Participant Information Sheet/Consent Form

Pharmacogenomics Study - *Adult providing own consent*

St Vincent's Hospital

Title	Towards Implementation of Pharmacogenomics-guided Therapy in Patients with Mental Illness
Short Title	ENACT Study
Protocol Number	2021/ETH00548
Project Sponsor	St Vincent's Hospital Sydney
Principal Investigator	*A/Prof Kathy Wu*
Associate Investigator(s)	*Dr Michael Millard, Prof Deborah Schofield, Dr Rupendra Shrestha, Dr Zhixin Liu, Dr Alison McLean*
Location	Departments of psychiatry at St Vincent's Public and Private Hospitals Sydney

Part 1 What does my participation involve?

1 Introduction

You are invited to take part in this pharmacogenomics research project. You're invited because you have a diagnosis of a Major Depressive Disorder and/or Anxiety Disorder requiring psychotropic medications (either antidepressants or antipsychotics, or both) as part of your standard of care, and you are either new to psychotropic medication treatment or had psychotropic medications changes in the last three months.

This Participant Information Sheet/Consent Form tells you about the research project. It explains the tests involved. Knowing what is involved will help you decide if you want to take part in the research.

Please read this information carefully. Ask questions about anything that you don't understand or want to know more about. Before deciding whether or not to take part, you might want to talk about it with a relative, friend or your local doctor.

Participation in this research is voluntary. If you don't wish to take part, you don't have to and you will still receive the best possible care.

If you decide you want to take part in the research project, you will be asked to sign the consent form or provide verbal consent over the phone. By signing it you are telling us that you:
• Understand what you have read
• Consent to take part in the research project
• Consent to have the tests that are described
• Consent to the use of your personal and health information as described.

You will be given a copy of this Participant Information Sheet and Consent Form to keep.

2 What is the purpose of this research?

Depression is a common form of mental distress that affects 1 in 7 Australians in their lifetime. People who are depressed not only feel depressed and sad, often find they sleep poorly, experience a change in appetite, have low energy, poor concentration and have lowered self-esteem. Sometimes, they might think of harming themselves. Often, they find it hard to enjoy life or be productive.

Recovery from depression is possible and treatment for depression includes psychotherapy (talking therapy), cognitive behavioural therapy and medication. In fact, almost 10% of Australians use antidepressant medications each year. Finding the right medication and the right dose can be challenging, often requiring several trial-and-error attempts. Approximately two thirds of people do not get better with the first medication they're prescribed and one third of people do not recover even after four different medications are tried.

Pharmacogenomics (PG) is a new, simple genetic test, which can determine the way a person's body will respond to medication. The ENACT Study is looking at how PG can help to find the right antidepressant medication for people with depression and/or anxiety disorder. PG analysis will tell us what medications are more suited for you, based on your genetic makeup. This may improve the likelihood of recovery from depression.

This study will look at the number of medication changes as a result of PG-guided care. This is based on the rationale that PG will help your treating doctor select the most suitable medication from the start to increase the chance of your recovery thus avoiding multiple medication trials and errors.

The study will also look at the cost effectiveness of the PG testing approach for selecting antidepressant therapy. A long-term goal of this project is to lobby for Medicare rebate status for pharmacogenomic testing to guide treatment(s) for major depressive disorder.

This research has been initiated by the study doctor, A/Prof Kathy Wu, Clinical Geneticist at St Vincent's Clinical Genomics, St Vincent's Hospital Sydney. This research has been funded by St Vincent's Health Australia Inclusive Health Program Grant. This research is a joint collaboration between the Departments of Clinical Genomics at St Vincent's Public Hospital and Psychiatry at St Vincent Private and Public Hospitals Sydney, University of NSW, as well as the Centre for Economic Impacts of Genomic Medicine at Macquarie University.

3 What does participation in this research involve?

<u>Online questionnaires</u>
If you agree to take part in this research project, your participation will include completing eight questionnaires at baseline and at weeks 2, 4, 8, 12 and 24 (Table 1). Altogether, the questionnaires will take approximately 25 – 35 minutes to complete and ask you about depressive symptoms, anxiety and stress, your quality of life, work productivity, work life (if applicable) and any antidepressant side effects you may experience, as well as medication

changes. These questionnaires will be sent to you electronically via email so you can complete them online. If you prefer you can complete them over the phone or face to face with the study coordinator or receive them in hard copy.

Table 1								
Study Procedure	SCREENING	BASELINE	DAY 0	WEEK 2	WEEK 4	WEEK 8	WEEK 12	WEEK 24
Eligibility Assessment	✓							
Informed Consent	✓							
Buccal swab		✓						
PG result returned via MDT virtual clinic			✓					
Self-reported depressive symptomatology questionnaire		✓			✓	✓	✓	✓
Depression, anxiety and stress scale questionnaire		✓			✓	✓	✓	✓
Health related quality of life questionnaire		✓			✓	✓	✓	✓
Living in the community questionnaire		✓					✓	✓
Work productivity and activity impairment questionnaire		✓					✓	✓
Self-Rated medication adherence questionnaire		✓		✓	✓	✓	✓	✓
Antidepressant side effect questionnaire		✓		✓	✓	✓	✓	✓
Medication change questionnaire				✓	✓	✓	✓	

<u>Pharmacogenomics test</u>

You will need to provide one buccal (cheek) swab during your routine face-to-face clinic with your treating psychiatrist/clinician. Alternatively, a pre-labelled (and de-identified with study ID) swab kit together with pre-paid return package can be sent to your home. The swab kit will contain clear step-by-step instructions on how to collect a cheek swab, and how to arrange courier pickup of collected sample from your home. This de-identified sample will be shipped to the laboratory in the USA in a prepaid DHL Express package. Your DNA sample will only be used for PG-testing purpose and no other genetic testing will be carried out. After PG testing, any remaining DNA samples will be destroyed securely as per laboratory protocol.

<u>Attendance at one virtual MDT clinic</u>

The results from PG-testing generally takes around 5 – 7 days (from the time of sample being received in the USA) and will be sent to SVCG. The study coordinator will then arrange a multidisciplinary team (MDT) telehealth (virtual) clinic with you when your report is available. You will receive your personalised PG results during the MDT telehealth appointment convened at St Vincent's Clinical Genomics (SVCG), St Vincent's Hospital, Sydney. The MDT may consist of study geneticist/genetic counsellor, a hospital pharmacist, and your psychiatrist. You and your treating psychiatrist/clinician will have opportunities to ask questions about your PG report during the virtual MDT clinic. Your PG report will be emailed to you and your treating psychiatrist and GP following the telehealth appointment. Your PG report will be used as a guide by your treating clinician in your standard-of-care treatment regime.

Medicare Benefits Schedule (MBS)/Pharmaceutical Benefits Scheme (PBS) Data

You will be asked to sign a consent form allowing the study researchers to access your complete MBS and PBS data as outlined in the MBS and PBS consent form. If you provide consent for access to your MBS and/or PBS data, the consent form will be sent securely to the Services Australia who is the agency that holds MBS and PBS data. These data include information about your medical visits and procedures, associated costs and prescription medicines. Data from 1 January 2021 to *31 December 2024* will be collected.

Hospital Admission and Emergency Department Data

With your consent, the study team would like to link your identifying information (e.g. name, date of birth, address) to gather data from hospital and emergency records. Throughout our lives, hospitals, health departments and other groups or organisations collect information about our health and health care (referred to as data). The collection of this data is usually required by law and is securely stored by the service or agency that collects it. This study will collect your hospital and emergency records through data linkage. Data linkage is a technique for creating links between data stored in different places (in this case hospital and emergency records) so that information about the same person can be brought together. With your consent, the study researchers will supply the data linkage agency, Centre for Health Record Linkage (CHeReL), with key fields, including but not limited to your name, date of birth and address. TCHeReL will then create a unique ID for you and send it to the data custodian responsible for managing hospital and emergency data. Your hospital and emergency records will be merged with the unique ID and sent to the study team. Data from 1 January 2021 to 31 December 2024from the following databases will be requested through third party data linkage agencies:

- *[State]* Admitted Patient Data Collection
- *[State]* Non-Admitted Patient Data Collection
- *[State]* Emergency Department Data Collection

Data linkage will provide no direct benefit to you as a study participant. However, the data gathered from this research may provide valuable information that can be used to improve the treatment, access to pharmacogenomic-testing, the pharmacogenomic-testing experience and support the needs of individuals with mental illness in the future

There are no costs associated with your participation in this research project, nor will you be paid. The genetic test carried out as part of this research project will be provided to you free of charge.

If you have a local doctor, we strongly recommend that you inform them of your participation in this research project.

All study procedures will be conducted virtually via online questionnaires or teleconference/phone calls. No physical visits will be required for the study procedures. You may still need to see your treating clinician for standard-of-care routine follow-up, as instructed by your doctor.

4 What do I have to do?

If you agree to take part in this research project, the study coordinator will coordinate the study procedures with your treating psychiatrist/clinician.

There are no lifestyle, dietary or medication restrictions while you participate in this study.

5 Other relevant information about the research project

This study aims to recruit 80 participants fromDepartments of Psychiatry at St Vincent's Public and Private Hospitals Sydney: both inpatient wards and outpatient clinics , as well as external sites. If you are not a patient of St Vincent's Hospitals, you may take part in this study if your nominated treating psychiatrist/clinician also agrees to take part in the study.

Study participants will require access to a telephone and videoconferencing equipment (eg. Smartphone, tablet or laptop computer) to be able to complete study procedures, including online questionnaires and a MDT teleconference appointment to receive your PG results.

The PG testing laboratory, OneOme, is a Clinical Laboratory Improvement Amendments (CLIA)-certified and College of American Pathologists (CAP) accredited PG laboratory based in Minneapolis, USA. CLIA/CAP accreditation represents the US equivalent of NATA/RCPA accreditation in Australia. The OneOme PG test includes 27 genes with high-level evidence (PharmGKB and CPIC levels 1/A and 2/B). You will receive a detailed PG report that covers over 200 medications, including many anti-depressants, anxiolytic and antipsychotic medications, as well as other medications that you may need in the future. This report can be used by your future doctors in guiding future choice of medications, outside of this study.

6 Do I have to take part in this research project?

Participation in any research project is voluntary. If you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage.

If you do decide to take part, you will be given this Participant Information and Consent Form to sign and you will be given or emailed a copy to keep.

Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your routine treatment, your relationship with those treating you or your relationship with St Vincent Public or Private Hospitals.

7 What are the possible benefits of taking part?

We cannot guarantee or promise that you will receive any benefits from this research; however, possible benefits may include a better response to antidepressant medication, where you experience less side effects and an improvement in your depression symptoms. The PG testing done as part of this study will generate a clinical-grade report that covers many other medications. There may be future benefit from this PG report which can be used by your future doctors in choosing a suitable medication that you may need in the future.

There may be indirect benefits: The data gathered from this research may provide valuable information that can be used to improve mental illness treatment, and access to PG testing in the future.

8 What are the possible risks and disadvantages of taking part?

Genetic testing involves the study of genetic material (DNA) that is shared between you and your blood relatives. Your DNA sample will only be used for PG-testing and no other genetic testing will be carried out.

PG testing is a type of personal genetic test that is only applicable to the individual tested, and has limited implications to the blood relatives of that individual. PG testing has limited insurance or employment implications, as it does not provide information about an individual's current or future health.

Possible risks and disadvantages associated with PG testing are very few, and may include emotional stress from learning about your results of PG testing, which may/may not explain your past experience with medications. The buccal (cheek) swab sample collected for PG testing is a non-invasive procedure with negligible complications.

9 What will happen to my test samples?

PG testing is a mandatory component of the research project. De-identified buccal (cheek) swab samples will be sent to OneOme Biotechnology Company in the USA for PG testing. This testing will examine the possible interactions between your DNA and antidepressant medication(s) and the impact this may have on your response to antidepressant medication(s).

Your DNA will be extracted from the buccal sample that you provided and the sample will be used only for this research purpose.

At the completion of testing, your DNA may be stored until the end of the project and will be destroyed securely in accordance to the laboratory's regulation.

10 What if new information arises during this research project?

Sometimes during the course of a research project, new information becomes available about the treatment that is being studied. If this happens, your study doctor will tell you about it and discuss with you whether you want to continue in the research project. If you decide to withdraw, your study doctor will make arrangements for your regular health care to continue. If you decide to continue in the research project you will be asked to sign an updated consent form.

Also, on receiving new information, your study doctor might consider it to be in your best interests to withdraw you from the research project. If this happens, he/she will explain the reasons and arrange for your regular health care to continue.

11 Can I have other treatments during this research project?

There are no restrictions to other treatments during your participation in this research project.

12 What if I withdraw from this research project?

If you decide to withdraw from the project, please notify a member of the research team before you withdraw. This notice will allow that person or the research supervisor to discuss any health risks or special requirements linked to withdrawing.

If you do withdraw your consent during the research project, the study doctor and relevant study staff will not collect additional personal information from you, although personal information already collected will be retained to ensure that the results of the research project can be measured properly and to comply with law. You should be aware that data collected by researchers up to the time you withdraw will form part of the research project results. If you do not want them to do this, you must tell them before you join the research project.

13 Could this research project be stopped unexpectedly?

It is unlikely, but this research project could be stopped unexpectedly in response to decisions made by local regulatory or health authorities; or in rare cases if the funding was withdrawn by the grant body.

14 Will I be given the results of the research project?

It is anticipated that this project will be completed in 2024. If requested you will be provided with a summary of the research project results.

15 Banking of Health Information

The health information we will collect and store in a secure electronic database for this research project include: your demographic information and personal health history, including that related to your mental health, and other medical history, medication changes, medication adherence, and any medication side effect experienced.

We will not use your personal health information for a different research project without the permission of a Human Research Ethics Committee. Once all personal identification is removed, the information might be used or released for other ethics-approved research purposes without asking you. Results of the research project may be presented in public talks or written articles but information will not be presented that identifies you.

Part 2 How is the research project being conducted?

16 What will happen to information about me?

By signing the consent form you consent to the study coordinator and relevant research staff collecting and using personal information about you for the research project. Any information obtained in connection with this research project that can identify you will remain confidential. Your identifiable information will only be used for the purpose of this research project and it will only be disclosed with your permission, except as required by law.

You will be given a unique study identification number (study participant ID) when you join the study. This study participant ID will be used to label your study documents and information collected by study staff, including answers you provide when completing study questionnaires. Information will be stored in a secure password-protected electronic database in a re-identifiable format. Your study participant ID will also be used to denote the cheek swab/DNA sample you provide for pharmacogenomic analysis. Only the study investigators and study coordinator will have access to the electronic database and study participant ID list and be able to identify your study documents and DNA sample.

Any study information shared with other parties such as research collaborators to enable analyses directly related to this research project will be shared in a de-identified (cannot identify the person) format.

Information about you may be obtained from your health records held at this and other health services for the purpose of this research. By signing the consent form you agree to the study team accessing health records if they are relevant to your participation in this research project.

Your identifiable information will only be used for the purpose of this research project and it will only be disclosed with your permission, except as required by law. Once all personal identification is removed, the de-identified information might be used for other ethics-approved research studies.

Your health records and any information obtained during the research project are subject to inspection (for the purpose of verifying the procedures and the data) by the relevant authorities or as required by law. By signing the Consent Form, you authorise release of, or access to, this confidential information to the relevant study personnel and regulatory authorities as noted above.

It is anticipated that the results of this research project will be published and/or presented in a variety of forums. In any publication and/or presentation, information will be provided in such a way that you cannot be identified, except with your permission. All research data presented will be at group level and will not contain individual participant level data.

Information about your participation in this research project may be recorded in your health records.

In accordance with relevant Australian and NSW privacy and other relevant laws, you have the right to request access to your information collected and stored by the research team. You also have the right to request that any information with which you disagree be corrected. Please contact the study team member named at the end of this document if you would like to access your information.

Any information obtained for the purpose of this research project that can identify you will be treated as confidential and securely stored. It will be disclosed only with your permission, or as required by law.

17 Complaints and compensation

If you suffer any injuries or complications as a result of this research project, you should contact the study team as soon as possible and you will be assisted with arranging appropriate medical treatment. If you are eligible for Medicare, you can receive any medical treatment required to treat the injury or complication, free of charge, as a public patient in any Australian public hospital.

If you suffer any distress or psychological injury as a result of this research project, you should contact the study team as soon as possible. They will assist you in arranging appropriate treatment and support.

You do not give up any legal rights to compensation by participating in this research project.

18 Who is organising and funding the research?

This research project is being conducted by A/Prof Kathy Wu, a Clinical Geneticist at St Vincent's Hospital Sydney.

This research project is funded by the St Vincent's Health Australia Inclusive Health Program Grant.

St Vincent's Public and Private Hospitals Sydney may directly or indirectly benefit financially from your samples or from knowledge acquired through analysis of your samples.

You will not benefit financially from your involvement in this research project even if, for example, your samples (or knowledge acquired from analysis of your samples) prove to be of commercial value to the above institutions.

In addition, if knowledge acquired through this research leads to discoveries that are of commercial value to the study doctors or their institutions, there will be no financial benefit to you or your family from these discoveries.

No member of the research team will receive a personal financial benefit from your involvement in this research project (other than their ordinary wages).

19 Who has reviewed the research project?

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this research project have been approved by the HREC of St Vincent's Hospital Sydney.

This project will be carried out according to the *National Statement on Ethical Conduct in Human Research (2007)*. This statement has been developed to protect the interests of people who agree to participate in human research studies.

20 Further information and who to contact

If you want any further information concerning this project or if you have any complaints or medical problems which may be related to your involvement in the project (for example, any side effects), you can contact the principal study doctor below:

Name	A/Prof Kathy Wu

Position	Principal Investigator and Head of St Vincent's Clinical Genomics
Telephone	02-83824899
Email	kathy.wu@svha.org.au

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then you may contact:

Name	Manager, St Vincent's Hospital Research Office
Telephone	02-83824960
Email	SVHS.Research@svha.org.au

21 What do I do if I have a privacy complaint?

If you have a privacy complaint in relation to the use of your MBS/PBS data you should contact the Office of the Australia Information Commissioner. You will be able to lodge a complaint with them.

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

If you have a privacy complaint in relation to the use of general study data or your bio-specimens you should contact the Privacy Commissioner in your relevant state. You will be able to lodge a complaint with them.

NSW Information & Privacy Commission
Website: www.ipc.nsw.gov.au
Telephone: 1800 472 679
Fax: 02 6446 9518
Email: ipcinfo@ipc.nsw.gov.au
Mail: GPO Box 7011, Sydney NSW 2001

Consent Form

Title	Towards Implementation of Pharmacogenomics-guided therapy in Patients with Mental Illness
Short Title	ENACT Study
Protocol Number	2021/ETH00548
Project Sponsor	St Vincent's Hospital Sydney
Principal Investigator	A/Prof Kathy Wu
Associate Investigator(s)	Dr Michael Millard, Prof Deborah Schofield, Dr Rupendra Shrestha, Dr Zhixin Liu, Dr Alison McLean
Location	Departments of psychiatry at St Vincent's Public and Private Hospitals Sydney

Declaration by Participant

I have read the Participant Information Sheet or someone has read it to me in a language that I understand.

I understand the purposes, procedures and risks of the research described in the project.

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I freely agree to participate in this research project as described and understand that I am free to withdraw at any time during the project without affecting my future health care.

I understand that I will be given a signed copy of this document to keep.

I give permission for my doctors, other health professionals, hospitals or laboratories outside this hospital to release information to St Vincent's Hospital Sydney concerning my condition and treatment for the purposes of this project. I understand that such information will remain confidential.

I understand that I can withdraw my consent to participate in this research project by completing a "Withdrawal of Consent" form. I can also specify whether I wish to have my DNA, which has already been collected and stored, deleted, destroyed or returned to me if it is still identifiable as mine.

I understand that, if I decide to discontinue the study participation, I may be asked to attend follow-up visits to allow collection of information regarding my health status. Alternatively, a member of the research team may request my permission to obtain access to my medical records for collection of follow-up information for the purposes of research and analysis.
By signing this consent section, I agree to the use of my tissue sample for pharmacogenomics testing, as outlined in the relevant sections of the Participant Information Sheet.

Name of Participant (please print) _____

Signature _____ Date _____

Verbal consent obtained by _____

Name of Witness* to Consent Process (please print) _____

Signature _____ Date _____

* Witness is not to be the investigator, a member of the study team or their delegate. In the event that an interpreter is used, the interpreter may not act as a witness to the consent process. Witness must be 18 years or older.

Declaration by Study Doctor/Senior Researcher†

I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation.

Name of Study Doctor/ Senior Researcher† (please print) _____

Signature _____ Date _____

† A senior member of the research team must provide the explanation of, and information concerning, the research project.

Note: All parties signing the consent section must date their own signature.

Participant Study ID: _____

Consent Form – MBS/PBS Data Linkage - *Adult providing own consent*

Title	Towards Implementation of Pharmacogenomics-guided therapy in Patients with Mental Illness
Short Title	ENACT Study
Project Sponsor	St Vincent's Hospital Sydney
Coordinating Principal Investigator	A/Prof Kathy Wu
Associate Investigator(s)	Dr Michael Millard, Prof Deborah Schofield, Dr Rupendra Shrestha, Dr Zhixin Liu, Dr Alison McLean
Location	Departments of psychiatry at St Vincent's Public and Private Hospitals Sydney

Consent to release of Medicare Benefits Schedule (MBS) and/or Pharmaceutical Benefits Scheme (PBS) claims by Services Australia to St Vincent's Hospital Sydney for the purposes of the ENACT Study.

Important Information
Complete this form to request the release of your personal Medicare claims information and/or your PBS claims to the ENACT Study.

Any changes to this form **must** be initialled by the signatory. Incomplete forms may result in the study not being provided with your information.

Rights and Privacy:
I understand that:
 my MBS and/or PBS information will be disclosed by Services Australia for the purposes of the study.
 the results of this research may be published in articles or journals.
 my real name will never be disclosed by Services Australia, used in the study or published.
 my participation in the study is completely voluntary.
 I can withdraw my participation in the study at any time (refer to participant information sheet and withdrawal of consent form) and I do not have to provide a reason for my withdrawal.

Consent:
 I understand the information provided to me about the study I am participating in.
 I have been given the opportunity to ask questions, and any questions I have asked have been answered to my satisfaction.
 I consent to the disclosure by Services Australia of my MBS and/or PBS information to researchers for the purposes of the study.

PARTICIPANT DETAILS

1. Mr □ Mrs □ Miss □ Ms □ Other □

Family name: _____

First given name: _____

Other given name (s): _____

Date of birth: ___ **/**____**/**_____
DD / MM / YYYY

2. Medicare card number: _____

3. Permanent address:

_____

Postal address (if different to above):

_____

AUTHORISATION

4. I authorise Services Australia to provide my:

□□Medicare & PBS claims history OR
□□PBS claims history OR
□□Medicare claims history

For the period* **01 / 01 / 2021** to: **31 / 12 / 2024** to the ENACT Study.
DD / MM / YYYY DD / MM / YYYY

*Note: As Services Australia can only extract 4.5 years of data (prior to the date of extraction), the consent period above may result in multiple extractions.

DECLARATION
I declare that the information on this form is true and correct.

5. Signed: _____ (participant's signature) Dated: ___ **/**____**/**_____

DD / MM / YYYY

A sample of the information that may be included in your Medicare claims history:

Date of service	Item number	Item description	Provider charge	Schedule Fee	Benefit paid	Patient out of pocket	Bill type	Hospital indicator	Item category
20/04/09	00023	Level B consultation	$38.30	$34.30	$34.30	$4.00	Cash	N	1
22/06/09	11700	ECG	$29.50	$29.50	$29.50		Bulk Bill	N	2

A sample of the information that may be included in your PBS claims history:

Date of supply	Date of prescribing	PBS item code	Item description	Patient category	Patient contribution (this includes under copayment amounts**)	Net Benefit (this includes under copayment amounts**)	Pharmacy postcode	ATC Name
06/03/09	01/03/09	03133X	Oxazepam Tablet 30 mg	Concessional Ordinary	$5.30	$25.55	2560	Oxazepam
04/07/09	28/05/09	03161J	Diazepam Tablet 2 mg	General Ordinary	$30.85		2530	Diazepam

** Under co-payments can now be provided for data after 1 July 2012

Privacy and your personal information

The privacy and security of your personal information is important to us and is protected by law. We need to collect this information so we can process and manage your applications and provide services to you. We only share your information with other parties where you have agreed, or where the law allows or requires it. For more information, go to **servicesaustralia.gov.au/privacy**

Form for Withdrawal of Participation

Title	Towards Implementation of Pharmacogenomics-guided therapy in Patients with Mental Illness
Short Title	ENACT Study
Protocol Number	2021/ETH00548
Project Sponsor	St Vincent's Hospital Sydney
Principal Investigator	A/Prof Kathy Wu
Associate Investigator(s)	Dr Michael Millard, Prof Deborah Schofield, Dr Rupendra Shrestha, Dr Zhixin Liu, Dr Alison McLean
Location	Departments of Psychiatry at St Vincent's Public and Private Hospitals Sydney

Declaration by Participant

I wish to withdraw from participation in the above research project and understand that such withdrawal will not affect my routine treatment, my relationship with those treating me or my relationship with St Vincent's Public or Private Hospitals Sydney.

I request that all my data/DNA collected and banked be deleted, destroyed or returned to me if it is still identifiable.

Name of Participant (please print) _____

Signature _____ Date _____

In the event that the participant's decision to withdraw is communicated verbally, the Study Doctor/Senior Researcher will need to provide a description of the circumstances below.

Declaration by Study Coordinator/Senior Researcher†

I have given a verbal explanation of the implications of withdrawal from the research project and

I believe that the participant has understood that explanation.

Name of Study Coordinator/
Senior Researcher† (please print) _____

Signature _____ Date _____

† A senior member of the research team must provide the explanation of, and information concerning, withdrawal from the research project.

Note: All parties signing the consent section must date their own signature