Participant Information Sheet

PROJECT TITLE: Improving Genotyping for Precision Medicine

HUMAN RESEARCH ETHICS COMMITTEE APPROVAL NUMBER: H-2020-34767

PRINCIPAL INVESTIGATOR: Martin Lewis.

STUDENT RESEARCHER: Kiflu Tesfamicael

STUDENT'S DEGREE: PhD

Dear Participant,

You are invited to participate in the research project described below.

What is the project about?

This research project is concerned with personalised or precision medicine, where an individual's genetics are used to guide the selection of suitable medications. A person's genotype or genetic variations can be measured using a range of technologies. This research project will apply new third generation DNA sequencing technologies to genotype up to 200 people. The aim is to test the accuracy and efficiency of the new technologies compared with those currently used. The objective is to see which of the new technologies are best suited for future genotyping. Precision prescriptions may reduce side-effects and or increase symptom relief for individuals.

DNA from blood only, or blood and saliva will be used to test newer methods for genotyping. The two genes to be genotyped are CYP2D6 and CYP2C19, as these code for the key enzymes that metabolise a large number of medications.

Who is undertaking the project?

This project is being conducted by Dr Martin Lewis, Prof David Adelson and Dr Michael Musker. This research will form part of the PhD degree of Kiflu Tesfamichael at the University of Adelaide under the supervision of Dr Martin Lewis, Prof David Adelson and Dr Michael Musker.

The Breakthrough Mental Health Foundation is supporting the PhD student Kiflu Tesfamicael to undertake this project.

Why am I being invited to participate?

You are being invited to participate as you have made an enquiry on the SAHMRI Clinical Trials Platform.

What am I being invited to do?

You are being invited to allow us to collect a blood sample or a blood and saliva samples once by visiting our SAHMRI clinic on North Terrace, Adelaide. You will be requested to complete some short surveys of details of your ethnicity, medications, illnesses and a mood assessment. These details will only be associated with a code and will not include your name, date of birth, address or any identifying information.

How much time will my involvement in the project take?

The single clinic visit will take approximately 30 minutes for the blood or blood and saliva collection. The surveys will take about 30 minutes to complete which are only required to be done once.

Are there any risks associated with participating in this project?

There are minimal foreseeable risks to participants in this project. Minor bruising can be experienced following blood collection. Blood collection is performed by an experienced qualified phlebotomist and experienced registered nurse (Dr Musker). When researchers engage with participants appropriate hygiene will be practiced. Participants will not undergo any treatments. All participants samples, surveys and results are assigned a randomised code to ensure deidentification. The researchers that engage with you in the clinic are also a workplace first aid officer (Dr Martin Lewis), and a mental health first aid trainer (Dr Michael Musker). Contact details for professional help services have been appended to this information sheet. It is important you talk with your GP in the first instance if you experience depression.

What are the potential benefits of the research project?

The outcomes of this project may contribute to better genotyping methods for Precision Medicine. Improvements in genotyping methods may contribute to greater uptake and access to Precision Medicine for treatment resistant patient groups. Currently, Precision Medicine is not widely used and limited to private services. There are no immediate benefits to participants in this project.

Can I withdraw from the project?

Participation in this project is completely voluntary. If you agree to participate, you can withdraw from the study up until two months after giving a blood sample and completing the surveys. After this time your deidentified results may be included in our research findings. The anonymous project results will not identify any participants, which will be submitted as part of a higher degree thesis and or publications.

What will happen to my information?

Confidentiality and privacy: All participation is anonymous; no participant names or pseudonyms will be used. The large number of randomly coded samples (200) to be used in this project further reduces the ability to identify any participants. The utmost care will be taken to ensure that no personally identifying details are revealed.

Storage: No identifying information will be stored with survey results or biospecimen samples. These will all be labelled with randomised codes. The only biospecimens retained after DNA isolation from blood and saliva will be the DNA. Records of participant consent forms, and any identifiable information will only be accessible to the researchers, hard copies will be securely locked and only accessible to researchers. Digital information will be securely password protected and only available to the researchers. All biospecimens, hard copies and digital information will be destroyed after five years.

Publishing: Results from this project will be presented to colleagues, reported in journal articles, to the funding body, and be part of a PhD thesis. No participants will be identified in any of these reports and only summary data will be published.

If consent is given participants data and biospecimens will be used in future research.

Your information will only be used as described in this participant information sheet and it will only be disclosed according to the consent provided, except as required by law.

Who do I contact if I have questions about the project?

All questions and enquiries are preferably made by email to the principal researcher Dr Martin Lewis.

Dr Martin Lewis
Neuropsychiatric Laboratory
Long Life Health Theme
South Australian Health & Medical Research Institute
martin.lewis@sahmri.com
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Prof David Adelson
Professor and Chair of Bioinformatics and Computational Genetics
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Mr Kiflu Tesfamicael
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What if I have a complaint or any concerns?

The study has been approved by the Human Research Ethics Committee at the University of Adelaide (approval number H-2020-34767). This research project will be conducted according to the NHMRC National Statement on Ethical Conduct in Human Research 2007 (Updated 2018). If you have questions or problems associated with the practical aspects of your participation in the project, or wish to raise a concern or complaint about the project, then you should consult the Principal Investigator. If you wish to speak with an independent person regarding concerns or a complaint, the University's policy on research involving human participants, or your rights as a participant, please contact the Human Research Ethics Committee's Secretariat on:

Phone: +61 8 8313 6028

Email: hrec@adelaide.edu.au

Post: Level 3, Rundle Mall Plaza, 50 Rundle Mall, ADELAIDE SA 5000

Any complaint or concern will be treated in confidence and fully investigated. You will be informed of the outcome.

If I want to participate, what do I do?

After reading the study information provided and asking any questions, you need to consent to join the study. A visit to the SAHMRI clinic will then be organised for you. During your clinic visit a blood sample will be collected. Some participants may also give a saliva sample. You will also be requested to complete surveys which include details of your ethnicity, medications, illnesses and a mood assessment.

Enquiries about the study should be sent to martin.lewis@sahmri.com

Dr Martin Lewis will answer questions and organise a time to visit a SAHMRI clinic on North Terrace, Adelaide.
The clinic will take about 30 minutes during which a blood sample will be collected, and a possible saliva sample.

Yours sincerely,

Dr Martin Lewis
Senior Research Fellow
Long Life Health Theme
South Australian Health & Medical Research Institute

Prof David Adelson
Professor and Chair of Bioinformatics and Computational Genetics
School of Molecular and Biomedical Science
University of Adelaide

Dr Michael Musker
Enterprise Fellow
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