**Participant Information Sheet**

***[Guidance to researchers: Please delete all wording in red italics which is provided for guidance. All wording in black is preferred wording that should remain unchanged wherever possible. (RIG PIS template: effective from 20th Jul 2018)]***

**Study Title**:

**Researcher**:

**ERGO number:**

You are being invited to take part in the above research study. To help you decide whether you would like to take part or not, it is important that you understand why the research is being done and what it will involve. Please read the information below carefully and ask questions if anything is not clear or you would like more information before you decide to take part in this research. You may like to discuss it with others but it is up to you to decide whether or not to take part. If you are happy to participate you will be asked to sign a consent form.

**What is the research about?**

*State if this is a student project or if you are working towards an academic qualification. Give a brief summary of who you are and why you are doing the research. What questions are you asking, and why, what is the objective and the expected outcomes of the research? If the research is externally funded (not self-funded) you may wish to state who is funding the study. Studies submitted on IRAS for HRA and/or REC (or MODREC) approval should include details of the research Sponsor.*

**Why have I been asked to participate?**

*Potential participants should know the reason why they have been approached and how many participants will be in the study. You should be careful to avoid any wording that could be coercive.*

**What will happen to me if I take part?**

*To help you write this section, consider what you would like to know if you were invited to take part in a study.*

*This section should state who will do what, what activities participants will be expected to do and in what sequence (e.g. lifestyle changes, diet, keeping diaries, completing questionnaires, measurements and biological samples taken). You should make clear the full extent of the involvement (e.g. how long the participant will be involved, how many visits, who they will need to meet with and where and whether there will be a follow up or if they will be contacted again). It is important to use this section to give potential participants an idea of the burden and the amount of time or commitment that will be expected from them. Tell them how long the research project is expected to last if this is different from the length of their involvement. Use diagrams or flow charts if this will make it easier to understand.*

*State here if you intend to audio- or video-record any part of the research process. You should state the reason for the recordings and how they will be used. State whether the recordings are optional or required for participation. Your consent form will require specific consent for these recordings.*

*You should state in simple terms the research methods that will be used.*

*For healthcare studies, it should be clear if any procedures will be over and above standard care, whether any normal treatment would be withheld during any part of the study and if there will be any long-term monitoring. Explain the reason for taking any biological samples, scans or measurements. Explain how health related information from tests/diagnostics will be used.*

**Are there any benefits in my taking part?**

*In this section state the potential benefits to the individual participant. There may be no direct benefit to the participant and this should be made clear if that is the case However, there may be a benefit to others perhaps, or the study may help improve our current understanding of the area.*

*You should state here if any reimbursements for participation will be provided e.g. travel expenses, vouchers to say thank you for participating.*

**Are there any risks involved?**

*State all risks however small. Risks involved in any invasive technique (e.g. taking blood) should be clear and comprehensive. Do not alarm the reader, but ensure they are properly informed. Consider any physical risks such as side effects or injury. If the study is exploring sensitive or personal issues there could be the possibility of psychological discomfort or distress which should also be included here. You should mention any support services that will be made available to participants who may become distressed either during or following their involvement in the study.*

**What data will be collected?**

*State here exactly what data will be collected, how this will be collected and by whom. You should be clear if you are collecting any personal information, for what purpose and how this will be managed (e.g. are any databases used, are any third parties involved such as labs etc).*

*You must state clearly if you will collect and/or use any personal data that is special category data according to Data Protection (this includes information on ethnicity; sexual orientation; gender identity; religious beliefs; genetic data; biometric data from which you can be uniquely identified; and health data).*

*You must provide details on how personal data will be handled securely, during collection, analysis, storage and transfer e.g. using encryption and password protected access, or lockable cabinets for hard data; personal data and consent forms may be kept separate from non-identifiable data; coding might be used to reduce the risk of identification.*

*You may also need to store contact details for the duration of the study, for example, to allow the study team to maintain contact with participants during the study. If so, please state this and provide as much detail as possible.*

*For healthcare studies you should include a section on how biological samples will be handled. In simple terms, explain how samples will be processed, stored, analysed and what will happen to unused samples.*

**Will my participation be confidential?**

Your participation and the information we collect about you during the course of the research will be kept strictly confidential.

Only members of the research team and responsible members of the University of Southampton may be given access to data about you for monitoring purposes and/or to carry out an audit of the study to ensure that the research is complying with applicable regulations. Individuals from regulatory authorities (people who check that we are carrying out the study correctly) may require access to your data. All of these people have a duty to keep your information, as a research participant, strictly confidential.

*Here you should explain what arrangements have been made to ensure their participation will be kept confidential and include details on how the information you hold (including consent forms) will be stored safely and in what format the data will be held e.g. electronic data will be encrypted and password protected and any other relevant security processes. If audio or visual recordings are being made, you should state the process for keeping these confidential. The University would normally expect recordings to be transcribed and the recordings to be destroyed which should be stated in this section. If recordings are required to be retained, you should state for what reason, how they will be kept secure and when they will be destroyed.*

*If it is not possible to safeguard the confidentiality of the data, due to the nature of the research, the reasons for this must be made clear along with any potential consequences to the participant.*

*Provide information on who will have access to the data and for what purposes, e.g. supervisors for student projects, GP for health and care research.*

*You should also include information on any third parties who may be involved in carrying out activities for the study.*

*For clinical studies, if you are not part of the clinical care team of patients, you cannot access their medical notes for research without their consent. If you are intending to check contact details or health status in future (e.g. for follow up) using NHS Digital then state this.*

*If you intend to ask to retain participant’s contact details for future research please state this clearly here and the purposes for which they may be contacted (in relation to what types of studies), along with your arrangements for the recording and storage of these details on a registry or database. It is preferable that a separate consent form should be used for this with a PIS specific for the contact list/registry/database.*

**Do I have to take part?**

No, it is entirely up to you to decide whether or not to take part. If you decide you want to take part, you will need to sign a consent form to show you have agreed to take part.

*Tell the potential participant how to inform the researcher they want to take part. If you are using ‘opt-out’ consent ensure you state this clearly here.*

**What happens if I change my mind?**

You have the right to change your mind and withdraw at any time without giving a reason and without your participant rights *(or routine care if a patient)* being affected.

*Provide information on how they can withdraw, e.g. by providing a contact.*

*If there is a point up to which data can be withdrawn/destroyed please ensure you state this here.*

*Please note that anonymous data (e.g. anonymous questionnaires) cannot be withdrawn after they have been submitted. If someone withdraws part way through the research process, e.g. during an interview, you must consider whether you are able to (or intend to) destroy any data collected up to this point. Be mindful of situations in which this is impossible, e.g. audio-recorded focus groups.*

*If at the point of withdrawal, you cannot remove the data or if removal will be detrimental to the objectives of the research, you may use the following wording (in accordance with the GDPR exemption for research):*

If you withdraw from the study, we will keep the information about you that we have already obtained for the purposes of achieving the objectives of the study only.

**What will happen to the results of the research?**

Your personal details will remain strictly confidential. Research findings made available in any reports or publications will not include information that can directly identify you without your specific consent.

*You should explain what will happen to the results. Will the project be written up or published? Will the participant receive a copy of the results? You should use the wording above if their personal details will remain strictly confidential and if they will not be directly identifiable from any report or publication unless they have given specific consent for this. If you cannot assure this you must state this here with an explanation why.*

*If you wish to use the data for future studies you must include the following:*

* *Explain the benefits of data sharing indicating whether research data will be deposited in a data repository, naming the organisation responsible for holding the data*
* *In what form will the data be held e.g. anonymised transcripts, audio recordings, survey database, unlinked data*
* *Specify where will the data be held, will a repository be used*
* *Specify whether the data will be anonymised and how*
* *Specify whether use or access restrictions will apply to the data in the future e.g. exclude commercial use, safeguarded access*
* *Provide contact details of the researcher and institution and how to file a complaint*

**Where can I get more information?**

*Provide contact details of anyone in the research team who could answer any questions that a potential participant may have after reading this information sheet. You should use University contact details and not personal phone numbers or email addresses.*

**What happens if there is a problem?**

If you have a concern about any aspect of this study, you should speak to the researchers who will do their best to answer your questions.

If you remain unhappy or have a complaint about any aspect of this study, please contact the University of Southampton Research Integrity and Governance Manager (023 8059 5058, [rgoinfo@soton.ac.uk](mailto:rgoinfo@soton.ac.uk)).

*Please include contact details of the research team.*

*For clinical research please ensure you include the details of the sponsor here. It is also helpful to reference NHS complaints procedures e.g. provide details of PALS or Patient Information Service.*

**Data Protection Privacy Notice**

The University of Southampton conducts research to the highest standards of research integrity. As a publicly-funded organisation, the University has to ensure that it is in the public interest when we use personally-identifiable information about people who have agreed to take part in research. This means that when you agree to take part in a research study, we will use information about you in the ways needed, and for the purposes specified, to conduct and complete the research project. Under data protection law, ‘Personal data’ means any information that relates to and is capable of identifying a living individual. The University’s data protection policy governing the use of personal data by the University can be found on its website (<https://www.southampton.ac.uk/legalservices/what-we-do/data-protection-and-foi.page>).

This Participant Information Sheet tells you what data will be collected for this project and whether this includes any personal data. Please ask the research team if you have any questions or are unclear what data is being collected about you.

Our privacy notice for research participants provides more information on how the University of Southampton collects and uses your personal data when you take part in one of our research projects and can be found at <http://www.southampton.ac.uk/assets/sharepoint/intranet/ls/Public/Research%20and%20Integrity%20Privacy%20Notice/Privacy%20Notice%20for%20Research%20Participants.pdf>

Any personal data we collect in this study will be used only for the purposes of carrying out our research and will be handled according to the University’s policies in line with data protection law. If any personal data is used from which you can be identified directly, it will not be disclosed to anyone else without your consent unless the University of Southampton is required by law to disclose it.

Data protection law requires us to have a valid legal reason (‘lawful basis’) to process and use your Personal data. The lawful basis for processing personal information in this research study is for the performance of a task carried out in the public interest. Personal data collected for research will not be used for any other purpose.

For the purposes of data protection law, the University of Southampton is the ‘Data Controller’ for this study, which means that we are responsible for looking after your information and using it properly. The University of Southampton will keep identifiable information about you for xx years after the study has finished after which time any link between you and your information will be removed.

*For studies involving other recruitment sites the following information must be included:*

*[NHS/ other site] will keep identifiable information about you from this study [for x years after the study has finished/ until x]*

To safeguard your rights, we will use the minimum personal data necessary to achieve our research study objectives. Your data protection rights – such as to access, change, or transfer such information - may be limited, however, in order for the research output to be reliable and accurate. The University will not do anything with your personal data that you would not reasonably expect.

If you have any questions about how your personal data is used, or wish to exercise any of your rights, please consult the University’s data protection webpage (https://www.southampton.ac.uk/legalservices/what-we-do/data-protection-and-foi.page) where you can make a request using our online form. If you need further assistance, please contact the University’s Data Protection Officer ([data.protection@soton.ac.uk](mailto:data.protection@soton.ac.uk)).

*Please refer to the University data management policy to determine how long you can keep data (*[*http://www.calendar.soton.ac.uk/sectionIV/research-data-management.html*](http://www.calendar.soton.ac.uk/sectionIV/research-data-management.html)

*The standard retention period is 10 years but this may be longer depending on funding and regulatory requirements or shorter for undergraduate projects- please amend the number of years in the paragraph above as necessary. You should also include details of any collaborators who may also be considered as Data Controllers (i.e. jointly agreeing the purposes, responsibilities and means of the processing of personal data as part of your study).*

*(You should add details of any 3rd parties who will be data processors i.e. those that will have access to personal data, including the reasons for their access and any further usage of participants’ data that they will carry out as related to this study (broad examples are useful). State if you will be obtaining personal data from a publicly accessible source (e.g. NHS Digital).).*

*Please state whether any data will be anonymised or pseudonymised.*

* *Anonymised data, is when all personal data is deleted and is no longer accessible and therefore the research data cannot be traced back to an individual. Anonymity can only be guaranteed if participants can no longer be singled out from the research data. Be particularly careful not to assure anonymisation of data in situations where individuals may be indirectly identifiable via recordings (e.g. focus groups or procedures involving face-to-face contact or video recording, etc.) or through small data sets.*

*Data that has been pseudonymised through key-coding and removal of personal identifiers still falls within the scope of the GDPR. This is because the data that allows identification of that person still exists, just not all in one place. Pseudonymised data can help reduce privacy risks by making it more difficult to identify individuals, but it is still personal data. If you are using pseudonymisation, i.e. linking data using a code, this should be explained with details on who can access the codes so as to enable an individual to be identified.*

**Thank you.**

*Thank the individual for taking the time to read the information sheet and considering taking part in the research.*