Guardian Information Statement

Resident Authorised Representative/Guardian

Research Study: Implementation of Pharmacogenomic Testing in Aged Care

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1. What is this study about?

We're conducting a research study about how to implement a genetic testing ('genotyping') service in aged care to improve what medication the residents are prescribed ('pharmacogenomics').

Genes are sets of instructions in our bodies that produce proteins to carry out many functions including processing of medications. There are different versions of genes that are passed down to us from our parents. Variations in certain genes can mean that your body processes specific medications too quickly or too slowly, affecting how well they work for you. For example, one version of the gene can mean that you breakdown the medication too quickly, making it less effective for you. In contrast, another version of the gene may indicate that you breakdown the medication too slowly, meaning it can build up in your body and increase your risk of unwanted side effects. Therefore, based on your specific genetic result (genotype) your doctor can be more informed as to which medication and dose are most suitable for you, to make sure you have the best outcome.

In this study, we are genotyping people who are residents at Whiddon aged care homes to see if knowing what version of gene they have changes what medication their doctor decides to prescribe. The person under your care has been invited to take part. Taking part in this study is voluntary.

Please read this sheet carefully and ask questions about anything that you don't understand or want to know more about.

2. Who is running the study?

The researchers conducting this study are:

- Dr. Sophie Stocker - *Senior Lecturer, The University of Sydney*
- Dr. Sam Mostafa - *Associate Clinical Director, myDNA*
- Prof. Carl Kirkpatrick - *Professor of Pharmacy Practice, Medicine Use and Safety, Monash University*
- Alyson Jarrett - *Deputy Chief Executive Officer, Whiddon Aged Care*

- Dr. Jennie Hewitt - *Senior Manager Research & Positive Ageing, Whiddon Aged Care*
- Michael Bonner - *CEO/Owner & Clinical Pharmacist, Choice Aged Care*
- Eman Wehbe - *PhD Student, The University of Sydney*

This study is funded by Whiddon Aged Care and Arrotex Pharmaceuticals Pty Ltd. The University of Sydney is the study Sponsor.

Dr. Sam Mostafa has a financial interest in the research as the Associate Clinical Director of myDNA, which is the commercial genotyping company that will provide the cheek swab testing kits and the pharmacogenomic reports. Dr. Sam Mostafa is employed by and holds shares in myDNA, which could benefit from our research findings.

3. Who can take part in the study?

The person under your care has been invited to take part in this study because they are a resident at one of the following Whiddon Aged Care facilities: Whiddon Redhead, Whiddon Belmont, Whiddon Largs, Whiddon Kyogle.

4. What will the study involve?

If you decide the person under your care can take part in this study, they will be asked to provide a cheek swab which will be used for **genotyping**, and to participate in an **interview** about their perspective on genotyping in aged care.

Genotyping
Time: approximately 5 minutes
Location: at Whiddon
Description: if you decide the person under your care can participate in genotyping, they will be given a cheek swab testing kit. Instructions will be provided within the testing kit package, and Whiddon staff members are trained to help them take the cheek swab if assistance is needed. If the person under your care would like you to be present during the cheek swab, this is allowed. Once the cheek swab is collected, a Whiddon staff member will send the swab to the genotyping lab (ran by the company, myDNA). This is the end of the requirements for genotyping of the person under your care.

The results will be provided to the pharmacist of the person under your care, who will share the results to their prescriber. We will tell the person under your care's prescriber (e.g., general practitioner) that they are participating in this study beforehand, so the prescriber will be aware that they will receive the genotyping results. If the person under your care would like to find out about their results, please contact their prescriber. For the purpose of analysing the genotyping results, study investigators may access the person under your care's medical records at Whiddon and Commonwealth health information at Services Australia. This is so we can list what medications they are currently

on, and so that we can see if their doctor decides to change their medication(s) after receiving the pharmacogenomic results.

You will be asked to sign a separate consent form authorising the study to access the person under your care's Commonwealth health information provided by Services Australia, see the separate Services Australia Participant Information Document and Participant Consent Form. Services Australia is not involved in this research other than to provide the information that you have consented to the release of, should you decide the person under your care will participate in this study. Services Australia has confirmed that this research and any associated documents have received approval from a Human Research Ethics Committee (HREC) that is registered with and operates within guidelines set out by the National Health and Medical Research Council (NHMRC).

Interview
Time: approximately 15 minutes
Location: in person at Whiddon or online (video or phone call)
Description: if you decide the person under your care can participate in an interview, they will be asked questions about their experience of having the cheek swab done, and whether their doctor spoke to them about their genotyping results. The interview will be audio recorded and transcribed. If the person under your care would like you, as their authorised representative/guardian, to be present during the interview, this is allowed.

5. Can we withdraw once started?

Being in this study is completely voluntary and the person under your care does not have to take part. They will also be asked if they agree to take part if you decide they can.

Any decision will not affect current or future relationships with the researchers or anyone else at The University of Sydney or Whiddon Aged Care.

If you and the person under your care decide to take part in the study and either of you change your mind, you can withdraw by informing a study investigator or a clinical staff member at Whiddon.

If the person under your care takes part in an interview, they may refuse to answer any questions that they do not wish to answer.

If you or the person under your care chooses to withdraw, we will not collect any more information. Any information that we have already collected will be kept in our study records and may be included in the study results (for example, if the person under your care has already provided a cheek swab). If you or the person under your care do not want the information already collected to be in the study results, please tell us at the time of withdrawal.

6. Are there any risks or costs?

There are no anticipated risks associated with participation in this study.

Doing a cheek swab may cause some discomfort. Rarely, it can cause soreness or minor bleeding in the mouth. This is easily treated. Only 11 genes are tested in this study, and no variants associated with disease will be examined. This research study is only focused on the impact of genes on medications, NOT disease.

Aside from giving up your and the person under your care's time, we do not expect that there will be any risks or costs associated with participating in an interview.

7. Are there any benefits?

There are no direct benefits for you or the person under your care as a participant in this study. The person under your care may decide to discuss their genotyping test results with their prescriber after the study, and the prescriber may decide to change their medication(s) based on the results, but this is independent from the study itself and is up to the prescriber.

There are potential benefits for the wider community from this study. From this research, we can improve how to implement genotyping in aged care, which we hope will help other people taking medications be sure they are taking the correct therapy.

8. What will happen to information that is collected?

By providing your consent, you are agreeing to us collecting information about you and the person under your care for the purposes of this study.

Any information provided to us will be stored securely and we will only disclose identifiable information with your permission, unless we are required by law to release information. We are planning for the study findings to be published. The person under your care will not be identifiable in these publications.

The cheek swab and associated genotype data will be collected. Interview data will be recorded verbatim. Some data from the person under your care's existing health record at Whiddon may be collected, such as what medication(s) they are currently taking. Any data collected will only be presented in combination with other participant's data, not on its own. This excludes quotes from interviews that may be published, but any quotes used will only refer to a study code (for example, 'Participant 1 reported "…"').

The only organisations who will have access to your or the person under your care's information during/after the study are those associated with study investigators (Whiddon Aged Care, Choice Aged Care, myDNA, The University of Sydney, and Monash University). Your cheek swab will only be used for the purpose of this research project.

The sample that you provide during the research project will be destroyed at the completion of this research project.

Electronic data will be retained for 15 years, as per the Australian Code for the Responsible Conduct of Research. All electronic data will be kept on a secure server with restricted access through the Highly Protected SharePoint available in the University of Sydney Office 365 license. All computer records will be password protected. All physical documents from this study will be digitalised and the hard copies will be securely destroyed.

9. Will I be told the results of the study?

You and the person under your care have a right to receive feedback about the overall results of this study. If you would like to receive an overall summary of the results of this study, please provide your contact details on the consent form. This feedback will be provided as a plain language summary.

If you or the person under your care would like any feedback about their specific pharmacogenomic report/genotyping results, this will only be provided if you ask the person under your care's nominated prescriber, or their Whiddon pharmacist. The study investigators are not involved in this.

10. What if I would like further information?

When you have read this information, the following researcher/s will be available to discuss it with you further and answer any questions you may have. If you or the person under your care would like to know more at any stage, please feel free to contact:

- Dr. Sophie Stocker, Senior Lecturer at the University of Sydney (sophie.stocker@sydney.edu.au, +61 2 9114 4756)

11. What if I have a complaint or any concerns?

The ethical aspects of this study have been approved by the Human Research Ethics Committee (HREC) of The University of Sydney [Approval No. 2024/HE000370] according to the *National Statement on Ethical Conduct in Human Research (2007).*

If you are concerned about the way this study is being conducted or you wish to make a complaint to someone independent from the study, please contact the University:

Human Ethics Manager
human.ethics@sydney.edu.au
+61 2 8627 8176

This information sheet is for you to keep

Australian Government
Services Australia

Participant Information Document for the release of Commonwealth health information provided by Services Australia

Important information

Services Australia is not involved in the conduct of this study other than to release your Medicare Benefits Schedule (MBS) and/or Pharmaceutical Benefits Scheme (PBS) claims Commonwealth health information. Services Australia will not provide your personal information to the Implementation of Pharmacogenomic Testing in Aged Care (the Study) without your consent. To agree to the release of your information you must complete the 'Services Australia Participant Consent Form'.

You will be asked to sign a consent form authorising the study to access your complete MBS and/or PBS Commonwealth health information provided by Services Australia as outlined in the consent form. Medicare collects information on your doctor visits and the associated costs, while the PBS collects information on the prescription medications you have filled at pharmacies.

The release of your Commonwealth health information provided by Services Australia to the Study is completely voluntary and there will be no cost to you. If you do not want to consent to the release of your information you do not have to. You should feel under no obligation to consent to the Study. Choosing not to consent to the release of your information will not affect your current and future medical care in any way.

Withdrawal of consent to release your Commonwealth health information provided by Services Australia

You are under no obligation to continue with the consented release of your Commonwealth health information. You may change your mind at any time about releasing your information to the Study. People withdraw from studies for various reasons, and you do not need to provide a reason.

You can withdraw your consent to release your Commonwealth health information by completing and signing the 'Services Australia Participant Withdrawal of Consent Form'. This form is to be completed by you and supplied to the research team if you choose to withdraw your consent at a later date. If you withdraw your consent to release your information to the study, you will be able to choose whether the study will destroy or retain your Commonwealth health information it has collected about you. You should only choose one of these options. Where both boxes are ticked in error or neither box is ticked, the study will destroy all information it has collected about you. If you do withdraw your consent from the study and your information has already been analysed and/or included in a publication, your Commonwealth health information may not be able to be withdrawn or destroyed. In such circumstances, your health information will continue to form part of the project study records and results. Your privacy will continue to be protected at all times.

Proof of consent - Power of Attorney, Guardianship and Administration Orders

Power of Attorney, Guardianship and Administration Orders provide people the legal authority to act on behalf of someone else. If you are unable to provide consent for yourself or you are consenting for someone over the age of 14 years, Power of Attorney, Guardianship or Administration Order may be accepted. Services Australia will only accept a certified copy of an original Power of Attorney (Enduring or Medical), Guardianship or Administration order. Services Australia cannot provide the Study with participant information without supplied evidence. Statutory declarations will not be accepted.

Storage, retention, and destruction of your Medicare Benefits Schedule (MBS) and/or Pharmaceutical Benefits Scheme (PBS) claims Commonwealth health information.

Your Commonwealth health information specified within the consent form will be sent securely to Services Australia to authorise the release of your Commonwealth health information to the Study. Services Australia will retain your consent form for the life of the study as a record of your consent. A copy of your consent form will also be retained by the Study for the life of the study. Your Commonwealth health information will be de-identified and stored securely by the Study on servers, or hosted through cloud computing providers, physically located within Australian borders. Your Commonwealth health information will not be sent outside of Australian jurisdiction and is governed by the Privacy Act 1988.

Your Services Australia information that has been included in de-identified databases will be securely destroyed after the final publication of the study (15 years). However, if you withdraw from the Study, you can request the destruction of your Services Australia information, provided it has not been de-identified, analysed and published. All information will be securely destroyed at the completion of the study in a manner appropriate to the security classification of the record content. Services Australia has confirmed that this research and any associated documents, have been approved by a Human Research Ethics Committee (HREC) that is registered with the National Health and Medical Research Council (NHMRC) and operates within guidelines set out by the NHMRC.

Obligations to protect your privacy and personal information

Beyond the NHMRC requirements mentioned above, the Study is bound by Commonwealth and State privacy laws and must protect your anonymity and the confidentiality of your information to the fullest extent possible. If you have a Study related question, complaint or concern you can phone the Study on +61 2 9114 4756, or email the study on sophie.stocker@sydney.edu.au.

If you have a privacy complaint in relation to the use of your Services Australia information, you should contact the Office of the Australian Information Commissioner. You will be able to lodge a complaint with them.

Website:	www.oaic.gov.au	Email:	enquiries@oaic.gov.au
Telephone:	1300 363 992	Mail:	GPO Box 5218, Sydney NSW 2001

Your personal information Services Australia hold is protected by the Privacy Act 1988 and cannot be given to a third party without your consent or where otherwise permitted by law. For more information about privacy, go to **servicesaustralia.gov.au/privacy**

Please keep this information sheet for your information.