

Participant Information Sheet

Study title: Development of a System for Measurement of Total Free Thiols – v1.0

Principal Investigator: Prof. Xize Niu – x.niu@soton.ac.uk

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ERGO number: 68007

IRAS number: 307839

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?

This research project is funded by the University of Southampton as part of a PhD project being conducted by Liam Carter. We will be developing a system which can take a small finger-prick blood sample and rapidly process it, to provide a measurement of total free thiols (TFT's), which are one of the body's antioxidant defence mechanisms and have important signalling and regulatory roles.

Measurement of TFT's has shown correlations with disease severity in numerous diseases including COVID-19 and sepsis, however, the manually intensive lab work required to measure TFT's has limited their use in practical medicine. Additionally, monitoring the dynamic behaviour of TFT's will provide greater insight into the body's antioxidant defence systems and how they react to disease or treatment progression than single measurements alone, however with existing testing methodologies this is difficult to do; further demonstrating the potential use of a rapid point-of-care system.

The development of this rapid, point-of-care system for measuring TFT's will enable increased research into the body's antioxidant defence systems, the impact of diseases on them and the effectiveness of treatments, ultimately leading to improved medical care. With future developments the system could be used as a routine diagnostic test in medical practice.

Why have I been asked to participate?

We require healthy volunteers to donate blood samples to be used in the development of our point-of-care system. Up to 50 people will be participating in this study.

What will happen to me if I take part?

You will donate up to 20ml of blood through venepuncture and/or up to 6 finger-prick blood samples, this will be conducted on a timescale to suit you, either being completed within 1 hour or spread over a longer time of up to 12 hours, during which you will be free to leave between sampling points. Blood samples will be taken at the University Hospital of Southampton site, finger prick samples will be taken either at the University of Southampton or the University Hospital Southampton site. You may return at a later date to donate further blood samples if you wish to do so. These blood samples will be used over the next 2-3 years to develop and test our measurement system.

Are there any benefits in my taking part?

There are unlikely to be any direct benefits to an individual participating in this study, however the work conducted may help improve medical practice in the future.

Are there any risks involved?

Drawing blood may cause some bruising, light pain, dizziness/light-headedness or very rarely a localised infection.

What data will be collected?

We will collect and store your consent form and a screening form to confirm you are eligible for the study; these will be held within a locked cabinet in a locked office at the University of Southampton. Blood samples will be pseudonymised, a process where the samples are labelled with a non-personal identification code, which can only be linked back to your personal data using a key, which will be stored securely in a separate location. Samples will either be used immediately or placed into appropriate cold storage in access-controlled labs at the University of Southampton. These blood samples will be separated, the plasma or serum collected and analysed using various tests, and the remaining blood products destroyed. All blood samples will be destroyed at the end of this study. Any published results from this testing will be anonymised.

If you agree the research team may store unused samples for use in future research projects. These projects would be conducted by the same research group using similar techniques to those proposed in this study, with slight modifications to allow the measurement of different compounds in the samples. All samples will remain pseudonymised and will not be used outside of the research group. This is optional, and you may indicate your preference on the consent form.

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.

All data collected will be securely stored at the University of Southampton or on University of Southampton password protected computers. Blood samples will be pseudonymised before analysis and any published data will be anonymous.

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 (TFT_Consent_Form_v1.0, 2021-11-23) to show you have agreed to take part. Please contact the research team to proceed (liam.carter@soton.ac.uk)

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 being affected. Please contact the research team (liam.carter@soton.ac.uk) at any time to withdraw your consent. 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?

The results from this study will be published in scientific journals and form part of a PhD thesis. 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.

Where can I get more information?

Please contact liam.carter@soton.ac.uk for any further information.

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. Please contact liam.carter@soton.ac.uk.

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).

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/Is/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 up to 10 years after the study has finished after which time any link between you and your information will be removed.

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).

Thank you.

Thank you for reading this information sheet and considering participating in this research study. Should you wish to proceed please let a member of the research team know or contact liam.carter@soton.ac.uk and they can arrange for a consent form to be signed.