the sticks in the bundle. This shows that one does not need to have all the sticks in the bundle to exercise property right. The bundle of sticks approach also helps to unpack and identify the rights, as the case may be the sticks of the relevant parties. Using *Catalona* as an illustration, the institutional proprietor of the biobank, in this case Washington University, could claim a right of management, a right to possess, and a right to use. While the tissue sources claimed, albeit unsuccessfully, a right of transmissibility and withdrawal. What this suggests is that with a bundle of rights approach to tissue, all stakeholders may have sticks in the bundle, but none has all the sticks to themself. If none of the parties can possess all the sticks in the bundle, the charitable trust model may go some way to providing the mechanism for governing biobank research and ensuring that most if not all the sticks are jointly exercised by all parties. Reiterating Winickoff and Neumann[661] argue that the charitable trust does not require a general property right in the body, but something narrower which they say is the recognition of personal rights of control and use and access to tissue.[662] This

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[658] Nwabueze, R. N. (2013). Body parts in property theory: an integrated framework. *Journal of Medical Ethics*.
[659] *Wash. Univ. v. Catalona*, 128 S. Ct. 1122, 552 U.S. 1166, 169 L. Ed. 2d 949 (Supreme Court 2008).
[660] Dickenson, D. (2007). *Property in the body: Feminist perspectives*. Cambridge University Press.p.136
[661] Winickoff, D. E., & Neumann, L. B. (2005). Towards a social contract for genomics: property and the public in the'Biotrust'Model. *Life Sciences Society and Policy*, *1*(3), 8.at p.14
[662] Winickoff, D. E., & Neumann, L. B. (2005). Towards a social contract for genomics: property and the public in the'Biotrust'Model. *Life Sciences Society and Policy*, *1*(3), 8.at p.14

structure relies on the recognition of property like interest for the purposes of creating an enforceable trust relationship in a manner represented by the notion of property as bundle of sticks . It will be further discussed in Chapter 5

Ownership is often used loosely as being synonymous with property. It can also describe the most extensive interest that an individual can have in a thing within the legal system.[663] Ownership is also used to indicate the content of property rights over the thing. It can be described as a bundle of entitlements that an individual has to a thing.[664] There is a range of different entitlements that a person may have with regard to a resource that others are obligated to respect as ownership.[665] One of the ways to view these various entitlements is to conceive each entitlement as an 'incident of ownership'.[666] In trying to determine what ownership actually is, Honoré, in his seminal essay *Ownership*, identifies eleven 'standard incidents' of 'the liberal concept of full ownership.[667]

These incidents are constitutive of, but not necessary to, the concept of ownership.[668] If, as Honoré contends, having full ownership consists in holding some of the incidents of ownership, then it is possible to argue for property rights in body parts if it can be shown that the body satisfies some of the incidents of ownership as outlined by Honoré in his list of incidents. This list contains the variety of entitlements that the property can be broken into. The incidents of ownership are:

1. The right to possess; to have exclusive physical control over the object;
2. The right to use or to exercise personal use of the object;
3. The right to manage; to determine how and by whom the object is used;

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[663] Goold, I. (2005). Sounds suspiciously like property treatment: Does human tissue fit within the common law concept of property. *UTS L. Rev.*, 7, 62.

[664] Wall, J. (2011). The legal status of body parts: a framework. *Oxford Journal of Legal Studies*, 31(4), 783-804 at 786.

[665] '[P]roperty is not things but rights, rights in or to things' – Macpherson, C.B. (1978) 'The Meaning of Property' in *Property: Mainstream and Critical Positions*, Basil Blackwell, 2.

[666] Honoré A.M. (1961) *Ownership' in Making Law Bind: Essays Legal and Philosophical*, Oxford: Clarendon Press.

[667] Honoré, T. (1987). *Making Law Bind: Essays Legal and Philosophical*. Oxford: Clarendon Press. 161-192. Honoré, A.M. Ownership in Guest A.G.(ed), *Oxford Essays in Jurisprudence* (OUP) 112-128; Honoré A.M., (2006) Property and Ownership; Marginal Comments, in Endicott, T. Getzler J. and Peel E. (eds) *Properties of Law: Essays in honour of Jim Harris* (OUP) 131-135.

[668] Quigley, M. (2007). Property and the body: Applying Honoré. *Journal of Medical Ethics*, 33(11), 631-634.

4. The right to income or to derive a benefit from foregoing personal use of the object;
5. The right to security and insurance that the person will remain owner of the object;
6. The rights of transmissibility – the ability to transfer ownership interests to another;
7. The right to absence of term – the presumption of indeterminate length of ownership;
8. The duty to prevent harm – the inability to use the object in harmful ways;
9. The liability to execution – the liability that the object may be seized in payment of debt; and
10. The incident of residuary – rights may expire or be abandoned so as to vest in someone else.

These incidents of ownership are incidents of legal interest in so far as the legal system backs them up with rules that protect the interest holder from interference from others. The viability of tissue being recognised as property will be examined in relation to biobanking research by evaluating some incidents of ownership. Although Honoré's incidents of ownership have been considered a useful starting point for the consideration of property rights in biological material, as well as a lens through which to view the current position of the law on ownership, in the opinion of Wall, by itself it is an insufficient account of ownership entitlements.[669] This is because ownership is not a unitary concept that is constituted by a sufficient number of incidents being present, but rather is best understood as a collection of smaller ownership bundles within Honoré's bundle of ownership. According to Wall, ownership can therefore be understood as a bundle of entitlements regarding an object that are protected from interference by others. He claims that trespassory rules must be applied to the smaller bundles of rights to determine whether they qualify as property.[670] This position acknowledges Honoré's incidents as a guide, and that ownership is a necessary but not a sufficient condition for there being property. Ownership can best be understood by a sub classification into

[669] Wall, J. (2011). The legal status of body parts: a framework. *Oxford Journal of Legal Studies*, 1-23.
[670] Ibid at 4.

smaller bundles of four rather than eleven. Goold on the other hand is of the view that Honoré's eleven incidents fragment the common law approach to ownership 'wherein a number of individuals may hold certain rights in an object and each will possess a property interest though not full ownership itself'.[671] Quigley[672] describes Honoré's approach as being open and flexible, because while each of the eleven incidents of ownership may not be applicable to things we consider to be property, each item within the group of property shares similarities and relations with other items in the group. She goes on to observe that the openness of the theory is its advantage over other theories of property and ownership, such as those derived from Lockean natural rights theory. Christman argues that since 'different aspects of property rights tend to perform different functions and serve different individual and societal interests',[673] ownership entitlements can be divided into four rights categories: control rights, income rights, derivative rights and structural necessities. Dickenson[674] argues that concerns about the loss or absence of property rights in the human body stem from modern biotechnology's feminisation of property in the body, and advances the concept of property as a bundle of right as one that gives a more nuanced analysis to the issue or tissue as a property. She posits that:

> The notion of property rights as a bundle of relationships – separate 'sticks' in the bundle – helps us to avoid ahistorical forms of essentialism and oversimplification, in analysing the extent to which women and their bodies have been objects or subjects'.

She also argues that that bundle of rights has been put to good practical effect in other contexts than biotechnology: for example, in developing a bundle of 'traditional resource rights' for indigenous communities from those concepts already recognised in international and national law, with the addition of new 'sticks' allowing more effective protections.

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[671] Goold, I. (2005). Sounds suspiciously like property treatment: does human tissue fit within the common law concept of property. *UTS L. Rev.*, 7, 62 at 69.

[672] Quigley, M. (2007). Property and the body: Applying Honoré. *Journal of Medical Ethics*, 33(11), 631.

[673] Chrstman, J. (1994). Distributive justice and the complex structure of ownership. *Philosophy & public affairs*, *23*(3), 225-250.at p.226

[674] Dickenson, D. (2007). *Property in the body: Feminist perspectives* Cambridge University Press.

Honoré's incidents not only give a detailed picture of the kind of rights an individual has in the ownership of a thing, his framework also gives a comprehensive picture of the sticks within the bundle of rights theory.

Having analysed what property is, the following paragraphs will examine whether human tissue can fit into the concept of property under the bundle of rights approach. It will also assess where applicable who can claim these rights.

4.3.1 The right to possess

Honoré's first incident is the right to possess. This right grants exclusive physical right of control over an object. According to Honoré, there are two aspects of this right: the right to be put in exclusive control, and the right to remain in control.[675] Both of these aspects of control within property flow from the right to exclusive possession.[676] Where the object cannot be physically possessed, or where it is intangible or immovable, this right can be exercised to exclude others from using it. It can therefore be used to assign rights of possession over an intangible object. Property systems protect the right to possession to enable the protection of other property rights. For instance, in many cases it would be nearly impossible for a legal system to protect the rights to use and manage if anyone was free to take possession of the objects of those rights.[677] In relation to biobanking, tissue can be possessed by the biobank. Tissue samples are also tangible visible objects, whether liquid or solid, and thus can be possessed or held under the physical control of an individual or organisation. It is also possible to exclude others from them either by placing them in a secure container which is protected from removal. Similarly, researchers can possess tissue samples in research and exercise control over who may have access to them.

According to Goold,[678] tissue is more amenable to being the object of a possessory right than many other objects which one may legally possess. Tissue is a tangible object. It

[675] Quigley, M. (2007). Property and the body: Applying Honoré. *Journal of Medical Ethics*, 33(11), 631-634 at 632.
[676] Penner, J. E. (1995). Bundle of Rights Picture of Property, The. *UCLA L. Rev.*, 43, 711 at 755.
[677] Goold, I. (2005). Sounds suspiciously like property treatment: does human tissue fit within the common law concept of property. *UTS L. Rev.*, 7, 62 at 71.
[678] Ibid 70.

can be held and put in the custody of one to the exclusion of another.[679] In *R v Kelly*[680] the right to possess received judicial recognition when the Court of Appeal created an exception to the no property rule by holding that, where a corpse had undergone a process or application of human skill to preserve it, the corpse or part of it acquired value and became property for the purpose of the Theft Act 1968. As a result of this position, the application of work and skill granted the applier of that work a right to possession.[681] Also in *Rothery*[682] and in *Welsh*[683] the police, having possession of blood and urine samples, were able to defend a right against interference even from the tissue sources. In new-born screening programmes, screening cards are securely stored in hospitals and others are prevented from using them. Therefore, human tissue can be possessed and, in fact, it is possessed both in fact and in law.

According to Penner,[684] in this incident Honoré identifies the central elements of the right to property which are exclusion and control. Control rights according to Wall function to enable the rights holder to be the primary arbitrator over what is to be done with a thing.[685] It also represents a juridical relationship between the rights holder and an open set of persons regarding what the rights holder does with the object. In relation to biobank research and the claim of the tissue source, a control right will give the tissue source control over the sample or data in determining whether to allow them to be used in future research. Control rights give expression to the autonomous choice of the tissue source. According to Radin,[686] in property for personhood theory, an individual needs to exert some control over resources in the external environment. This control consists of property rights which are necessary for personal autonomy and liberty. According to Penner, there should not be too much reliance on the words 'physical thing', since it is

[679] Goold, I. (2005). Sounds suspiciously like property treatment: does human tissue fit within the common law concept of property. *UTS L. Rev.*, 7, 62 at 71.
[680] *R v Kelly* [1998] All E.R.3 741.
[681] Wall, J. (2011). The legal status of body parts: a framework. *Oxford Journal of Legal Studies*, 783-804 at 786.
[682] *R v. Rothery* [1976] R.T.R. 550.
[683] *R v. Welsh* [1974] R.T.R. 478.
[684] Penner, J. E. (1995). Bundle of Rights Picture of Property, The. *UCLA L. Rev.*, 43, 711 at 755.
[685] Wall, J. (2011). The legal status of body parts: a framework. *Oxford Journal of Legal Studies*, at 8.
[686] Radin, M. J. (1982). Property and personhood. *Stanford Law Review*, 957-1015.

clear that a lot of property such as copyright and information are not tangible,[687] and yet they are fully accounted for within the incidents.[688]

4.3.2 The right to use

According to Honoré, the right to use, the right to manage and the right to income overlap, because the latter falls within the definition of use.[689] The right to use does not necessarily include the right to manage and to reap income. It is a claim right to the personal enjoyment of the thing as well as a privilege to use it. There are various uses to which human tissue can be put. It can be used in pathological examinations, treatment, and forensic or biobank research. The many uses to which it can be put lend credence to the suggestion that a right to use can be exercised over tissue samples, some of which have been recognised by the courts and, by implication, the legislature.[690] Jesse Wall argues that the recognition of property entitlement in tissue based on a right to use did not necessarily create referable property rights in tissue. This, according to him, was because in most cases where the courts recognised some ownership entitlement in separated tissue they did it against a backdrop of the no property rule in tissue.[691]

In *Yearworth v North Bristol NHS Trust*[692] six cancer patients acted on the advice of clinicians and produced samples of semen, prior to their chemotherapy treatment, which were frozen and stored for possible future use. Unfortunately, the semen was improperly stored by the hospital and consequently thawed and expired. The six men sought damages for personal injury in negligence and in bailment, and were successful in both actions. More importantly, property rights in the separated biological materials were recognised for the purpose of these two actions because, according to the Court of Appeal, the patients had a right to use the semen since by their bodies they alone

[687] Where the object cannot be physically possessed, for instance where the object is intangible, this may be regarded as a right to exclude others from use or derivable benefits.
[688] Penner, J. E. (1995). Bundle of Rights Picture of Property, The. *UCLA L. Rev.*, 43, 711 at 756.
[689] Honoré, A.M, Ownership' in Guest A.G. (ed), *Oxford Essays in Jurisprudence* (OUP) at 116.
[690] Wall, J. (2011). The legal status of body parts: a framework. *Oxford Journal of Legal Studies*, 783-804 at 786.
[691] Ibid at 786-787.
[692] Yearworth v North Bristol NHS Trust [2009] E.W.C.A. Civ 37.

generated and ejaculated the semen for the sole purpose that it might later be used for their benefit.[693]

In *Moore v. Regents of University of California*,[694] the Court recognised the right of the researcher to use excised tissue in research, but refused to recognise Moore's assertion that he owned the cell. Technological advances in genetics have enabled researchers to manipulate tissue in various ways that were not previously envisaged hence this has widened the scope of uses to which human biobanked tissue can be put. The Human Tissue Act (HTA) 2004 can be said to be a legislative recognition of the right to use excised tissue. The HTA 2004 was passed to update the 1961 Act in the wake of the Alder Hey and Bristol scandals to strengthen the consent requirements for the removal, storage and use of human tissue. The 2004 Act makes provision for the use and storage of tissue by requiring that consent be given.[695] This implies that once consent is given licensed authorities acquire a right to possession through storage and a right to use under the Act.[696]

Today the value and utility of body parts has changed. Tissue can be stored and used over and over again almost for ever. DNA can be extracted from the smallest sample for forensic analysis, and tissue taken for an initial study can be stored and used in several other studies by various other researchers; thus, the progressive breakthroughs in science dictates protection for the tissue source. While others can use the samples of the tissue source for a number of reasons, it should be done with the permission of the tissue source.

4.3.3 The right to manage

The right to manage includes the power to determine who may use the thing and how it may be used, as well as a claim right that the object is dealt with as directed. The right to manage allows a person to enable others to deal with the thing.[697] It includes activities such as lending and contracting out. With regard to tissue samples or data, it is possible

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[693] Ibid at 45f.
[694] *Moore v. Regents of University of California* [1990] 793 2d 479, 51 Cal. 3d 120, 271 Cal. Rptr. 146.
[695] Human Tissue Act 2004 S.1.
[696] Ibid Sch 1.
[697] Honoré, A.M., Ownership' in AG Guest (ed), *Oxford Essays in Jurisprudence*, OUP, at 117.

to exercise a right to manage in the sense that the owner of the body parts who is the holder of the enabling power – i.e. the tissue source – has the power to determine the conditions of use of their tissue as contained in the informed consent form.[698] The tissue source can allow or prohibit the use of his sample or data by others to perform other types of research. In fact, the right to manage works well in the context of tissue banking and secondary research because it allows several people who have an interest in the sample to pursue the interest, while giving overarching control to the person who will be most detrimentally affected if it is dealt with in a way that conflicts with their interest.[699] Where tissue is stored, as in the case of a biobank, the biobank exercises management powers by being the one who may grant access to use of the tissue. This power is subject to the type of the consent upon which the tissue was given to the biobank. According to the HTA, tissue can only be removed from the source after consent has been obtained. S 1 of the Act requires consent for the removal and use of tissue, and by requiring consent before tissue can be used for a particular purpose, it follows that since the tissue source can determine how tissue is to be used under the Act, their right to manage and determine how tissue and data can be used in future unspecified research can also be recognised if biobanks are viewed as managers in the sense of stewardship.

4.3.4 The right to the income

According to Honoré, income in the more ordinary sense includes the fruits, rent, profits and benefit derived from relinquishing personal use of a thing and allowing others to use it for reward.[700] This right overlaps with the right to use in that one can derive income from the use of a property. It allows owners to benefit from the income generated by the object. In the context of biobank research, researchers and biobanks as well as the tissue sources are not precluded from profiting and making income from the developments generated from research especially pharmaceutical companies. Tissue samples can be used to test pharmaceuticals which are sold for profit. In the case of *Moore*, a highly lucrative cell line was developed which is used to generate income.

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[698] Quigley, M. (2007). Property and the body: Applying Honoré. *Journal of Medical Ethics*, 33(11), 631-634 at 632.
[699] Goold, I. (2005). Sounds suspiciously like property treatment: does human tissue fit within the common law concept of property. *UTS L. Rev.*, 7, 62 at 73.
[700] Honoré, A.M., Ownership' in AG Guest (ed), *Oxford Essays in Jurisprudence*, OUP, at 117.

4.3.5 The right to the capital

This is, 'the power to alienate the thing, and the liberty to consume, waste, or destroy the whole or part of it'.[701] It is a right to access the value held in the object itself. This includes the power to transfer the holder's title to the object during his lifetime or after death.[702] This power may be exercised via sale gift or other means. It should be highlighted that the power to alienate under this incident of ownership does not equate to a power to alienate within a market. It can simply mean gifting or transferring by organ donation, blood donation or giving tissue samples for biobank research. This power can be exercised by the tissue source if he voluntarily participates in research by giving tissue to a biobank. Biobanks can in turn exercise this power once the tissue is in their custody and they have control over the tissue samples

4.3.6 The right to security

This right to security is right against unauthorised taking, which gives the assurance that a person 'should be able to look forward to remaining owner indefinitely if he so chooses and if he remains solvent'.[703] This right has been exercised over the body especially in cases of compensation for wrongful death which is seen as compensation to the next of kin.[704]

In the context of biobank research, the right to security can be exercised through the option of withdrawal from biobank research. When a tissue source wishes to withdraw from a study, de-identification of samples and data (making it impossible to link it to specific individuals) has been considered a satisfactory security for the tissue source.[705] According to Dickenson,[706] there are pragmatic advantages in granting this along with

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[701] Björkman, B., & Hansson, S. O. (2006). Bodily rights and property rights. *Journal of Medical Ethics*, 32(4), 209-214.

[702] Goold, I. Sounds Suspiciously like Property Treatment: Does Human Tissue Fit within the Common Law Concept of Property?'(2005). *University of Technology Sydney Law Review*, 7, 62.

[703] Björkman, B., & Hansson, S. O. (2006). Bodily rights and property rights. *Journal of medical ethics*, *32*(4), 209-214.

[704] Quigley, M. (2007). Property and the body: Applying Honoré. *Journal of Medical Ethics*, 33(11), 631-634 at 632.

[705] UNESCO. International declaration on human genetic data. *Eur J Health Law* 2004; 11: 93−107.

[706] Dickenson, D. (2007). *Property in the body: Feminist perspectives* Cambridge University Press.at 130

the right to downstream management of tissue to the tissue source. Recognising this right will protect the tissue source from exploitation.

4.3.7 The right to transmissibility

The right to transmissibility of property gives the owner the power to pass the property or transfer the object to another. The transfer can be on the death of the owner or it could be during his lifetime. Applied to the body, the power to transfer our rights to the body to another can be done by delegating proxies to take certain decisions on our behalf. In relation to stored tissue research the law does not currently allow for bodies or their parts to be transferred by the tissue source.

In *Washington University v Catalona*[707] the parties were in dispute over the ownership of biological materials donated for medical research. Catalona, a respected urologist, was employed by the University, where he was instrumental in establishing a bio repository of biological materials. In 2003 he left the University for North-Western, where he continued his research. Before leaving Washington University, Catalona sought to take along with him the biological samples of some of his research participants. Washington University refused to release the samples and requested a declaratory judgement that they owned them. The University argued that once the tissue source had made a voluntary donation of the sample, the recipient (in this case, the University), became the owner of the biological samples with the right to control their use and storage. The defendant's position was that the University was not the recipient, and that the tissue sources donated the samples with the intent that the materials should stay with him for the purposes of research.

The Court, relying on *Moore* and *Greenberg*, found that donation of the biological samples to the University constituted an *inter vivos* gift. In adopting this approach, the Court seemed to have adopted the position of Moreno J. in *Greenberg* that, although an individual may have property rights in biological materials, those rights evaporate once they are voluntarily given to a third party.[708] This position presupposes that a tissue source has property rights in tissue until such rights are divested by donation or

[707] Washington University v. Catalona, 490 F.3d 667 (8th Cir. 2007).
[708] *Greenberg v. Miami Children's Hospital Res. Inst., Inc*., 264 F. Su2d 1064 (S.D. Fla. 2003) at 1059.

otherwise to a third party. This position appears to rest upon the proposition that property rights were created on severance or excision of the biological materials by way of gift. The case further highlights the importance of express conditions when making a gift and the need for the tissue source to be able to control who has access to the tissue in relation to future research. This inevitably puts an onus on the source to be aware of the limitations they wish to place on the gift. It also raises concerns about the ability of the tissue source to do so. However, it is authority for the proposition that tissue is capable of being transmitted legally and physically, as the Court ruled that both custody and ownership passed from the tissue sources to the University.

4.4 Rationale for property right in tissue and biobanking research

According to Hardcastle,[709] there are two broad interests that the tissue source may have in excised tissue: economic interest in the value that may be derived from excised tissue, and the controlling its use and disposal. The issue of control becomes significant to the tissue source in at least four situations.

First, an individual may wish to determine the forms of research for which his biological materials and data are used. Radin, in asserting that property rights give control to the person, describes property rights for personhood as a relationship that is essential for self-identification. She distinguishes between personal property and fungible property. The former, Radin says, is a category of property necessary for personal autonomy or liberty,[710] whilst the latter is purely instrumental. According to Radin, personal property should have greater legal protection because it is constitutive of the individual's personality. She goes on to argue that interference with the body is interference with personal property.[711]

In the United States, questions of property rights in tissue are at the forefront of discussion. Government agencies in the U.S. have expressed concerns about how laws creating a property right in tissue will affect research. The fear expressed by these agencies was shared by the judges in *Moore*, but the central issue remains one of

[709] Hardcastle, R. J. (2007). *Law and the human body*. Hart. 1.
[710] Radin, M. J. (1982). Property and personhood. *Stanford Law Review*, 957-1015 at 960.
[711] Ibid.

control. Property is a tool which can enable control through the bundle of rights that it confers, even though it also carries with it the baggage of the possibility or potential for commerce:

> 'A proprietary approach confers on the claimant the advantage of continuing control that is tellingly lacking in non-property frameworks underpinned, for instance by consent, negligence, privacy and unjust enrichment rules'.[712]

In spite of this advantage, the position being advocated is not to further the purpose of commercialising or creating a tissue market, but rather to find a legal basis for tissue sources to determine whether they want their biobanked tissue used in future research. The choice of a property framework is adopted based on utility and also because in comparison to non-property frameworks, as Nwabueze[713] observes, it gives the required control to the tissue source. Moreover, most of the non-property frameworks, such as tort remedies, still depend on the proof of a property right.[714] In the same vein, Mason and Laurie[715] suggest that property is a powerful device for the bundle rights it confers, and to recognise a quasi-property claim to material is to support a normatively strong connection to that material as well as establishing a justiciable legal interest in it.

> 'To recognise a 'quasi-property' claim to material is to support a normatively strong connection to that material and, accordingly, to establish strong, justiciable legal interest; by the same token…..'full' property rights will only be recognised where there is little or no prospect of exploitation or other harm, which can include the 'harm' of disrespect for the dignity of the human organism'.[716]

It has been suggested that a modified form of property right – quasi property – be recognised to give limited continuing control over tissue samples to the tissue source.[717] Recognised quasi property rights include the right of the next of kin to possession of the corpse for burial,[718] and the right to donate organs. Limited property rights would help to

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[712] Nwabueze, R. N. (2013). Body parts in property theory: an integrated framework. *Journal of Medical Ethics*.
[713] Ibid.
[714] *Moore v Regents of the Uni of California* [1990] 793 2d 479, 51 Cal. 3d 120, 271 Cal. Rptr. 146.
[715] Mason, K., Laurie, G., & Smith, A. M. (2005). *Mason and McCall Smith's Law and Medical Ethics*. Oxford University Press.
[716] Ibid at 514-515.
[717] Mason, J. K., & Laurie, G. T. (2001). Consent or property? Dealing with the body and its parts in the shadow of Bristol and Alder Hey. *The Modern Law Review*, 64(5), 710-729.
[718] Boulier, W. (1994). Sperm, Spleens, and Other Valuables: The Need to Recognise Property Rights in Human Body Parts. *Hofstra L. Rev.*, 23, 693 at 709.

resolve some of the issues related to possession of excised tissue. In the case of a biobank, for instance, quasi property rights in tissue will make remedies available to a researcher or a biobank in the event that tissue samples are stolen or wilfully destroyed.[719] It would also allow for a legally recognised voice on how tissue samples are used in the future. A limited recognition of property rights in the human body can be developed by drawing analogies from non-proprietary areas of the law that affirm property rights, such as law of torts that protects bodily integrity and the inviolability of the person.

Individuals may not wish separated biological materials to be used in commercial settings.[720] This desire or stance may be dictated by religious, moral or philosophical beliefs against commercial dealings in body parts. The direct involvement of commercial enterprises in the procurement distribution, handling and research on human tissue may be cause for concern.[721] This is because a commercial orientation may sometimes conflict with the values of the custodial nature of biobank research. It may also lead to a lack of public trust on the part of the tissue source in the research enterprise.

In *Moore* where the question of property arose in the context of human tissue used in biotechnological engineering, a U.S. court held that a donor of tissue is not entitled to share in the profits of a commercially successful biotechnological product engineered from the donor's tissue. The rationale was that such material is the subject of gift regardless of what use is subsequently made of it. Moore's reaction shows that a donor may be willing to part with tissue for a number of therapeutic and research purposes, but he may not want to do so where the recipient is to make a significant profit from it.

Property rights may be the legal tool that enables a tissue source to determine how separated biological samples and associated data are used in future unspecified research. Property as rights sees property not as a thing but as rights exercisable against others in or over things and it can be used as a legal tool to define the obligations of persons with

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[719] *U.S. v. Arora*, 860 F. Su1091 (D. Md. 1994).

[720] Green D. et al (2006) Obtaining informed consent for genetic studies: The multi-ethnic study of atherosclerosis *Am. J. Epidemiology* 164 *(*9*)* 845 at 849.

[721] Anderlik, M. R. (2003). Commercial biobanks and genetic research. *American journal of Pharmacogenomics*, 3(3), 203-215.

respect to a tangible or intangible thing. Intangibles to which property rights have been exerted include whiteness,[722] personhood,[723] racial identity,[724] and a university degree.[725] A property interest does not necessarily imply that the holder owns something, but that someone owes him an obligation. Property rights, unlike contractual rights, are enforceable against the whole world as rights *in rem*. In the words of Mathews:

> The common law sees property as essentially negative, the right to exclude others from something, or from some aspect of something. This negative right may be absolute, as for example 'This is my pen'. I can exclude everyone from everything in relation to it. Or it may be limited – even isolated as in for example 'I have a right to light over (your) land'. I can prevent you from building in a certain way on your land. Sometimes the negativity imposes a positive obligation on another person, as in 'You owe me £10…'.[726]

This concept of property as a right can be traced to the work of Hohfeld which was used by Honoré as a basis for his classification of rights as a framework to define property.[727] In the context of biobank research, if property rights are exercisable over tissue and associated data as tangible and intangible objects of property, it will give the tissue source a right to exclude the use of his tissue and data from research that he has not specifically consented to.

For a number of reasons which may include religious and moral, individuals may not want their cells immortalised.[728] Immortalised cells are population cells which would not normally proliferate indefinitely, but due to mutation can keep undergoing division. A HeLa cell is an example of immortalised cells and also an example of why people may not want their cells immortalised. HeLa cells are a cell line derived from Henrietta Lacks, an African American woman who died of cancer and whose had cells taken from her tumour without her consent. The cells have been used in multiple researches since her death without any recognition or compensation to the family. The HeLa genome has laid the foundations for the multi-billion dollar biotech industry, but the Lacks' family

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[722] Harris, C. I. (1993). Whiteness as Property, 106 HARV. *L. rev*, 1707(1782), 10-2307.
[723] Radin, M. J. (1982). Property and personhood. *Stanford Law Review*, 957-1015.
[724] Chen, Jim. 'Embryonic Thoughts on Racial Identity as New Property.' *U. Colo. L. Rev.* 68 (1997): 1123.
[725] *Woodworth v. Woodworth* [1983] 337 N.W.2d 332, 126 Mich. A258, 126 Mich. 258 (Ct. App).
[726] Matthews, (1995). Man of Property, The. *Med. L. Rev.*, 3, 251.
[727] Honoré, A.M. (1961). Ownership. *Oxford essays in jurisprudence*, 107-147.
[728] Skloot, R. (2010). *The Immortal Life of Henrietta Lacks*. Random House Digital, Inc.

have never shared in any income generated by the immortal cell line. It was only in 2013 that the American National Institute of Health conceded to give some control to the family over scientists' access to the cells' DNA code, as well as giving acknowledgement in the resulting studies to the Lacks family.[729] The agreement came about after the relatives raised privacy concerns when German researchers published Lacks's DNA code.

The control of biological materials becomes significant when materials are used to obtain personal genetic information. This is because, privacy and the possibility of invasions of privacy from secondary uses of biological materials is a matter of concern. These are some of the reasons why individuals seek to control the use of biological materials. In the context of genetics, the right to confidentiality of genetic information could form the basis for the protection of a person's privacy as well as a basis to exclude others from using such information without prior consent. Grubb describes three rules that define a proprietary relationship.[730] One is user entitlements that allow a person to exploit or enjoy the thing, the second is exclusionary control that prevents a person from dealing with it, and the third is dispositional liberty that allows them to transfer it as a gift or by sale. A different approach to defining the nature of property or a property is taken by Gray whose main criterion is excludability. According to Gray:

> '…a resource can be propertised only if it is … excludable. [It] is excludable only if it is feasible for a legal person to exercise regulatory control over the access of strangers to the various benefits inherent in the resource. … Property' resides not in consumption of benefits but in control over benefits. 'Property' is not about *enjoyment of access* but about *control over access*. 'Property' is the power-relation constituted by the state's endorsement of private claims to regulate the access of strangers to the benefits of particular resources. If, in respect of a given claimant and a given resource, the exercise of such regulatory control is physically impracticable or legally abortive or morally or socially undesirable, we say that such a claimant can assert no 'property' in that resource and for that matter can lose no 'property' in it either. Herein lies an important key to the 'propertiness' of property.[731]

If property relates to control and access then a property right can be the basis of the entitlement of a tissue source to control or refuse future unspecified research on a

[729] Callaway, E. (2013). Deal done over HeLa cell line. *Nature*, *500*(7461), 132-133.
[730] Grubb, A. (1998). 'I, me, mine': bodies, parts and property. *Medical Law International*, 3(4), 299-317 at 301
[731] Gray, K. (1991). Property in thin air. *The Cambridge Law Journal*, 50(02), 252-307.At 301

sample or data. Based on Gray's analysis, control over access should entail being in a position to give consent on use of sample or data. Gray[732] described property as being not a thing, but rather a power relationship of social and legal legitimacy existing between a person and a valued resource. He described property not only as a relationship but as a tool of control:

> 'Once property is recognised as a relationship of socially approved control, it becomes infinitely more accurate to say that one has property *in* a thing rather than to declare that something is one's *property*. To claim 'property' in a resource is, in effect, to assert a strategically important degree of control over that resource. 'Property' is simply the word used to describe particular concentrations of *power over* things and resources, and every claim of 'property' comprises the assertion of some *quantum* (or amount) of socially permissible power as exercisable in respect of some socially valued resource. The implications of this perspective are significant'.[733]

Whether an individual has an established right to determine what happens to biological materials that were once a part of him remains an unanswered legal question. However the foregoing description by Gray describes the underlying position of this chapter that while property is viewed as a thing it is more helpful in relation to the tissue source that property is seen not only as a right but also as a relationship between persons over a thing in this case sample or data.

In spite of the foregoing arguments justifying excised tissue or data as capable of being property, and that the property rights of the tissue source to his biological materials should be recognised,[734] others contend that the property rights of the tissue source are not justifiable, and that the rights of the recipient should be recognised. The current position of the common law remains one of no property rights in tissue.

4.4.1 No property rule

Human tissue scholarship has been traditionally characterised by the common law position on cadavers as things outside the zone of property protection. The nineteenth century doctrine that a body may not be property would suggest that no property right

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[732] Gray, K, and Gray S.F. (2011), *Land law*. Oxford University Press.

[733] Ibid at 32.

[734] Hammond, C. (2002). Property Rights In Human Corpses and Human Tissue: The Position in Western Australia. *University of Notre Dame Australia Law Review*, 4, 97-113.

vests in the user of a body or, arguably, the parts of a body. Sir Edward Coke's opinions seem to represent one of the earliest recorded considerations of the body in a property context at common law.[735] Blackstone followed the same opinion that 'though the heir has property in the monuments and escutcheons of his ancestors, yet he has none in their bodies or ashes'.[736] Although there are criticisms of these views, the so called no-property rule was established.[737] The *Nuffield Council on Bioethics Report on Ethical and Legal Issues*[738] prompted by the medical and scientific use of tissue, has summarised the exception to the doctrine of no property in a body as follows:

> Despite the no-property rule, the common and civil law still recognised a number of interests that continue to enjoy legal protection today. For example, although the common law did not grant an absolute right to the control of one's body after death through one's will, it and the civil law have long recognised one's right to a decent burial. To effect the deceased's right to a decent burial, the law imposed on the deceased's executor or family a duty of burial and a corresponding right to possession of the decedent's body for burial: In Canada [as in England], this duty of burying a dead body falls upon the executors of the deceased's estate. In the absence of a will naming executors, the right to possession for burial goes to the surviving spouse.. If no spouse survives, the right belongs to the next of kin. Some courts and jurisdictions refer to the right of possession as a 'quasi-property' right. It empowers spouses or the next of kin who are wronged by interference to sue for damages. The essence of such suits is damages for injury to the emotional or mental tranquillity of the next of kin, in the legal form of the wrongful infliction of emotional distress. Thus, instances of interference with the right of possession arise in diverse cases, including the negligent handling or transporting of dead bodies, the withholding of a body for payment of funeral expenses, the unauthorised removal of hair from the deceased by a funeral home, the withholding of a body for an unreasonable length of time to determine organ donor status and the mutilation of the deceased during the course of an unauthorised autopsy'.

Some of the reasons for the rule that a corpse was incapable of being owned were, as implied by Coke and by Blackstone, that the body was the temple of the Holy Ghost and it would be sacrilegious to do other than to bury it and let it remain buried.[739] Secondly,

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[735] Coke wrote '[t]he buriall [sic] of the [c]adaver (that is *caro data vermibus)* is *nullius in bonis,'* and belongs to [e]cclesiastical cognisance. *Hayne's Case,* (1614) 77 Eng. Re1 389 KB.

[736] Blackstone, W. (1879). *Commentaries on the laws of England: In four books* (Vol. 2). Callaghan.

[737] Matthews, (1983). Whose body? People as property. *Current Legal Problems*, 36(1), 193-239.

[738] McLean, S. (1995). Human Tissue: Ethical and Legal Issues -- the Report From the Nuffield Council on Bioethics Provides a Coherent Legal and Ethical Approach . Available at http://nuffieldbioethics.org/wp-content/uploads/2014/07/Human-tissue.pdf last accessed on 3/12/2015

[739] *Re Estate of Johnson* (1938) 7 NYS 2d 81 (Sur. Ct

it was strongly in the interests of public health not to allow people to make cross-claims to the ownership of a corpse.[740] In *Williams v Williams*,[741] a woman who disposed of a friend's body by cremation as requested in his will and private conversations, sued the estate for the expenses. It was stated that '[i]t is quite clearly the law of this country that there can be no property in the dead body of a human being'.[742] In dismissing her suit, the court reasoned that if there was no property in a corpse, then it could not be disposed of by will, and thus she had no claim against the estate for doing what the decedent had no right to legally order.[743] One of the authorities cited by the Court in *Williams* was *R v. Sharpe*[744] where the court stated that 'our law does not recognise the right of any one child to the corpse of its parent as claimed by the defendant. Our law recognises no property in a corpse'. The no property rule has been invoked and used to protect unauthorised dealings with dead bodies over the years.[745]

While the no property rule would appear to have evolved within the context of corpses, it has nevertheless been applied to excised human tissues.[746] This traditional approach to the concept of property in tissue has been the subject of criticisms and objections. This is not unexpected as it was an approach that developed prior to the age of technological advancements and there are now uses for body parts and tissue previously unimagined.[747] The rule has also been criticised as 'not entirely logical' and as inflexible[748] because unless a claim falls within the exceptions, a no property verdict is likely to result.

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[740] *Yearworth and others v North Bristol NHS Trust* [2009] EWCA Civ 37.
[741] *Williams v Williams* (1882) 20 L.R.-Ch. D. 659.
[742] Ibid at 663.
[743] Ibid at 662-663.
[744] *R v. Sharpe* (1857) 169 Eng. Re959 (Crim. App).
[745] *R v. Lynn* [1963] All E.R.3 659.
[746] The observation of Pring in *Doodeward v. Spence, 6 C.L.R. 406 (1908).*: that 'there can be no property in a human body dead or alive. I go further and say that if a limb or any portion of a body is removed that no person has a right of property in that portion of the body so removed'
[747]Nwabueze, R.(2011). Legal paradigms of human tissues. In Lenk, C. (2011). *Human tissue research: a European perspective on the ethical and legal challenges*. Oxford University Press. At 87 at 89
[748] *Jonathan Yearworth and others v North Bristol NHS Trust* [2009] EWCA Civ 37

4.4.2 Exceptions to the no property rule.

There are two exceptions to the no property rule. The first relates to the quasi property rights of personal representatives of the dead and the second is based on the application of work and skill.

4.4.2.1 Personal representatives of the dead

Recognised quasi property rights in the dead include the right of the personal representatives to possess the corpse for burial, an enforceable right to be free from interference with the possession of the corpse. In *Dobson v. North Tyneside Health Authority,*[749] the Court of Appeal, whilst accepting that there was no general right of property in a dead body, concluded that a deceased's personal representatives had a right to the custody and possession of the body until its proper burial; this is an incidence of their legal duty to dispose of it. This exception may extend to other persons charged by law with the duty of interring the body, for example, a parent of an infant child, who dies where the parent has sufficient financial means to bury the child.[750]

4.4.2.2 Application of work and skill

In the early 20th century, another exception to the no property rule was upheld by the Australian High Court in *Doodeward v Spence.* In that case, it was held, *obiter*, that there could be lawful, continuing possession of a corpse and that bodies and parts could become-the subject of property rights:

> 'when a person has by lawful exercise of work or skill so dealt with a human body or part of a human body in his lawful possession that it has acquired some attributes differentiating it from a mere corpse awaiting burial, he acquires a right to retain possession of it, at least against any person not entitled to have it delivered to him for the purpose of burial'. [751]

For the exception to apply, the initial possession of the body or body part must be lawful, there must have been an application of work and skill, and the possession must not conflict with public health requirement under the law.

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[749] *Dobson v. North Tyneside Health Authority* [1996] 4 All E.R. 474, CA; *Williams v. Williams* (1882) 20 Ch. 659.
[750] *Clark v. London General Omnibus Co Ltd* [1906] 2 K.B. 648, at 659, per Lord Alverstone CJ
[751] *Doodeward v Spence* (1908) 6 CLR 406. At 413

In *Dobson* the Court of Appeal held that the deceased's brain could not be said to have undergone a 'process or application of human skill' (despite being fixed in paraffin prior to its eventual disposal) to bring it within the *Doodeward* principle. In *Dobson,*[752] the deceased (a woman aged 22) had collapsed at work and later died from brain tumours at a hospital run by the defendant health authority. During a post-mortem examination, the deceased's brain was removed and preserved in paraffin by the doctor who conducted the autopsy, and later delivered to the hospital for storage. The Court of Appeal concluded that the mere fixing of the deceased's brain in paraffin (for the limited purpose of preserving it until the coroner's determination of the deceased's cause of death) did not transform it into an item of 'property', the right to possession of which belonged to the next of kin. According to Gibson LJ:

> There is nothing in the pleading or evidence before us to suggest that the actual preservation of the brain after the post mortem was on a par with stuffing or embalming a corpse or preserving an anatomical or pathological specimen for a scientific collection or with preserving a human freak as a double-headed foetus that had some value for exhibition purposes.'[753]

In determining work and skill it is not just a matter of what is done to the body or body part, but also the purpose for which the work or skill is carried out:

> 'The suggestion is that the application of skill must convert the corpse (or relevant part) into a new object with a function or use beyond that of a mere body (i.e., as a specimen for medical collection or exhibition)'.[754]

It was the absence of this feature which distinguished the case from *Doodeward*. The case however does not answer the question of what level of work is required to transform biological materials into property. In *Doodeward,* the foetus was preserved in a container, while in *R v Kelly,*[755] the work done was for anatomical dissection of body parts. In *Re Organ Retention Group litigation,*[756] Gage J highlighted the work that went into the preservation of the samples by detailing the three stages of the process used on the samples. According to him:

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[752] *Dobson v. North Tyneside Health Authority* [1996] 4 All E.R. 474, (CA).
[753] *Dobson v. North Tyneside Health Authority* [1996] 4 All E.R. 474, at 478
[754] Pawlowski, M. (2009). Property in body parts and products of the human body. *Liverpool Law Review*, 30(1), 35-55 at 43-44.
[755] *R v Kelly* [1998] 3 All ER 741.
[756] *Re Organ Retention Group litigation* [2005] 2 WLR 358.

> '[t]he evidence in the lead cases show that to dissect and fix an organ from a child's body requires work and a great deal of skill, the more so in the case of a very small baby such as Rosina Harris of the present case. The subsequent production of the blocks and slides is also a skilful operation requiring work and expertise of trained scientists'.[757]

In the context of biobank research, it is not clear how the courts will apply the work or skill exception in in relation to the ownership rights of tissue sources. In *Yearworth v North Bristol NHS Trust*[758] the Court of Appeal held that the work in ensuring that sperm was preserved came within this exception. It is, therefore likely that in the context of biobank research, the work that goes into preparing the tissue samples for preservation and storage should fall into the work or skill exception, making the tissue sample a thing capable of ownership within the exception.

Who then owns the tissue ?

In *R v Kelly,*[759] the defendants had been convicted of the theft of about 35 human specimens (including three human heads, part of a brain, six arms, ten legs or feet, and parts of three human torsos) from the Royal College of Surgeons between 1991 and 1994. The first defendant, an artist, made casts of the various parts, some of which were later exhibited in an art gallery. The second defendant was employed at the College as a junior technician and was asked by the first defendant to remove the various specimens for his artistic work. Neither of the defendants intended to return the specimens, many of which were buried in a field. Part of a leg was found in the first defendant's attic and the remaining parts were found in the basement of a flat belonging to his friends. All the specimens in question had been preserved or fixed by the College staff or other medical agencies. They were all subject to a regular scheme of inspection, preservation and maintenance, and most of them had been the subject of further work by prosection,[760] whereby they had been expertly dissected so as to reveal, in highlighted form, the inner workings of the body. There was evidence that the preparation of the specimens by prosection would have involved many hours, even weeks, of skilled work. The Court of

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[757] Ibid at 148.

[758] *Yearworth v North Bristol NHS Trust* [2010] QB 1.

[759] *R v Kelly* [1998] 3 All ER 741.

[760] A prosection is the dissection of a cadaver (human or animal) or part of a cadaver by an experienced anatomist in order to demonstrate for students' anatomic structure.

Appeal held that the common law rule that there was no property in a corpse was firmly established in English law, but subject to the exception that if a dead body or its parts had undergone a process of skill with the object of preserving it for the purpose of medical or scientific examination or teaching purposes, it thereby acquired a usefulness or value and was, accordingly, capable of becoming property and of being stolen. The court further held that:

> '[t]he common law does not stand still. It may be that if, on some future occasion, the question arises, the courts will hold than human body parts are capable of being property for the purposes of s.4 [of the Theft Act 1968], even without the acquisition of different attributes, if they have a use or significance beyond their mere existence. This may be so if, for example, they are intended for use in an organ transplant operation, for the extraction of DNA or, for that matter, as an exhibit in a trial'.[761]

With respect to property rights in excised tissue from living people, *Moore* would have presented itself as an example of the application of work and skill exception. However in *Moore,* the Court refused to accept his claim to property rights in the cell line. It held that the cell line was factually and legally distinct from the cells taken from *Moore's* body,[762] and that the patent constituted a certification that the cell line was a product of invention by the researchers and therefore belonged to the researchers.[763]

If the position in *Moore* is anything to go by, it is possible that the court may recognise property rights in tissue for the biobank, and not the tissue source because the argument would be that the cell lines produced for instance from the samples are not the same as the samples from the tissue source, and that the biobank applied work and skill of extracting storage and preservation of the tissue. On the other hand in *Catalona* the Court applied the law of possession as a basis of granting ownership right to the university. One wonders why the application on of work and skill exception was not employed. It could be that the provision of storage facilities for Catalona was not sufficient in comparison to the skill and the work Catalona and his research team put into the tissue. *Catalona* demonstrates that the University, as an institutional biobank, need not put in much effort into processing tissue before being considered to have fallen

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[761] *R v Kelly* [1998] 3 All ER 741 at 750

[762] *Moore v. Regents of University of California*, 793 P.2d 479, at 487.

[763] Ibid at 492.

within the exception of the no property in tissue rule. In comparison to *Yearworth*, the NHS could also have claimed property rights based on possession and provision of a storage facility but for the distinction that the parties did not abandon of gift the tissue. They gave the tissue on the understanding that they would come back for it at a future date.

In line with the focus of this thesis, it is most desirable that in relation to public and national biobanks, that tissue sources be given property rights in tissue along with personal privacy and informed consent. Based on the application of the work and skill exception, it may be difficult to quantify and assess what would constitute application of work and skill on the part of the tissue source. In Nigeria, for instance, the efforts, cost of transportation and the pains of some of the processes of extraction may constitute effort and work. In other cultures, the pain and overcoming a needle phobia may be the deciding factor which, if weighed against the efforts of the patients in *Catalona,* , may justify the recognition of property rights in tissue. The argument in *Yearworth*[764] is another basis for recognising the right of the tissue source to assert some property rights over tissue. If biobanks are deemed to be in a bailment relationship with the tissue source in relation to the use of their samples for future unspecified research then the tissue source would be able to control future uses of his tissue. What the foregoing discussion is suggesting is that the bundle of sticks be shared between the biobank and the tissue source. This means that both the biobank and the tissue source can exercise property rights in tissue, but the appropriate choice of sticks in the bundle for either parties may differ. For instance, right to possession should be exercised by the biobank, as was the case in *Catalona,* while the right to determine future uses of the tissue be exercised by the tissue source. In *Catalona* this right was expressed by the patients request to determine downstream uses of their tissue.If the court is reluctant to recognise property rights of a tissue source in tissue, the notion of trust may go a long way in resolving this. In a trust, the beneficiaries the tissue sources have an equitable interest; they do not have all the sticks in the bundle, yet the mechanism of the trust imposes legal fiduciary duties on the trusties. Like the bundle of sticks approach to property, the trust mechanism provides a flexible and amenable alternative to managing some of the

[764] *Yearworth v North Bristol NHS Trust* [2010] 1 QB 1.

issues arising out of new technologies such as biobanking. This alternative is discussed in Chapter 5.

Biobank research involving the secondary use of tissue is dictating a review of the no property rule as well as an extension of its exceptions beyond the application of work and skill. Fairness and justice dictates that the tissue source whose tissue is used in research should have a limited right in the tissue,[765] but Palmer has suggested that liability rules should be applied in the biobanking context as an attempt to optimise the benefits and risks of knowledge distribution.[766] Nwabueze[767] thinks that tissues in biobanks raise different problems than those involved in other contexts of body parts, and because of that, it is not obvious that liability rules which might be good for biobanks are generalisable to every situation in which a dispute might arise. In other words, the application of property rules to protect the tissue source's interest in stored tissue is desirable, but liability rules can be applied in conjunction with property rules for greater protection of the tissue source.

Moore could not own his cells but the researcher could, and was also able to obtain a patent on the cell lines. It would appear that the decision in *Yearworth*[768] suggests a basis for accepting the position that bodily parts may be owned and be capable of transfer as a commodity and subject to legal protection against theft, damage and exploitation. If that is the case, it is possible for a tissue source to claim ownership right as basis for determining what secondary uses that his body materials may be used for.

4.4.3 The current approach to property rights

Many parts of the body have been judicially treated as property. Blood,[769] semen,[770] hair, teeth, sweat, and urine have been treated as commodities capable of theft and sale,

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[765] Boulier, W. (1994). Sperm, Spleens, and Other Valuables: The Need to Recognise Property Rights in Human Body Parts. *Hofstra L. Rev.*, 23, 693.

[766] Palmer, L. I. (2005). Should liability play a role in social control of biobanks? *The Journal of Law, Medicine & Ethics*, 33(1), 70-78.

[767] Nwabueze, R. N. (2014). Body parts in property theory: an integrated framework. *Journal of Medical Ethics*, 40(1), 33-38.

[768] *Yearworth v North Bristol NHS Trust* [2010] 1 QB 1.

[769] *R v. Rothery* [1976] R.T.R. 550.

[770] *Hecht v. Superior Court*, (1996) 59 Cal. Rptr. 2d 222; *Jonathan Yearworth and others v North Bristol NHS Trust* [2010] 1 QB 1

however, the law is yet to pronounce authoritatively on excised tissue and who has property rights if any. Skegg commented on the lack of clarity of the law on the issue of property and body parts,

> 'It would be desirable for the English courts to go further than Scots authority yet does, and take the view that it is only while corpses or the remains of corpses are buried, or dispersed following cremation, that they are not the subject of property. This would enable the courts to extend more effective legal control, not only over corpses awaiting burial and cremation, but also over ashes which had not been buried or dispersed, and human remains which had been disinterred'.[771]

The Human Tissue Act authorises the donation of body parts for transplants and or medical research. The statutory acceptance of organ donation is an example of how the law treats some parts of the body like property and does not recognise others. The concept of donation in itself is conception of property.[772] The giving voluntarily of something is typically envisaged as the giving of some sort of 'thing' which is considered property. Some gifts of certain parts of the body are highly esteemed in current society, because they are considered desperately needed.

4.5 Human Tissue Act and property rights in tissue

The Human Tissue Act 2004 (HTA) is a comprehensive Act that repealed all other previously enacted statutes on human tissue except the Human Fertilisation and Embryology Act 1990 (HFEA). It reconstituted all these Acts into a single and harmonised framework. The Act uses the concept of consent as a basis for the removal, storage and use of human tissue;[773] to that extent, that it can be said that since the tissue source has the ability to determine how and by whom the material is used, they can be said to have a right to manage. This is because it is only after the tissue source has given consent that the licensed authority acquires possession and use of the samples.[774] This was also alluded to when it was asserted in the Parliamentary debates on the HTA, that the statute was built upon the notion of the right of an individual to control his or her

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[771] Skegg, D. G. (1975). Human corpses, medical specimens and the law of property. *Anglo-Am. L. Rev.*, 4, 412.

[772] Gift is defined as a 'voluntary transfer of property to another made gratuitously and without consideration.' Black's Law Dictionary 688 (6th ed. 1990).

[773] Human Tissue Act 2004 s.1.

[774] Human Tissue Act 2004 Sch 1.

own body materials. Dr Ladyman, in the House of Commons said, '[t]he principles of the Bill are that we all own our own bodies, we are entitled to determine how material from our bodies is used, and we should have consented to the use made of that material … the fundamental principle that we must apply to interpreting the Bill is that material provided by people from their own body is theirs to control, and they must consent to how it is used'.[775] This position can be said to be asserting a specie of property in tissue which, as Price observes, should be viewed against the backdrop of the existing common law of the no property in tissue and its exceptions.[776] Price goes on to argue that property rights are an inevitable and indispensable backdrop of the activities comprised within the HTA despite modifications to the Act which obviate the need for consent for the use and storage of non identifiable tissue.

The HFEA 1990 also appears to give tissue sources of reproductive material rights to control, manage and use. This was demonstrated in *Evans v Amicus care*[777] where the claimant was diagnosed with ovarian cancer; she then sought in vitro fertilisation and produced with her partner a fertilised embryo for the purpose. After the loss of her natural fertility, Ms. Evans's partner, who had become estranged from her, withdrew his consent before she could use the fertilised embryo. The Court held that part of the policy of the HFEA was to ensure the continuing consent of both parties from the commencement of treatment to the point of implantation;[778] putting it into context in terms of the incidents of ownership, it can be said that both Ms. Evans and her partner had management and use rights in the fertilised embryo. It is also worth noting that in contrast to *Yearworth* where property in reproductive tissue was recognised, the Court in Evans prioritised the rights of ownership entitlements to be exercised in favour of non-use over ownership entitlements in favour of use of the reproductive material without treating the fertilised embryo as property. Wall[779] argues that both *Yearwoth* and *Evans* allocated property interests to the claimants, but the difference was that in *Evans* the interference triggered a statutory liability under the HFEA, whilst in *Yearworth*,

[775] HC Standing Committee G col 59, 27 Jan 2004.
[776] Price, D. (2005). The Human Tissue Act 2004. *The Modern Law Review*, 68(5), 798-821 at 816.
[777] *Evans v. Amicus Healthcare Ltd*, 2004 E.W.C.A. Civ 727.
[778] Ibid para 36.
[779] Wall, J. (2011). The legal status of body parts: a framework. *Oxford Journal of Legal Studies* at 16-17.

remedies were sought via property rules. This may be because the HFEA did not have provisions that covered the type of interference complained of in *Yearworth*.

Whilst not explicitly acknowledging it, some of the incidents of ownership can be imputed to the tissue source under the HTA and the HFEA as a basis for a claim to a right to control and determine what future research their samples and data will be used for. That notwithstanding, the HTA is grounded in property rights and interests, and the fact that the Act does not explicitly acknowledge its property interest underpinnings makes them inadequate for the protection of property rights of tissue source in the secondary use of their tissue. Sections 31 and 32 contain provisions that represent a partial codification of the common law work or skill exceptions to the no property in tissue rule. The provision relates to controlled material as defined in the Act which is intended for transplantation purposes. This provision also establishes that property rights are created where there is an application of human skill. The Act does not however describe what amounts to human skill. Neither does it state what level of work or skill is required for the controlled material to fall within the exception. This further compounds the issue of what degree of human skill is required for the exception to apply. In *R v Kelly*, it was established that at common law, property rights are created where a body part acquires attributes by virtue of the application of work and skill. The Act does not make reference to the common law exception as established in *R v Kelly*.[780] The lack of specificity of the work and skill exception in S.32(9) of the Act raises question on defining the standards to be applied in determining whether human skill has been applied to the tissue sample. In *Re Organ Retention group litigation*,[781] Gage J, highlighted the potentially wide breadth of this vague exception when he observed that:

> '[t]he evidence in the lead cases shows that to dissect and fix an organ from a child's body requires work and a great deal of skill, the more so in the case of a very small baby such as Rosina Harris. The subsequent production of blocks and slides is also a skilful operation requiring work and expertise of trained scientists'.

Prior to this judgement, techniques used in preservation of an anatomical specimen were considered sufficient to trigger the exception, while preservation of a brain in formalin

[780] supra
[781] [2004] EWHC 644

was held not. In so far as work and skill would be frequently applied to tissue to make it usable such as being converted into a wax block, this exception would be easily triggered across board.

Section 32 establishes that property rights are created when there has been an application of human skill to the controlled material, but this raises the issue of what level of work or skill is required. This is not settled under common law, and neither is it stated under the HTA. The undefined nature of the nature of the work and skill exception is a matter of concern. For instance s. 32 requires the application of human skill to trigger the exception; it is not clear what the implication of the qualifier 'human' to the word 'skill' has. The insertion of the word raises the question of whether the exception is only applicable in circumstances where the work is performed by human beings and inapplicable where it is done by machines or computers. In biobank research a lot of the work that is carried out on the tissue and especially the data is carried out by machines. In the context of biobank research, it is not clear from the explanatory notes, whether extraction of DNA constitutes an application of human skill. It should be noted that even though s.32 is not primarily on biobank research, the uncertainty demonstrates the lack of clarity surrounding the work or skill exception.

In a clinical setting for instance, excised tissue is more to be treated in a professional manner i.e. tested, preserved and stored. The question would then be whether this amounts to work and skill. Advances in science, and the possibilities of what can be done with biobank research on tissue parts shows the limitations of the no property argument in remedying losses and giving control to tissue sources. In situations where unauthorised studies are performed on a tissue sample obtained with consent, property law may be the only avenue the tissue source has to obtain remedy.[782]

The HTA 2004 does not also vest property rights in individuals who have bodily materials separated from them. Brazier[783] argues that bestowing property rights on tissue would bring to the fore the notion of ownership of human beings and people may say that '[i]f my relative's body is *mine,* be she child, mother, or sister, I may do with my

[782] Nwabueze, R. N. (2014). Body parts in property theory: an integrated framework. *Journal of Medical Ethics*, 40(1), 33-38.
[783] Brazier, M. (2003). Organ retention and return: problems of consent. *Journal of Medical Ethics*, 29(1), 30-33.

property as I wish. I may elect to sell her component parts in public auction. I may donate her for display as a plastinated exhibit'.[784] She thinks that a legal recognition of property rights in tissue will give untrammelled rights of disposal to the so-called owner of tissue. The apprehensions of Professor Brazier may be real, but they do not seem sufficient for the wholesale rejection of the property right concept in tissue. The issue of commodifying and thinking in terms of owning a fellow human being is not a consequence of a property rights concept. In spite of the fact that the law does not recognise tissue rights, people still claim ownership[785] and they do seek to control what happens to their tissue.

The common law 'no property rule' can no longer be supported in the context of the modern case law. There are not many insurmountable issues with using the property model in tissue. There is also a growing move in support of human body parts and products of the living human body to be given full legal status as property capable of control by the tissue source. Property law affords valuable protection to the tissue source in so far as it provides accountability for the use and (more importantly) misuse of such material.

4.6 Conclusion

In the light of the foregoing arguments, it is concluded that excised tissue can be treated as property and as a consequence of that, the entitlement of the tissue source to having a say in what happens to his sample or data should also be recognised as a property right. Given the various arguments and apprehensions about according the body and its parts the status of property, safeguards could be introduced as may be agreed by society through the legislature to further restrain commercial trafficking[786] and exploitation. The analysis presented in this chapter shows that most of the reasons presented for rejecting the idea of property in human tissue have a common theme in the reification of property i.e. the notion of objectifying the human body. This Blackstonian notion of property is not applicable in the context of biobank research in light of the 21st century technological advances in science. A mission to abandon the 'thingification' of tissue

[784] Ibid.
[785] *Moore v Regents of the University of California*; *Washington University v Catalona* 490 F.3d 667 (8th Cir. 2007).
[786] HTA 2004 s.32. This section prohibits the use of the controlled, biological materials for financial gain.

and embrace a rights based notion of property is the position of this chapter. With regard to the recognition of a proprietary approach to tissue, it appears that the courts are not keen on intervening, which shifts the burden of this subject to the shoulders of the legislature.

The interest that should be protected is the right of the tissue source to have a say over whether or not his sample or data are used in future unspecified research, and it has been shown that a proprietary approach can be applied to enable the tissue source express their choice. A proprietary approach confers on a claimant the advantage of continuing control that is lacking in non-property frameworks. The consent model, and in particular the broad consent model discussed in Chapter 2, has significant limitations that make it imperative for alternative or complementary models to be considered for the protection of the right of the tissue source in biobanking research. These limitations and the proposed model of dynamic consent are an excellent complimentary approach to the consent model.

5. Governance

5.1 Governance of biobanking research

Innovations in research coupled with advances in bioinformatics and genetics have changed research practices over the years. Rather than having a researcher work alone in his laboratory, they now share data and samples in international collaborative research. Reflecting this, the number of biobanks has not only increased substantially, but they have also become valuable sources for pharmacogenomics research.[787] These resources are now seen as a pre requisite by many researchers conducting studies on complex diseases as many of these biobanks act as research platforms for sharing tissue and data for a wide range of researchers.[788] The use of large sets of tissue samples and health data in future unspecified research have raised profound, legal, ethical and social concerns for infringement of privacy of the tissue source, and autonomous consent issues relating to future unspecified research for the tissue source.[789] As discussed in chapter 4, recognising property rights in tissue by using the bundle of rights approach is a desirable adjunct to rights to privacy (which was discussed in chapter 3) and consent (in chapter 2) of the tissue source.

In reaction to perceived concerns about the involvement of the tissue source in biobank activities, there have been calls to review the governance mechanisms of biobanks. Some have suggested greater participant involvement in the running and oversight of these endeavours.[790] For instance, following the publication of the *UK Biobank's Ethics and Governance Framework*, Tutton, Kaye and Hoyer suggested the inclusion of representatives of participants in the EGC and other management bodies as a way of

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[787] Cambon-Thomsen, A. (2004). The social and ethical issues of post-genomic human biobanks. *Nature Reviews Genetics*, 5(11), 866-873.

[788] Eiseman E, Haga SB. *Handbook of human tissue sources: a national resource of human tissue samples*. Santa Monica, Calif.: RAND, 1999.

[789] Greely HT. Breaking the stalemate: a prospective regulatory framework for unforeseen research uses of human tissue samples and health information. Wake Forest Law Rev 1999;34:737-766

[790] Stranger, M., & Kaye, J. (2009). Governing biobanks: an introduction. *Principles and practice in biobank governance*, 1-12.

securing public trust and support.[791] They suggest that, given the opportunity, the general public would contribute well-considered views to policy discussion.[792] Winickoff has proposed a partnership model which seeks to move beyond mere consultation with research participants through the process of consent, to representation of the tissue source in governance and power sharing.[793] Drawing on corporate modelling, Winickoff refers to the UK Biobank as an example to argue for more representation of participants in the decision-making and governance processes. An analysis of these models will be set out to highlight the scale of the challenges facing governing biobanks and how these challenges can be resolved using an alternative charitable trust model.

5.2 Governance in the context of biobanking

There are no universally accepted definitions of governance; its definition is largely dependent on the differing theoretical perspectives and research methodologies and assumptions of those using them.[794] The way governance is described and used also varies according to the context being studied.[795] Traditionally, governance was associated with government and the exercise of power held by political leaders. This understanding of governance is referred to as the old governance approach. The term has now developed a broader meaning which includes processes and actors outside the realms of government.[796] Thus, no longer is governance seen solely in relation to governmental organs as being the only relevant actors but as inclusive of the role of networks, processes and relationships involved in exercising authority in the pursuit of goals.[797] This diversity of use of the term governance has generated a move from the traditional state centered definitions of governance and regulations towards broader

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[791] Tutton, R., Kaye, J., & Hoeyer, K. (2004). Governing UK Biobank: the importance of ensuring public trust. *Trends in Biotechnology*, 22(6), 284-285 at 285

[792] Ibid.

[793] Winickoff, D. E. (2007). Partnership in UK Biobank: a third way for genomic property? *The Journal of Law, Medicine & Ethics*, 35(3), 440-456 at 451

[794] Stoker, G. (1998). Governance as theory: five propositions. *International Social Science Journal*, 50(155), 17-28 at 17.

[795] Ibid.

[796]Kaye J, Gibbons SMC, Heeney C, Parker M, Smart A. (2012). *Governing Biobanks: Understanding the Interplay Between Law and Practice*. Oxford, UK: Hart. 12.

[797] Kjaer, A. M. (2004). Governance. Cambridge: Polity. Knill, C.(2001) The Europeanisation of National Administrations, Cambridge: Cambridge UP.

understandings of the role of private and non state actors.[798] This has resulted in broader definitions of governance that encompass the powers of the state to govern to the understandings of governance as the intentional activity of attempting to control order or influence the behaviour of others.[799] For example, when considered in terms of corporate governance, it relates to the business and administrative structures set up to manage the institution and ensure that it achieves the desired outcomes.

Governance and regulation are often used interchangeably to explain the activities they cover. Kaye[800] et al. have defined and articulated the differences between these terms. They define governance as being a multifaceted compound situation of institutions systems, structures, processes, procedures, practices, relationships and leadership behaviour in the exercise of social, political, economic and managerial and administrative authority in the running of public or private affairs. This definition includes laws as well as the professional culture and guidelines and concepts that guide biobanking practice. These guidelines need not be written but, according to Kaye, they have become 'the way we do things'.[801] Regulation is narrower in scope and applies to the formal structures of law. For the purpose of this thesis, adopting Kaye's definition, governance will be used in its broadest form (covering multiple actors, activities and mechanisms) as a concept that includes regulation as well as less formal constructed mechanisms that dictate behavioural patterns.

In the context of biobanking research, governance can also constitute of statutes, legal instruments, directives and policies of informal mechanism, such as advisory boards, professional bodies and biobank policies, as well as norms that guide decision making in biobank research. Such governance frameworks have been described as '… the agreements, procedures, conventions or policies that define who gets power, and how

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[798] Kaye, J., Gibbons, S. M., Heeney, C., Parker, M., & Smart, A. (2012). *Governing biobanks: Understanding the interplay between law and practice*. Bloomsbury Publishing, 12

[799] Black, J. (2002) Critical Reflections on Regulation'. *Australian Journal of Legal Philosophy*, 27, 1.

[800] Stranger, M., & Kaye, J. (2009). Governing biobanks: an introduction. *Principles and practice in biobank governance*, 1-12.

[801] Kaye, J., Gibbons, S. M., Heeney, C., Parker, M., & Smart, A. (2012). *Governing biobanks: Understanding the interplay between law and practice*. Bloomsbury Publishing.

accountability is rendered'.[802] Governance in this broad sense will also be described as the intentional activity of attempting to control order or influence the behaviour of stakeholders including the tissue source in the biobank research context.[803]

Governance in the biobank research context has been approached from several points of view. Brownsword[804] approaches it from a rights and ethics angle, arguing that in most European societies where there are political and legal commitments to respect for human rights, the regulatory environment for biobanks should be made compatible with human rights commitments. In particular, he suggests that it is essential that the rights of participants are respected. In his paper, he discusses governance as a regulatory tripod with one of the prongs of the tripod representing the larger picture of the rights of the community and its members including the individual tissue source, while the second represents regulators acting as stewards of the samples and associated data and the third representing a regulatory environment that is non reliant on anonymisation.[805] The notion of rights is important in articulating a governance approach for biobanking research; however, there are conflicts between the interests of the various stakeholders within the biobank context that can only be resolved through an appropriate governance model or structure.

In articulating a governance framework for biobanks, even along the lines of governance in the broad sense, Brownsword[806] cautions that there is a need to be particularly careful when articulating a governance framework for biobanks to avoid what he calls the 'mistake of legal exclusivity' (i.e. to assume that the only signals in the regulatory environment are formal legal signals) and the 'mistake of normative exclusivity' (meaning to assume that the only signals in the environment are normative).

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[802] Bedard, K., Wallace, S., Lazor, S. (2012). Potential conflicts in governance mechanisms used in population biobanks in Kaye, J., & Stranger, M. (eds)(2012). *Principles and practice in biobank governance*. Ashgate Publishing, Ltd.

[803] Black J. Critical reflections on regulation 27 *Austl. J. Leg. Phil*. 1 (2002) 1-35

[804] Brownsword, R. (2013). Regulating Biobanks: Another Triple Bottom Line. In Pascuzzi**,** Giovanni, Izzo**,** Umberto, Macilotti**,** Matteo (Eds.) *Comparative Issues in the Governance of Research Biobanks* (41-62). Springer Berlin Heidelberg.

[805] Yassin, R., Lockhart, N., del Riego, M. G., Pitt, K., Thomas, J. W., Weiss, L., & Compton, C. (2010). Custodianship as an ethical framework for biospecimen-based research. *Cancer Epidemiology Biomarkers & Prevention*, 19(4), 1012-1015 at 1013

[806] Brownsword, R. (2009). Rights, responsibility and stewardship: beyond consent. In Widdows, H., & Mullen, C. (Eds.). *The governance of genetic information: who decides?* Cambridge University Press. 99-125.

He also goes on to suggest that in the consideration of legal frameworks for a biobank, that such frameworks should not just concern 'rights' issues but should create a balance by dealing with what he calls the two other bottom lines which are (1) the obligations to act as stewards and to provide a supportive infrastructure for transactions and interactions between stakeholders, and (2) to respect the participants' freedom to exercise their moral choice or moral responsibilities.[807] In his paper *Rights responsibility and stewardship*, Brownsword[808] addresses the key fault lines of genetic governance, namely, that of a balance between private rights and the public good. In disagreeing with the current practice of consent which he considers to be over individualised, he suggests an alternative approach based on a reassessment of the ethic of the individual right. He also argues that if this approach is properly implemented, it is capable of recognising both communal and state obligations as well as the rights of the individual. In his narrative, he corrects the tendency of overstating the constraints imposed by an ethic of rights. An ethic of rights is not simply a matter of consent but of positive obligation to others in the community balanced by the stewardship responsibilities. In other words once an ethic of rights is fully elaborated, there is the potential for research practices to be justified by reference to the stewardship responsibilities of the biobank. These triple bottom lines of Brownsword reflect some of the concerns that have generated discussions on governance of biobanks and in turn biobank research. These perceived concerns and issues, particularly on how to manage both public and private in the governance of biobanking, have resulted in calls for participant involvement in the running and oversight of biobanks. Writers such as Winickoff have responded to these calls by offering models of governance along the lines of participation and not consultation.

5.3 Governance models

In his approach to governance, Winickoff noted that the various models of governance which have emerged have in the main ignored property rights in favour of focussing on obtaining consent and IRB review to remedy issues of access, rights of control and exclusion in biobanking. In the process, he says, they have failed to sufficiently address

[807] Ibid 117-120.
[808] Ibid.

issues of procedural justice which, he says, is the constitution of distributive power over resources for genomic research.[809] Winickoff criticises these models on the grounds that they exclude research participants from governing the resources they help to create.[810] He also criticises the position of Pullman and Latus[811] who developed a model to solicit and negotiate collective benefits that will flow from deals between genomic biobanks and commercial companies (this model was adopted by the Edinburg group) as one that deprives donors from having real control, either as individuals or as a collective group, in the disposition of the biovalue they have been instrumental in creating.[812]

Even though Winickoff acknowledges that consultation enables the public to have some soft form of ownership over this collective techno-scientific endeavour[813] which, in turn, has resulted in a new type of relation between science and the tissue source,[814] he goes on to propose a model of governance which would move governance beyond public consultation to a participatory model of governance that would ensure resource entitlement for the tissue source. [815] This participatory model, he says, has the advantage of bringing about a move from 'benefit sharing which he refers to as 'a distributive value, to power sharing', a procedural one.[816] According to him:

> 'benefit sharing as a discourse tends to settle political questions of distributive agency—the power to make distributive choices—in ways that exclude research participants from governing the resources they help to create'.[817]

He also notes that partnership governance gives participants a share in distributive decision making in return for contributing to the project. He argues that implementing a

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[809] Winickoff, D. E. (2008). From benefit sharing to power sharing: partnership governance in population genomics research. *Center for the Study of Law and Society Jurisprudence and Social Policy Program*. 4
[810] Ibid.
[811] Pullman, D., & Latus, A. (2003). Reconciling social justice and economic opportunism: regulating the Newfoundland genome in Knoppers, B. M. (Ed.). (2003). *Populations and genetics: legal and socio-ethical perspectives*. Martinus Nijhoff Publishers.
[812] Winickoff, D. E. (2008). From benefit sharing to power sharing: partnership governance in population genomics research. *Center for the Study of Law and Society Jurisprudence and Social Policy Program*.
[813] Winickoff, D. E. (2007). Partnership in UK Biobank: a third way for genomic property? *The Journal of Law, Medicine & Ethics*, 35(3), 440-456 at 445
[814] Ibid.
[815] Winickoff, D. E. (2007). Partnership in UK Biobank: a third way for genomic property? *The Journal of Law, Medicine & Ethics*, 35(3), 440-456 at 451.
[816] Winickoff, D. E. (2008). From benefit sharing to power sharing: partnership governance in population genomics research. *Centre for the Study of Law and Society Jurisprudence and Social Policy Program*. 5.
[817] Ibid.

partnership form of governance may be easier since there are legal structures existing within a charitable trust model that would help achieve partnership governance. To achieve this he notes that control is a major concern for research participants, therefore in the context of biobank research, an important pragmatic goal for preserving the trust and interest of the tissue source would be to give the source some sort of role in decision-making. Thus it can be said that procedural justice and pragmatism in governance require the constitution and recognition of real rights to guarantee an element of control of future use of samples and data by the tissue source. Admittedly, the extent to which policies should be modelled solely on public opinion data is controversial.[818] However, it is important to identify and gauge as accurately as possible people's actual concerns and opinions in other to proffer solutions and, at the same time guard against skewing responses to legitimise policy choices. For instance, participants in the UK Biobank consultations did suggest that donors' should be involved in the governance structure, and they also advocated for representation for the general public. One of the concerns of the respondents as contained in the comments made by respondents on the first draft of *UK Biobank's Ethics and Governance Framework* (EGF), was in relation to future use of their samples and data. One respondent:

> '…wondered whether the consent process would include information about new commercial uses or contracts concerning their samples? Only by providing such information will participants genuinely be allowed to exercise a right of conscience, on the *same model as shareholders* who have ethical objections to particular… practices'.[819]

From this, Winickoff concludes that:

> '…concerns around governance were explicitly cast in terms of who exactly would be making resource allocations, and addressed the lack of channels for meaningful donor input. (As the italicized portions indicate)…respondents explicitly invoked shareholder models and the principles of checks and balances, indicating a search for a different governance framework than that of a rule of experts'.[820]

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[818] Caulfield, T. (2007). Biobanks and blanket consent: the proper place of the public good and public perception rationales. *KLJ*, 18, 209 at 210.

[819] Winickoff, D. E. (2007). Partnership in UK Biobank: a third way for genomic property? *The Journal of Law, Medicine & Ethics*, 35(3), 440-456 at 446.

[820] Ibid.

Considering Winickoff's view in context, a potentially different interpretation emerges. This is because the respondent's concern appears to be with the kind of information that would be made available to participants to enable them make informed decisions, and not about the governance model being a shareholder model or otherwise. Similarly, the concern that there should be adequate checks and balances is more in resonance with a general view that policies and decision-making processes in relation to research should be clearly explained to participants, and not necessarily about the lack of channels for meaningful participation of the tissue source in governance. It is true that participants did raise concerns about the lack of input by the tissue source in decision-making, as well as a desire for a framework that would articulate and enable their choices in relation to future research, but not, as Winickoff puts it, as an invocation of shareholder models. Thus, although Winickoff is correct in his observation that there is a crucial gap in biobank governance, and that project planners over the years have missed an important opportunity to involve tissue sources in the decision-making process, this does not adequately provide support for implementing a shareholders model. Winickoff does raise some important issues, which have bearing on the type of model that might best suit the biobanking context.

5.4 Partnership model of governance

In his paper on partnership as a model for governance, Winickoff maintains that granting representational power to the tissue source would improve participation in biobank research, enhance trust, and in turn project sustainability.[821] He notes that 'in the wake of the failures of the Human Genome Diversity project, community participation in research governance of population genetics emerged as a central concern[822] because 'bioethicists have argued that where researched populations share some genetic characteristics or privacy risks',[823] some form of group consent or community consultation would be required. Winickoff favours participation in governance by the donors being the representatives over and above developing

[821] Winickoff, D. E. (2007). Partnership in UK Biobank: a third way for genomic property? *The Journal of Law, Medicine & Ethics*, 35(3), 440-456 at 446.
[822] Ibid.
[823] Ibid.

representational forms of governance through a donor collective union in biobanking.[824] He maintains that if donors had some form of real representative power then project goals would be better achieved.[825]

The practical challenges of adapting representational structures within this context, a national scale project involving 500,000 donors, are considerable. Nevertheless, if donors had some form of real representative power, then project goals would be better achieved. Although existing ideas related to 'benefit sharing' and labour organising are useful, project planners and potential research participants ought to consider new forms of 'partnership governance' that draw upon the legal logic of corporate governance in order to solve the agency problems involved in the management of collective genomic assets. Such structures could improve UK Biobank's ability to realise a true partnership between donors and researchers and find the elusive 'third way' for genomic property.

For Winickoff, the core problem underlying the challenges of biobanks as to governance is one of *agency*; that is, the problem of representing the interests of the tissue source who provides crucial biological samples and associated data to the biobank.[826]

He notes, and rightly, that mounting evidence suggests that there may be a divide between the expectations of the tissue source and those of biobank managers, thereby creating an agency gap with potential destabilising effects.[827] The answer to this lies in a partnership form of governance, which Winickoff favours. The partnership model he suggests is based on a corporate shareholder model which he supports with the example of the UK Biobank which, after all, is a legal corporation.[828] In rejecting the proposition of Fortun[829] on governing biobanks using a trade union model, Winickoff proposes constituting a committee of direct representatives of the research participant group, which would play a formal governance role within the governance of the biobank

[824] Ibid.
[825] Ibid.
[826] Ibid at 450.
[827] Ibid.
[828] Ibid at 451.
[829] Fortun, M. (2003). Towards genomic solidarity: lessons from Iceland and Estonia. *Open Democracy*, 10.

corporation as a charitable trust.[830] The rules governing charitable trusts would be applied in a way that specifies that use of the resource would be contingent on review and approval of two bodies, namely the ethics review board and a Donor Approval Committee (DAC). This body would approve research protocols, but would also serve as a conduit between the donor group, the board of trustees, and the researchers in order to address controversial projects or issues as they arise.[831]

Although Winickoff acknowledges the operational challenges, nevertheless, he maintains (1) that it might solve the agency gap between tissue source and biobanks which may work towards solving the trust problem between them; and (2) that it will provide direct representation for the tissue source which is required if the social aspect of biobanking is to be achieved.[832]

Thus, Winickoff has to a large extent, contributed to the debate of governance of biobanks and biobank research, by attempting to turn the rhetoric of participation and participant autonomy into reality; he correctly identifies trust as a central problem between the tissue source and the biobank and that there may be an agency gap between the expectations of the tissue source and those of biobank managers; however it is not clear whether proposals for a form of partnership are necessarily the optimal means to give the tissue source a say in future unspecified use of his samples and data in biobank governance. In addition to the issues outlined above, there are some conceptual issues with the shareholder analogy, particularly as it relates to the notion of partnership governance. For instance, according to Winickoff, the notion of partnership '… connotes a form of cooperative human relations with respect to shared conditions and aims'.[833] This, however, is manifestly different from the relations between shareholders and managers in the real corporate world. As Winickoff himself notes, the relationship between shareholders and managers in corporations is fraught with the potential for mistrust and misappropriation rather than cooperation as his notion of partnership depicts.

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[830] Winickoff, D. E. (2007). Partnership in UK Biobank: a third way for genomic property? *The Journal of Law, Medicine & Ethics*, 35(3), 440-456 at 450.
[831] Ibid.
[832] Ibid at 451.
[833] Ibid at 443.

The second issue, and something Winickoff himself raises, is whether anybody could adequately represent the tissue source in a population biobank such as the UK Biobank, which has a collection of 500,000 donors without a clearly shared goal. A body that would represent the tissue source collectively would need to reflect the diverse interests and views of the whole collective. However, since the process for the donor association would be self-selecting,[834] it would be difficult to ensure that it embraces a broad range of voices and views and, therefore, the likelihood of the DAC being representative of the interests of the various tissue sources is very slim.

These potential dangers raises the question of whether a partnership approach would necessarily address the problem of trust and access to decision making that Winickoff identifies. In a report on a series of focus groups around the UK Biobank, Levitt and Weldon note that: 'there was a general suspicion of all vested interests, not just commercial ones. People with an axe to grind included patient groups and scientists themselves, who would try to orientate research to their particular interests'.[835] The concerns among some focus groups with how individuals would be recruited, stressed the importance of ensuring their independence and having no conflicting interests. Since tissue sources are unlikely to agree on their preferences for the types of research to which their samples are used in future unspecified research, representation will always be just that; representation and not participation in decision making. Winickoff identifies this and states that:

> 'Donors are unlikely to agree in their preferences, and new forms of representation will always be just that, representations. Somebody has to speak for somebody else, and it will be specific donors who take these positions, and they will hold particular views, which could equally be said of any form of political representation'.[836]

This observation echoes a deep concern about the role of representatives and their ability to act in the interest of the people they are representing. In another work[837]

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[834] Ibid at 449.

[835] Levitt, M., & Weldon, S. (2005). A well placed trust?: Public perceptions of the governance of DNA databases. *Critical Public Health*, 15(4), 311-321 at 318.

[836] Winickoff, D. E. (2007). Partnership in UK Biobank: a third way for genomic property? *The Journal of Law, Medicine & Ethics*, 35(3), 440-456 at 452.

[837] Winickoff, D. E., & Neumann, L. B. (2005). Towards a social contract for genomics: Property and the public in the 'biotrust' model. *Life Sciences Society and Policy*, 1(3), 8.

Winickoff attempts to address this concern by suggesting a biotrust model, a model he says adds important governance mechanisms to the basic charitable trust framework he had earlier suggested. In this model, the by-laws he proposed would specify that use of the trust property would be contingent on review and approval of two bodies, (as opposed to one proposed under the partnership model) namely the Ethical Review Committee (ERC) and the Donor Advisory Committee (DAC).[838] The ERC of the biorepository would provide peer review and ethical analysis of research protocols that require access to biobank materials. This committee would be roughly equivalent to an Institutional Review Board (IRB), except that it would be more directly responsive to the collective interests of the donor group. Ideally, it would involve a significant number of donors so as to be more representative of the research subject population.

Indeed, Winickoff has rightly identified some of the issues of governance, principally that of an agency gap between the expectation of the tissue source and that of the biobank, and issues of control and access to samples and data especially as they relate to future research. However, a model that seemingly gives power to the tissue source to elect representatives without ensuring the protection of his privacy and choice does not sufficiently protect the tissue source. Moreover, the inclusion of a few participants on a biobank's board of directors and the DAC might well become merely tokenistic in outlook or at best a quick institutional fix,[839] and that could forestall productive deliberation. Democratic theorists have also argued that representative government can be discriminatory and can exclude many groups from the political decision-making process;[840] and that it does not necessarily involve nor lead to wider participation in decision-making processes.

As Pimbert and Wakeford[841] noted, representative democracy has been heavily criticised for its inability to protect the interest of citizens and in particular the interests of marginalised groups, 'who often do not participate effectively in such representative

[838] Ibid at 11.

[839] Irwin has said that we should not be looking for ―institutional fixes, but rather the development of an open and critical discussion between researchers, policy makers and citizens. See: Irwin, Constructing the scientific citizen at 16.

[840] Urbinati, N., & Warren, M. E. (2008). The concept of representation in contemporary democratic theory. *Annu. Rev. Polit. Sci.*, 11, 387-412 at 390-391.

[841] Pimbert, M., & Wakeford, T. (2001). Overview: Deliberative democracy and citizen empowerment. *PLA notes*, 40, 23-28. at 23.

democracy, and are ill-served by the organisations that mobilise their votes and claim to represent their interests'.[842] One of the main concerns of representative governance is that representation is understood as a principal-agent relationship, in which principals or constituencies '…elect agents to stand for and act on their interests and opinions, thus separating the sources of legitimate power from those that exercise that power'.[843] In other words this approach may not address Winickoff's central concern, viz the agency gap. It may only widen the gap by installing additional parties as representatives.

The fundamental challenge is a commitment to engage with and take into account the views and preferences of the tissue source through governance processes which are robust, transparent and would endure throughout the life of the project. What is needed is a mechanism that ensures the participation of the tissue source in decision making on future unspecified research as well as making the biobank responsible for protecting the interest of the tissue source.

5.5 Concepts of stewardship and custodianship

One way in which commentators have tried to negotiate competing claims to biobanked human tissue is via the concept of stewardship.[844] Stewardship has been characterised as the 'responsible use of resources, accountability for the wellbeing of another and service to others. The steward acts to benefit others with awareness that what is stewarded is something of value'.[845] The World Health Organisation report of 2000[846] identified stewardship as one the four core functions of all health systems regardless of how they are organised or where they are. The report broadly defines stewardship as 'the careful and responsible management of the wellbeing of the population' and in more general terms as the very essence of governance.

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[842] Ibid

[843] Urbinati, N., & Warren, M. E. (2008). The concept of representation in contemporary democratic theory. *Annu. Rev. Polit. Sci., 11*, 387-412. at 389;

[844] Stewart C., Aparicio,L., Lipworth W.,& Kerridge I. (2014). Public Umbilical Cord Blood banking and Charitable trusts in Persons, Parts and Property,: How Should we Regulate Human Tissue in the 21st Century ? Eds Imogen Goold, Kate Greasley, Jonathan Herring, Loane Skene 53-65.

[845] Jeffers, B. R. (2001). Human biological materials in research: ethical issues and the role of stewardship in minimizing research risks. *Advances in Nursing Science*, 24(2), 32-46.

[846] Musgrove, P., Creese, A., Preker, A., (2000). *The World Health Report: 2000: Health Systems: Improving Performance*. World Health Organisation. Geneva.

In relation to biobanks, Jeffers[847] describes stewardship thus:

> 'Using a model of stewardship to guide the ethical conduct of research using human biological materials obligates the researcher to conserve the donor's values, traditions, and culture in ethical decision making. Stewardship recognises the importance of not only preserving the human dignity of individual research participants, but also changing what is stewarded to benefit the community of the participant. The change that occurs within a stewardship model increases the value of what is stewarded in order to achieve the outcomes of preservation of human dignity and benefit for the common good. It does not rule out possible benefits to the individual donating the material or the steward; however, the primary obligation of the steward is to improve what is given for the common good. The emphasis is protection of entrusted resources to serve common humanity'.

Some authors refer to this way of holding tissue, as described by Jeffers, as custodianship.[848] The concept of custodianship or stewardship emphasises the duty of the biobank to protect the privacy of the tissue source as well as preserve the tissue.[849] It addresses the governance challenges relating to common areas of concern in biobank research such as preserving the dignity and privacy of the tissue source, enabling the right to choice of the tissue source, as well as conserving the values of the tissue source.

According to Fullerton et al.,[850] as the practice of biobanking grows to large-scale population biobanks acting as platforms for domestic and international collaborative studies, the concept of stewardship must also evolve to meet these challenges. In most first-generation biorepository research, the burden of stewardship fell to the originating investigator or institution and was achieved by faithfulness to the terms of informed consent and the adoption of data protections like anonymisation. However, with the retention of identifying information, an expectation of ongoing oversight coordinated across independent institutions, and the need to maintain communication with

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[847] Jeffers, B. R. (2001). Human biological materials in research: ethical issues and the role of stewardship in minimizing research risks. *Advances in Nursing Science*, *24*(2), 32-46.

[848] Verlinden, M., Ectors, N., Nys, H., & Huys, I. (2012). Legal Nature of Custodianship of Human Biological Material Stored in Biobanks. *Biopreservation and Biobanking*, 10(5), A39-A39., Hallmans, G., & Vaught, J. B. (2011). Best practices for establishing a biobank. In *Methods in Biobanking* (241-260). Humana Press.

[849] Yassin, R., Lockhart, N., del Riego, M. G., Pitt, K., Thomas, J. W., Weiss, L., & Compton, C. (2010). Custodianship as an ethical framework for biospecimen-based research. *Cancer Epidemiology Biomarkers & Prevention*, 19(4), 1012-1015.

[850] Fullerton, S. M., Anderson, N. R., Guzauskas, G., Freeman, D., & Fryer-Edwards, K. (2010). Meeting the governance challenges of next-generation biorepository research. *Science Translational Medicine*, *2*(15), 3

participants in light of the open-ended nature of the research commitment, next-generation biorepository research entails far greater demands for stewardship and researcher accountability. These responsibilities may include taking due care with the analysis and sharing of confidential genetic and linked health information, the adoption of research goals consistent with the intentions of participants, and the avoidance of forms of dissemination (publications and similar) that promote harmful or derogatory conclusions about certain populations or groups.

In line with the observations of Fullerton et al. above, the practice of biobanking is complicated by the competing claims of the research needs of the society and the entitlements to privacy and personal autonomy of the tissue source. Incorporating the concepts of stewardship into the regulatory framework of biobanking would help to provide a framework that both reflects the purpose of biobanking as well as protect the privacy and autonomy interests of the tissue source. The concept of stewardship is used in this chapter to develop and advance a model that can serve as a framework to guide legal protection of the entitlement of the tissue source to participation in decisions relating to future use of his sample and data in biobank research. The challenge from a legal perspective is the choice of legal mechanism that would provide for the powers of the biobank to carry out research on biobanked samples and data but regulated by the concept of stewardship.

5.6 Alternative models to stewardship in biobanking

5.6.1 Informed consent

One method to achieve this would have been to employ the doctrine of informed consent which would require that biobanks fully inform the tissue source of the material risks of the research and how the tissue is going to be stored and used.[851] Informed consent as a legal doctrine is primarily focussed on providing research subjects with enough information to enable them to decide whether or not to become involved in the research. In the context of biobanking, however, informed consent is very difficult to obtain given that tissue sources will be asked to consent to use of their samples and data

[851] See Chapter 2; Clayton, E. W., Steinberg, K. K., Khoury, M. J., Thomson, E., Andrews, L., Kahn, M. J. E., & Weiss, J. O. (1995). Informed consent for genetic research on stored tissue samples. *Jama*, 274(22), 1786-1792.

in future research where risks are completely unknown. Given the inability to ascertain what will happen to tissue samples in future, broad consent processes are adopted; so broad that they bear little resemblance legally to consent as a concept.

The essence of biobanking research lies in its ability to provide resources for unknown research, therefore using the informed consent doctrine in biobanking dictates that researchers would re-approach tissue sources for consent to use their samples and data in new studies which at the moment is not being done. The model of consent as a model for governance has proved problematic for biobanking research.

5.6.2 The law of contract

Another option would have been to employ the mechanism of contract law. However contract law suffers a shortcoming in terms of biobanking in the sense that a contract is only enforceable between the contracting parties due to the doctrine of privity of contract. In biobanking research, where tissue and or data is shared with others, researchers contract law can no longer be applied as the tissue source does not have a relationship with the downstream researcher.

5.6.3 Property law

A third option is to apply a property law approach. Unlike contract, property law creates an enforceable right against the whole world (see Chapter 4). Where property is viewed as a bundle of rights, these rights flow with the thing and can therefore control how third parties such as downstream researchers have access to and use property. Property has the potential of avoiding the pitfalls and shortcomings of the doctrine of informed consent and contract law because of its potential to run with the object of property and also control access to use of the property in future.

5.6.4 Parameters of stewardship in biobank research

Stewardship is often cited as an alternative paradigm and not a legal paradigm in and of itself as there are few laws directly addressing stewardship, (although the laws of trusts, agency and other bodies of law that encompass fiduciary duties include elements of the concept of stewardship). Stewardship, as commonly understood, entails taking care of something. While one can own that which one is the steward over, ownership is not central to the concept. Rather, responsible management is the underlying element in

stewardship. It connotes a relationship in which there is a duty to manage in a responsible manner. As to natural resources, for example, stewardship entails managing them so as not to deplete them but rather to use them so that value is maximised for current and future generations.

Stewardship, unlike property and privacy, can encompass subjects at both ends of a relationship or an object or thing at one end. It does not necessarily imply object-hood without subjectivity, which property implicitly creates, nor does it require a subject at both ends, as privacy does. Dignity can also be read into stewardship because the duty to manage or use responsibly can promote the thing managed as being entitled to respect and dignity. For instance, stewardship could impose duties on the researchers to use the tissue samples and associated data in a manner consistent with the intentions of the tissue source. It might also impose a responsibility on the part of the tissue source not to withhold use unreasonably, thus meeting justice concerns. But it would not necessarily give the tissue source the power to disrupt the research and directly control the disposition of a research sample.

What stewardship does not provide, however, are concrete rules. It is an ethical precept, not a body of law.[852] The stewardship model on its own without a legal basis might expand the frontiers of public accountability of biobanks and ensure new modes of governance over samples and data, but whether it would address the fundamental underlying problem – an imbalance of power between donors and researchers that tilts strongly in favour of the latter – remains uncertain[853] The concept of stewardship is thus proposed using the law of trust to give it some teeth as well as a backbone.

5.6.5 Role of stewardship in protecting human rights of the tissue source

There are certain features of biobanking that may affect the dignity of the tissue source in relation to his participation in biobank research. The first is the open-ended nature of; biobanking that it cannot say for certain what kinds of research may be conducted in future. Nor can it guarantee that the samples, associated information, or research results will never be used for malicious purposes. This means that participation in a biobank

[852] Appel Blue, E. E. (2007). Redefining stewardship over body parts. *JL & Health*, 21, 75.
[853] Appel Blue, E. E. (2007). Redefining stewardship over body parts. *JL & Health*, 21, 75.

carries risks to a person's dignity because it may lead to information or practices (e.g. genetic discrimination, breaches of confidentiality, damage to reputation) that place additional limits on a person's potential to live a meaningful life.[854]

Another peculiar feature of biobanking which has implications for the dignity of the tissue source is its being a platform for future research. This has dictated the wide use of broad consent in biobanking which may impinge on the dignity of the tissue source because broad consent does not accommodate the choice of the tissue source in future unspecified research. Broad consent explicitly undermines the existential importance of being able to decide on morally meaningful matters for oneself. Since it is acknowledged that the individual is an autonomous person who would like to make informed choices on matters, especially those that affect their own person, consent should always be accompanied with sufficient information about what biobanking is, its uses, and its risks to enable the tissue source in decision making: a prerogative that broad consent does not offer.

In deciding whether to extend the law of informed consent to apply to researchers who obtain tissue from other researchers, tissue banks, or repositories, Gitter stated that:

> 'it is worth noting that, as a practical matter, a system that exempts researchers from obtaining informed consent if they procure tissue from anyone other than the research participant might slow the pace of biomedical research by encouraging scientists to leave the tissue collection to others rather than risk incurring the duty of informed consent'[855]

Moreover, '[t]he fundamental principle underlying the need for consent for medical or research purposes is respect for personal autonomy' and strict adherence to this principle militates against exempting such researchers from the duty of informed consent. In order to assist researchers in tracking whether informed consent was given for the use of tissue obtained from tissue banks and repositories, governance mechanisms can be put in place to require these institutions to confirm consent relating to the tissue source. Considerations of equity militate in favour of a system or

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[854] Kirchhoffer, D. G., & Dierickx, K. (2012). Human dignity and consent in research biobanking. *South African Journal of Bioethics and Law*, 5(2), 74-77.

[855] Gitter, D. M. (2004). Ownership of Human Tissue: A Proposal for Federal Recognition of Human Research Participants' Property Rights in Their Biological Material. *Wash. & Lee L. Rev.*, 61, 257.

governance approach that recognises the right of a tissue source to having a say in the way his tissue and data are used in future unspecified research. This challenge can be overcome by using a regulatory mechanism which respects the power of the biobank to control and use the tissue in a way that the bank adopts, regulated by the concepts of stewardship and custodianship.[856]

Another feature of the concept is that it emphasises the duty of the biobank to protect and preserve the tissue, to protect the privacy of the donors and to promote observance of and compliance with the tissue source's consent.[857] This can be achieved by employing the doctrine of informed consent as opposed to broad consent which would require that biobanks fully inform the tissue source how the samples and data are to be stored and used.

Stewardship promotes the responsible use of resources and accountability for the wellbeing of another[858]. Stewardship in the context of biobanking research will seek the protection of dignity and autonomy within the context of the common good. This implies that the concept will uphold the entitlement of the tissue source to choice of what happens to his sample or data in future research. According to Fullerton et al., because 'the researcher acts as representative with responsibility for the one who has true ownership of the tissue, to serve, protect and benefit the donor of the human biological material',[859] using a stewardship model to govern the practice of biobank research will impose a legal obligation on the biobanks to account for the use of sample or data. This responsibility includes taking due care with the analysis and sharing of confidential genetic information, the adoption of research goals consistent with the intentions of the tissue source, and avoiding dissemination of information that will negatively affect or prejudice the tissue source and research populations.[860]

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[856] Stewart C., Aparicio,L., Lipworth W. & Kerridge I. (2014). Public Umbilical Cord Blood banking and Charitable trusts in Persons, Parts and Property: How Should we Regulate Human Tissue in the 21st Century ? Eds Imogen Goold, Kate Greasley, Jonathan Herring, Loane Skene Hart publishing 58

[857] Ibid.

[858] Jeffers, B. R. (2001). Human biological materials in research: ethical issues and the role of stewardship in minimizing research risks. *Advances in Nursing Science*, 24(2), 32-46.

[859] Fullerton, S. M., Anderson, N. R., Guzauskas, G., Freeman, D., & Fryer-Edwards, K. (2010). Meeting the governance challenges of next-generation biorepository research. *Science Translational Medicine*, 2(15).

[860] Goering, S., Holland, S., & Fryer-Edwards, K. (2008). Genetic Research Practices with Marginalized Communities. *Hastings Center Report*, 38(2), 43-53.

Another feature of biobanking, which has dignity implications is that it deals with human tissue and, increasingly, human genetic material. A person may consider their genes to be an extremely intimate and integral part of their identity and dignity. For example, it is possible to hold a religious belief that all human beings have dignity because they are created in the image of God and that therefore genes – as containing that image – are sacred and should not be tampered with (this of course is not the only position that a belief in divine creation necessarily supports). For such people, use of genetic research that does not promote the will of God is an offence to dignity.

The stewardship model assumes that the caretaking responsibility for samples and data by the biobank begins at enrolment of the tissue source and that it continues through the various studies on the samples. In recognising this responsibility, stewardship requires a formal adoption of defined research governance mechanism that is flexible yet can respond to dynamic technical developments of an ever changing scientific world.[861] The terms for granting data access to the downstream researcher would be elaborated in the governance policy of biobanks. The establishment of governance boards and data access committees has been suggested, whose composition would include representatives of the tissue source to vet proposed research uses.[862]

5.6.6 Minimising risks to privacy and confidentiality

Protecting the privacy and confidentiality of the tissue source is one of the challenges posed by biobank research. The practice of using samples and data in future research without permission remains a source of debate. People have interests in how their banked tissue is used, even if their tissue is 'de-identified'. They still have interests in the protection of privacy and confidentiality, and interests in supporting research consonant with their values while avoiding participation in research that contravenes them.[863]

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[861] Knoppers, B. M. (2009). Genomics and policymaking: from static models to complex systems? *Human genetics*, 125(4), 375-379.

[862] Winickoff, D. E., & Winickoff, R. N. (2003). The charitable trust as a model for genomic biobanks. *New England Journal of Medicine*, 349(12), 1180-1184.

[863] Tomlinson, T. (2009). Protection of non-welfare interests in the research uses of archived biological samples. *New Challenges for Biobanks: Ethics, Law, and Governance. Ant-werp, the Netherlands: Intersentia*, 99-110.

Anonymisation used to be the preferred method of protecting the confidentiality of the data of the tissue source by researchers. Anonymisation in this sense is the severing of the identity of the tissue source to prevent future identification.[864] However, in spite of the efforts of researchers to protect the identity of the tissue source, a number of the features peculiar to biobank research, as well as improved bioinformatics tools for data mining, have combined to make it increasingly difficult to achieve true anonymisation in practice.[865] A demonstration that individual participants can be determined from aggregate genotypic data has strengthened the position that fool-proof anonymisation may no longer be possible. Greely, for instance, argues for a complete abandonment of anonymisation; he argues that anonymisation does not protect the tissue source and that the whole premise of anonymisation is undesirable and unethical.[866] The concept and promise of absolute anonymisation should be done away with because it does not guarantee the privacy of the tissue source. The stewardship concept provides approaches that ensure the protection of privacy and confidentiality of the tissue source by limiting the nature of specimen or data provided to downstream researchers based on the level of access agreed to with the tissue source. Applying the concept of stewardship, to ameliorate the risks of privacy and confidentiality that arise in biobank research also places a duty on the biobank to be more circumspect in the dissemination and sharing of samples and data. Using the stewardship concept allows for a follow up of the tissue source. It also accommodates a mechanism for providing information on future research to the tissue source as well as the integration of the electronic means of granting consent to future research through the medium of dynamic consent. This model also prompts biobanks to act not only as ethical stewards but as fiduciaries by demonstrating respect for their choice in terms of research.

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[864] Godard, B., Schmidtke, J., Cassiman, J. J., & Aymé, S. (2003). Data storage and DNA banking for biomedical research: informed consent, confidentiality, quality issues, ownership, return of benefits. A professional perspective. *European Journal of Human Genetics*, 11, S88-S122.

[865] Roden, D. M., Pulley, J. M., Basford, M. A., Bernard, G. R., Clayton, E. W., Balser, J. R., & Masys, D. R. (2008). Development of a large-scale de-identified DNA biobank to enable personalized medicine. *Clinical Pharmacology & Therapeutics*, 84(3), 362-369.

[866] Greely, H. T. (2007). The uneasy ethical and legal underpinnings of large-scale genomic biobanks. *Annu. Rev. Genomics Hum. Genet.*, 8, 343-364.

5.7 The charitable trust model

The charitable trust model was advanced to protect in particular the privacy and autonomy of the tissue source of academic biobanks who 'when faced with financial constraints […] transfer blood, tissue, and medical information of tissue sources directly to private biobanks in return for access to research funding and in some cases equity participation'.[867] In order to protect the rights of these tissue sources and at the same time maximise scientific value, Winickoff suggests that biobank research be based on a new form of agreement between the medical institution, the researcher and the tissue source: modelled on a charitable trust. This model, which he describes as a creative way of solving the problems of governance of biobanks would also enhance the viability of genomic biobanks.[868] He goes on to identify one of the problems of governance in biobanking, as one of enabling the autonomous choice of the tissue source in relations to how his samples and data are used in future unspecified research. To this, Winickoff rightly advanced a charitable trust model as a promising legal structure for handling obligations, for promoting donor participation in research governance, and for stimulating research that will benefit the public.[869] Under this arrangement, the biobank becomes a trustee with a fiduciary duty to use the tissues for the furtherance of the charitable purpose. 'When a person agrees to donate tissue, the recipient has a responsibility to serve as a trustee, or steward, of the tissue in order to ensure protection of the contribution'.[870] Under a trust agreement the tissue source agrees to formally transfer his or her property interest in the tissue to the trusts. Trusts are especially suited to accommodate the needs of large-scale biobanks because biobanks organised as a trust

[867] Winickoff D.E. & Winickoff, R., The Charitable Trust as a Model for Genomic Biobanks, 349 *New Eng. J. Med.* 1180, 1182–83 (2003) at 1180 and 1182.
[868] Ibid.
[869] Winickoff D.E. (2003). Governing population genomics: law, bioethics, and bio politics in three case studies. *Jurimetrics* 43:187-228; Gottlieb K. (1998) Human biological samples and the laws of property: the trust as a model for biological repositories. In: Weir RF, ed. *Stored tissue samples: ethical, legal, and public policy implications*. Iowa City: University of Iowa Press, 1998.
[870] Winickoff, D. E., & Winickoff, R. N. (2003). The charitable trust as a model for genomic biobanks. *New England Journal of Medicine*, 349(12), 1180-1184; Jeffers BR. (2001) Human biological materials in research: ethical issues and the role of stewardship in minimizing research risks. *ANS Adv Nurs Sci*; 24, 32-46; Ashburn TT, Wilson SK, Eisenstein BI. (2000) Human tissue research in the genomic era of medicine: balancing individual and societal interests. *Arch Intern Med* 160, 3377-3384

can accept heightened ethical obligations toward those who provide samples and dedicate the benefits of research to the public.[871]

5.7.1 What is a trust?

Trusts are property relationships that originated in the equitable jurisdiction of the chancery during the Middle Ages. They remain useful and popular even today. A trust is a formal legal institution in which property interest is held by one person or set of persons (the trustees) at the request of another (the settlor) for the benefit of a third party (the beneficiary).[872] The property is usually conveyed to the trustee in writing using a document called the trust instrument. The property interest is conveyed to the trustee in a trust instrument that must clearly express the intentions of the settlor to create a trust. In a trust a trustee is recognised as the legal owner while the beneficiaries have an equitable interest in the property. The settlor appoints a trustee for the property who has legal fiduciary duties for safeguarding the interests of the beneficiaries meaning that the trustee is obliged to refrain from acting in ways that cause conflicts between his own interests and that of the beneficiaries. A settlor can also convey property to a trustee for himself, so that the settlor and the beneficiary can be one and the same person.[873] It is also possible for a trustee to be one of the beneficiaries. A settlor can also declare himself trustee.[874] What is however not possible is for there to be a lone trustee who is also the sole beneficiary.

Charitable trusts are species of express trust, but they are distinct in the sense that they exist for a purpose rather than for identifiable beneficiaries. In a charitable trust, the legal title is transferred to the trustee with directions on how the property is to be applied for the charitable purpose that serves the public interest. The charitable trust can be said to employ private property rights in accordance with the instructions of the settlor and for the public interest. There are three main requirements for a valid charitable trust:

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[871] Gottlieb, K. (1998). Human biological samples and the laws of property: the trust as a model for biological repositories. *Stored Tissue Samples: Ethical, Legal and Public Policy Implications*, 183-97 at 192–95

[872] Penner, J. (2014). *The law of trusts*. Oxford University Press at 16

[873] Penner, J. (2014). *The law of trusts*. Oxford University Press at 16

[874] *T Choithram International SA v. Pagarani* [2001] WLR 1, 1.

1. The trust must be created for a charitable purpose;
2. The trust must benefit the public; and
3. It must be exclusively charitable.

5.7.2 What is a charitable purpose?

There is no exhaustive definition of the term charitable purpose but the courts have traditionally referred to the preamble of the Statute of Charitable Uses 1601 as a starting point. The preamble identifies them to include trusts for the relief of poverty, the care of the aged and the sick; the care of soldiers and mariners; the advancement of education through building universities and schools; the repair of bridges, havens and ports churches and highways; the care of the orphans; and the maintenance of prisons. Until recently in UK, the courts still employed the preamble as a tool for determining whether or not a purpose was charitable. The test was whether the purpose was within the spirit and intendment of the preamble.[875] Later on, in *Commissioner for Special Purposes of Income Tax v Pemsel,*[876] Lord MacNaughten simplified the process by dividing up the preamble into four heads namely, trusts for the relief of poverty, trusts for the advancement of education, trusts for the advancement of religion, and trusts for purposes beneficial to the community not falling under the preceding heads. In *Scottish Burial Reform and Cremation Society v Glasgow Corp,*[877] Lord Reid further discussed the process for determining whether or not a purpose was charitable and said that the courts should look for an analogy between the intended purpose and one that is either in the preamble or one that has been recognised as charitable by the courts. In the UK, the preamble has been codified and replaced by S.3 of the Charities Act 2011. In Nigeria the interpretation is based on *Pemsel*[878] meaning that the old preamble approach still applies.

A charitable trust must confer a benefit on the general public; as a result they are often referred to as public trusts. The public nature of a charitable trust does not prevent it from charging for services and making profit as long as the profit is reinvested in the

[875] *Ex parte Gilmore. Gilmouru. Coats* [1949] AC 426 at 442-443
[876] *The Commissioners for Special Purposes of the Income Tax v. Pemsel*, (1879) A.C. 531.
[877] *Scottish Burial Reform and Cremation Society v Glasgow Corp* [1968] A.C. 138.
[878] *Iyanda v. Ajike* (1948) 19 N.L.R. 11

charitable purpose.[879] Charities may own other businesses not associated with the charity and run them at a profit and still claim the benefit of charitable status.[880] As a check on the legal owner, the law does not recognise a situation in which a person would have an obligation to hold property for himself and at the same time have an obligation to enforce it against himself. This emphasises the checks on the legal owner of property as well as create a dichotomy which also presents it with three advantages.

The first is that charitable trusts favour a separation between control and use of the collected samples. In the context of biobanking, where large collections are developed to enable future research, the party who stores it may not be the user. This dichotomy also reduces the possibilities of conflicts of interests between having custody of samples and using them, especially in making prioritisation decisions. In the context of biobank research, whoever manages a collection of human material in the public interest would face prioritisation decisions regarding the use of the samples; for example, who should access the database, for what purposes, in which countries and under what conditions. Therefore, if the manager of the collection is one of the potential users of the material, he faces a situation of conflict of interest in making decisions about the use of the collection. It is also possible for him to favour a project in which he has a personal stake over one where he has no interest, without focusing exclusively on the public interest.[881]

The second advantage is that the dichotomy enhances the possibility to perform an ethics review of the genetic research. By having an independent body, based on the separation between storage and future use of samples and data, the areas for conflict of interest are minimised. Under this model, third party researchers would be required to make a request to access samples or data. Upon filing such an application, third party researchers would be required to make explicit the intended purposes of their request for access. This practise would also favour a transparent process for access to data and enhance accountability of downstream researchers to the trustees.

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[879] R*e Resch's Will Trusts* [1969] A.C.1 514.

[880] In Nigeria see for example, Section 17 Capital Gains Tax Act, Cap C1, Laws of the Federation of Nigeria, 2004 states that donations made by companies for charitable purposes are deductible from the income of companies for the purposes of tax computations. See Section 21(5)(e) of the Companies Income Tax Act Cap. C 21, Laws of Federation of Nigeria, 2004. Charitable trusts are in some cases either wholly or partly exempted from stamp duties.

[881] Boggio, A. (2005). Charitable trusts and human research genetic databases: the way forward? Life Sciences Society and Policy, 1(2), 41 at 44.

The third advantage favours the participation of different interest groups in deciding the fate of stored tissue.[882] This would also help to mediate among diverse interests implicated by the research.[883] The creation of a trust establishes a fiduciary relationship in which a trustee holds title to property subject to an equitable obligation to keep or use the property for specified charitable purposes. In spite of the advantages outlined in the preceding paragraph, the- charitable trust model has its limitations.

5.7.3 Fiduciary obligations of the trustee

A fiduciary obligation is one owed to another person to act with loyalty and good faith in dealings which affect the person. A person who owes a fiduciary obligation is called a fiduciary and the one who is owed the duty is called the principal. In the words of Millet LJ in *Bristol and West Building Society v Mathew*:

> 'A fiduciary is someone who has undertaken to act for or on behalf of another in a particular matter in circumstances which give rise to a relationship of trust and confidence. The distinguishing obligation of a fiduciary is the obligation of loyalty. The principal is entitled to the single-minded loyalty of his fiduciary. This core liability has several facets. A fiduciary must act in good faith; he must not make a profit out of his trust; he must not place himself in a position where his duty and his interest may conflict; he may not act for his own benefit or the benefit of a third person without the informed consent of his principal'.[884]

The trustee/beneficiary relationship exemplifies the fiduciary relationship. The fiduciary obligation to act with loyalty and in good faith implies that the fiduciary must act solely with the interests of his principal in mind. According to Penner,[885] fiduciary law is the origin in modern society of the legal notion of conflict of interest. A fiduciary must not only act so as not to favour his own interest over that of his principal, but must also avoid putting himself in positions of conflicts of interests. A fiduciary obligation as described above is different from contractual obligations in the sense that contractual parties are simply required to comply with their contractual obligations and are not required to act selflessly. What they owe each other is mainly in relation to the terms of the contract. Strictly defined, a fiduciary relationship exists:

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[882] Ibid.

[883] Winickoff, D. E., & Neumann, L. B. (2005). Towards a social contract for genomics: Property and the public in the 'biotrust' model. *Life Sciences Society and Policy*, 1(3), 8 at 12.

[884] *Bristol and West Building Society v. Mothew* [1998] Ch 1.

[885] Penner, J. (2014). *The Law of Trusts.* Oxford University Press.

> 'Whenever any person acquires a power of any type on condition that he also receives with it a duty to utilize that power in the best interest of another and the recipient of the power uses that power. The essence of this theory of fiduciary relationship is that powers are specie of property, which can be beneficially owned by another person who may be referred to as the legal owner of the power'.[886]

A fiduciary relationship exists when one party, the fiduciary, agrees to undertake legal authority to affect the legal position of another. Fiduciaries cannot perform their duties unless they are entrusted with the property or power to do so. In the context of biobank research, a tissue source may, through the process of informed consent, give power to the biobank to conduct research on his tissue and use his medical records and or any other associated data. In this situation the fiduciary has discretion in the way he will exercise these legal powers.

A fiduciary is both a legal and ethical relationship of trust between two or more parties. Traditionally, the courts have developed fiduciary relationships by defining some relations as fiduciary and designing rules for these relations. The definitions proffered for fiduciaries merely describe the arrangements that the parties establish and bring before the courts. For example, a trust is defined as a fiduciary relation in which property is transferred to the trustee.[887] In a trustee/beneficiary relationship, the trustee is free from the beneficiary's control, and their consent is not necessary to establish the relationship.

Agency, another fiduciary relationship, is defined as a consensual arrangement under which one party acts on behalf of another, subject to the other's control. Fiduciary relationships arise in various forms including, but not limited to: trustees, agents, directors, partners, trustees, bailees and administrators. Fiduciaries are found in many areas of the law, such as criminal law, corporate law, health law, labour law, contract and the law of trusts. The various types of fiduciaries and the rules that govern them are similar, yet there are marked differences among them.[888] The differences and similarities among fiduciaries are complicated by the fact that they evolved separately over time and because they evolved over time, the class of fiduciaries is not closed. Whilst the

[886] Shepherd, J. C. (1981). *The law of fiduciaries*. Carswell Company at 35-36.
[887] Scott, A.W., & Fratcher, W. F. (2000). *Scott on Trusts*. Aspen Publishers.
[888] Frankel, T. (1983). Fiduciary law. *California Law Review*, 795-836.

above named examples are classic cases of fiduciary relationships, the concept has been stretched to cover cases[889] not mentioned above. The twentieth century has, for instance witnessed an unprecedented expansion of the fiduciaries and fiduciary law.[890]

5.7.4 Applying a charitable trust framework to population biobanks

According to the information booklet of the UK Biobank,[891] its purpose is to set up a resource that can support a diverse range of research intended to improve the prevention, diagnosis and treatment of illness, and the promotion of health throughout society. Given that the focus of the UK biobank, as an example of a population biobank, it can be argued that population biobanks can be classified as trusts for the advancement of education or trust for other purposes beneficial to the community. A trust for the advancement of Education conventional education, therefore, trusts for schools, colleges and universities are valid. Education in the charitable sense is not limited to teaching activities. Trusts for the advancement of education also include research, as long as the subject is useful and the gift makes some requirement that the information be made available to others and disseminated. In Re Hopkins,[892] a gift was given to the Francis Bacon Society to find proof that William Shakespeare's plays were written by Bacon. Wilberforce J held that it was a valid gift, as 'the discovery would be of the highest value to history and to literature'[893]. He also gave the definition of research required for a gift to be valid:

> The word education must be used in a wide sense, certainly extending beyond teaching, and the requirement is that, in order to be charitable, research must either be of educational value to the researcher or must be so directed as to lead to something which will pass into the store of educational material, or so as to improve the sum of communicable knowledge in an area which education must cover - education in this last context extending to the formation of literary taste and appreciation'.

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[889] *Reading v. Attorney General* [1951] A.C. 507.

[890] Ibid 796.

[891] Last accessed 27/04/2015 from www.ukbiobank.ac.uk/wpcontent/uploads/2011/06/Participant_information_leaflet.pdf?phpMyAdmin=trmKQlYdjjnQIgJ%2CfAzikMhEnx6

[892] *Re Hopkins* [1965] Ch 669.

[893] Op cit at 675

This definition was expanded on by Slade J in McGovern v Attorney General,[894] where he said that:

> 'A trust for research will ordinarily qualify as a charitable trust if, but only if (a) the subject matter of the proposed research is a useful object of study; and (b) if it is contemplated that the knowledge acquired as a result of the research will be disseminated to others; and (c) the trust is for the benefit of the public, or a sufficiently important section of the public.
>
> (2) In the absence of such a contrary context, however, the court will be readily inclined to construe a trust for research as importing subsequent dissemination of the results thereof. Furthermore, if a trust for research is to constitute a valid trust for the advancement of education, it is not necessary either (a) that the teacher/pupil relationship should be in contemplation, or (b) that the persons to benefit from the knowledge to be acquired should be persons who are already in the course of receiving an education in the conventional sense'.

The UK Charities Act 2011, at S.3 (1) d, includes advancing health and saving lives as a charitable purpose. The Act also states that advancing health includes the purpose of preventing and relieving sickness, disease or human suffering. Gifts to hospitals and similar institutions have been judicially recognised as falling under the head of trust for the relief of poverty.[895] The reference to the advancement of health under this section includes the prevention of diseases.[896] According to Hudson,[897] research into medical procedures would ordinarily fall under educational purposes therefore 'it is supposed that this category is aimed at other purposes'.[898] The advancement of health can encompass many activities including biobanking research. The fact that population biobanks provide samples and data for secondary research means that they can be trusts for the advancement of education. The term education includes research.[899] A number of research trusts have been found to be charitable.

Population biobanks can also qualify as charitable trust under the *Pemsel* head of trusts for other purposes beneficial to the community. This is because biobanking research can

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[894] *McGovern v. Attorney General*, 1982 Ch 321 at 352-353

[896] Charities Act 2011, s3(2)(b)

[897] Hudson, A. (2012). *Equity and trusts*. Routledge

[898] Ibid 1148

[899] *McGovern v. Attorney General* [1982] Ch 321.

be said to have purposes that are both charitable,[900] and beneficial to the community. There are very strong reasons for concluding that population biobanks have a charitable purpose. Apart from the fact that population biobanks can be classified as trusts for the advancement of education, the fact that they have the potential to provide therapies for a wide range of diseases, for people from diverse backgrounds and that they are research platforms for research they also qualify as trusts for other purposes beneficial to the community,

5.7.5 Advantages of charitable trust approach

One of the benefits of using a charitable trust model in biobanking governance is that it provides a legal mechanism for the regulation and enforcement of the concepts of custodianship and stewardship.[901] The charitable trust model gives a legal backing to these ethical standards and concepts. This is achievable by giving the tissue source an interest in the management of the trust and it also gives him an opportunity to approach the courts if there are concerns about breaches. The charitable trust provides a robust and flexible tool of governance for biobanking because it recognises the legal ownership interests of the biobank and its capacity to deal with the resources even commercially in accordance with the terms of the trust. Where a biobank adopts and encourages other charitable trust forms such as the DAC as suggested by Winickoff, or the dynamic mode of consent, tissue sources will have the benefit of greater involvement in how their samples and data are used in future unspecified research. Whichever form is adopted a continued and involving relationship with the tissue source will no doubt reduce the dilemmas of consent to future unspecified research. The charitable trust model is also of benefit to the biobank in the sense that the biobank can operate as a profit making venture whilst retaining its charitable status. Where circumstances change and the biobank requires change to its focus, it can apply to the court to amend its operation using the *cy pres* doctrine.

The charitable trust model accommodates the peculiarity and the need for biobanks to relate to other researchers as a sharing platform. Trustees offer services that are socially

[900] *AG v National Provincial and Union Bank of England* (1924) A.C. 262

[901] Stewart, C.,Apacio, L., Lipworth, A.,(2014). Public UCB Banking and charitable trusts in (2014) Persons, Parts and Property: How Should We Regulate Human Tissue in the 21st Century? Edited by Imogen Goold, Kate Greasley, Jonathan Herring, and Loane Skene, Oxford: Hart Publishing, at 64

important such as that of a biobank. They are also generally costly to acquire, drawing on significant ability and investment of time and money. Therefore, it is in the interest of society that non-experts such as the tissue source use the services of these trustees and avoid mayhem through wasteful duplication of these services. In the case of biobank research, it makes no sense for every tissue source to deal with each and every prospective future researcher who will conduct research on his sample or data. It is more desirable for the tissue source to rely on the biobanks to provide the platforms for using the samples and data. In other words biobanks and downstream researchers should be empowered by an appropriate consent mechanism to work on the tissue and data.

Another benefit of the charitable trust model is that the Attorney General and the Supreme Court both have power to supervise and manage the trust, as a way of protecting the interests of the public. The charitable trust also protects the interests of the biobank by recognising the biobank's legal ownership of the tissue and its capacity to use the tissue commercially in accordance with the terms of the trust.

5.7.6 Limitations

The cost of adopting this model is that there will be need for more oversight and accountability and this may add to the running costs of the organisation. Charitable trusts are subject to reporting and accounting requirements, but this should not be greater than the reporting requirements that the biobanks already face.

The charitable trust model does not adequately address the controversial issues relating to ownership of the samples and data. Under a trust agreement, the settlor in this case the tissue source would formally express his desire to transfer his interest in the samples to the trust. In other words, this model as designed by Winickoff and Winickoff assigns the property right in samples to the trust, thus assuming that owning human material is legally admissible, whereas, the recognition of property rights in the tissue is controversial. Therefore, in the words of Boggio:

> the charitable trust model might not be compatible with many legal systems to the extent that it requires a formal recognition of property in the body. Alternatively, in order to avoid the intricate question of whether donated tissue becomes the property of the recipient or the participant in biomedical research,

> commentators and policymakers have proposed the less drastic arrangement of 'custodianship' or 'stewardship'.[902]

This section has argued that biobanking research practices need to incorporate the concepts of stewardship into their governance mechanism using the tool of charitable trust. The charitable trust has the ability to balance both public and private interests of biobanking. While it does not solve all the ethical problems of biobanking research a charitable trust is the most suitable mechanism for introducing and enforcing the fiduciary obligations of a biobank.

5.8 Conclusion

In most first generation biobank research, the burden of stewarding the samples fell on the Principal investigator (PI) or the institution and this was achieved by trust and faithfulness to the terms of the informed consent and the adoption of data protection methods of anonymisation. However with the retention of identifying data, data sharing, and the open-ended nature of biobank research commitment, biobank research requires far more commitment to stewardship and researcher accountability than first generation research. Legal and ethical principles should be incorporated into the governance schemes for biobank research. These principles include respecting the autonomy of the tissue source and protecting it from privacy and confidentiality breaches. A framework for biobank research should then take the form of a process that considers the values, hopes and concerns of all stakeholders involved.

Secondly, the legal framework should also provide for legally binding rights and obligations between all stakeholders in biobank research. This would also enable a more effective system than broad consent has for obtaining consent. The framework also accommodates legal solutions that adapt the consent process using the notion of dynamic consent and find a halfway house between the legal regulatory models of consent to institutions through the concept of stewardship.

The charitable trust model attempts to create a framework for these aspirations. It is an attempt to create an elusive balance between respecting the right to choice of the tissue

[902] Boggio, A. (2005). Charitable trusts and human research genetic databases: the way forward? *Life Sciences Society and Policy*, 1(2), 41 at 45.

source and generating public value; this balance has been unsettled by the new ways of conducting research. In accomplishing this, the charitable trust model gives legal identity to the relationship between the biobank, downstream researchers and the tissue source. A notion of stewardship that is perhaps apt and relevant to biobanking is one that signifies a legal duty towards the tissue source.[903]

[903] Brownsword, R. (2009). Rights, responsibility and stewardship: beyond consent. In Widdows, H., & Mullen, C. (Eds.). *The governance of genetic information: who decides?* Cambridge University Press. 99-125 at 117-120

6. Conclusion

Throughout the thesis, I have argued that engaging the tissue source in the decision making process relating to future use of their samples and data in future unspecified research is an essential aspect of biobank research and its governance. This argument is rooted in the concept of consent which, as I have argued, is linked with other concepts and themes such as expressing choice and expressing self-determination in relation to research, rights to privacy, right to make choices autonomy and recognition of property rights in tissue. Autonomy and the right to make decisions in relation to one's self and body connote an involvement in decision making processes. This is further linked to participation in decision making of future use of excised tissue in biobank research. Indeed these themes and concepts are informed by ethical and legal considerations of equity, justice, inclusiveness and participation that seek to give a voice to the tissue source in matters of genomic research.

I have also argued that a charitable trust model based on a concept of stewardship reflects a number of key themes that have been discussed throughout the thesis, particularly inclusiveness based on autonomy and privacy, and participation based on recognising property rights in tissue inspired by the ideals of consent. Along with this, a shift to a more duty-oriented model of governance which has the potential to redistribute power has been suggested. This however requires a commitment from those responsible for governance and decision making in biobank research.

The main issue that this thesis discusses is the recognition of the interest and right of the tissue source to having a say in how his samples and data are used in future unspecified research. To assist in this, the following research questions served as a guide to framing the enquiry and focus on future unspecified use of tissue in biobank research:

- What is the nature of the relationship between the biobank, the researchers, and the tissue source?

- Does the legal concept of informed consent and more specifically broad consent protect the interest of the tissue source in future unspecified biobank research?
- Can the tissue source's right to have a say in the secondary use of the tissue be protected?
- If so, can such protection be based on the recognition of tissue as property?
- Is the interest of the tissue source in not having the sample and associated data used in future unspecified research a protectable privacy right in law?
- Is the tissue source entitled to ground a property right claim on excised tissue within the context of biobank research?
- What role can stewardship and custodianship serve in engaging individual participation as an aspect of biobank governance within a charitable trust model?

The analysis of the first question necessitated an examination of consent in biobanking research, as well as an overview of the concept of biobanking in Chapters 1 and 2. In conducting this analysis the chapters examined the challenges that biobank research presents to the concept of informed consent, the concept of consent and informed consent, and the ideals of informed consent as a tool for ensuring autonomous choice of a research participant.

This analysis led to the conclusion that broad consent does not adequately fit into the mould of informed consent and it does not ensure the right of the tissue source to having a say in future unspecified research. However since the essence of the question revolves around the tissue source and them having a say in how their tissue is used in future research, the dynamic model of consent as opposed to use of broad consent in biobanking research was found to be more instructive in this regard.

The criticism presented against a dynamic consent model was raised in Chapter 2, the main one being that tissue sources will be asked to re-consent over and over again, for both trivial and essential reasons. The consequences of this could either be that people will become reluctant to participate in biobanking research, or they will participate with

a degree of reluctance. These consequences may in turn affect participation in research. However according to Steinsbekk et al.,[904] the opposite is the case. Participants, who do not use this opportunity of exercising their potential power of choice in research, rather experience that they fall short on the implicit demands of participation. In spite of this criticism of dynamic consent, this thesis argues that since dynamic consent will enable the participation of the tissue source in deciding how tissue is used in future research, they need to engage in the decision making process. Secondly the utility of the recognition of the right of tissue sources to having a say in future research is better served using a dynamic consent model because of the opportunity for participation in decision making that it avails the tissue source. The chapter concludes that broad consent does not protect the interest of the tissue source in future unspecified biobank research.

Having concluded that broad consent does not adequately protect the right of the tissue source to have a say in future unspecified research, the thesis goes on to enquire about other means of ascertaining that the interests of the source in future uses are protected. As biobanking research increases, public health genetic information will accumulate about the genomes of individuals and groups. This information will most likely have a far-reaching impact on these individuals and groups in question, and according to Rothstein[905], if they are to cooperate freely in the development and use of this information, they should have assurance about how the information will be used and who will have access to it.

This position formed the basis of the enquiry of the second research question: Is the interest of the tissue source in not having his sample and associated data used in future unspecified research a protectable privacy interest in law? An examination of this question involved engaging in a discussion of the concept of privacy and confidentiality of data of tissue sources in future uses by later researchers. The thesis examined privacy from several angles and concluded that the entitlement of the tissue source to non-

[904] Steinsbekk, K. S., Myskja, B. K., & Solberg, B. (2013). Broad consent versus dynamic consent in biobank research: Is passive participation an ethical problem. *European Journal of Human Genetics*, 21(9), 897-902.
[905] Rothstein, M. A. (1997). Genetic secrets: a policy framework. *Genetic secrets: Protecting privacy and confidentiality in the genetic era*, 451-495.

consensual secondary use of his samples and data is a protectable privacy entitlement that can engage Art. 8 of the ECHR. Though an argument was made for the protection of the privacy and confidentiality of information of the tissue source, the discussion revolved around recognising the right of the tissue source on the grounds of privacy to having a say in future unspecified use of his tissue in biobanking research. It was argued that recognising an entitlement to privacy protection of the samples and data of the tissue source gives an element of control to the tissue source that would enable him have a say in future use of his sample and data.

Whilst acknowledging that there are limitations to privacy protection, an entitlement to informational privacy and confidentiality of information will serve as a yardstick for measuring the boundaries of informational infractions by researchers and form the basis of asserting control over future use of data and samples of the tissue source. Following an examination of cases in Chapter 2, as well as an examination of provisions of the ECHR and the UDHR, the thesis concluded that on the whole, privacy is a protectable interest and that it can be infringed, especially when it is related to identifiable people.

In the enquiry into the protection of the tissue source and future uses of his sample and data the thesis questioned the use of property rights as a means of giving control and protecting the tissue source. Chapter 4 examined the meanings of property and concluded that excised human biological material may be recognised as property under a reified understanding of property because it is tangible and therefore physical. However, because the focus of the thesis was mainly on the recognition of entitlements of the tissue source, the bundle of rights perspective was found to be more appropriate. This theory offers better protection to the tissue source's interests in comparison to the reified theory in terms of the empowerment that it will potentially give to a source in controlling what happens to their excised biological material as well as the greater flexibility that it offers. An entitlement could potentially qualify as a property interest and a stick in the property bundle under a bundle of rights conception of property, even if it does not constitute full ownership. Similarly, the interest of the tissue source can qualify as property interests because they are entitlements within the ownership spectrum. Even though *Yearworth* related to gametes, the thesis notes it was the opinion of the Court there was a need for a change in the judiciary's approach in its treatment of

excised human biological tissue, and argues that there is no justification for refusing to recognise ownership entitlements of the tissue source.

As noted in Chapter 5, the more involved approach to governance of the stewardship model reflects a number of issues that have been proposed in the thesis: especially participation and involvement in decisions relating to future use of the tissue by the tissue source, which is inspired by legal essence of the doctrine of consent. This engaging approach of the stewardship approach through the machinery of the institution of trusts envisions a relationship between biobanks and researchers and the tissue source; a relationship that engenders a continuing process of communication and in turn gives the tissue source a chance to make a choice about whether or not to enrol in future research.

A move to a more research participant-focussed model of governance has the potential to redistribute decision making powers between the biobanks and the tissue source. If a stewardship model is adopted then ensuring participation by the tissue source becomes an aspect of the duty of biobanks towards the tissue source. In the light of the relatively young age of biobanks and biobanking research in Nigeria, it may be necessary in the near future for there to be some form of regulation that creates a statutory duty to recognise the rights of the tissue source to privacy and autonomy in relation to future research.

I am mindful of the opinions of Flear and Vakulenko[906] 'that human rights helps to combat popular fears that new technologies move at a pace that law and morality find hard to match', but while the law may lag behind science and technology, one of the ways to keep abreast of changes that meet the needs of evolving science is to ensure participation by the tissue source.

[906] Flear, M. L., & Vakulenko, A. (2010). A human rights perspective on citizen participation in the EU's governance of new technologies. *Human Rights Law Review*, 10(4), 661-688 at 662.

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