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Participant Information Sheet/Consent Form

Interventional Study - *Adult providing own consent*

[Insert site name]

Title	An Australian Multicentre Double-Blinded Randomised Controlled Trial of Genotype-guided versus Standard Psychotropic Therapy in Moderately-to-Severely Depressed Patients Initiating Pharmacotherapy
Short Title	ALIGNED Study
Project Sponsor	The George Institute for Global Health, Sydney
Coordinating Principal Investigator/ Principal Investigator	*[Coordinating Principal Investigator/ Principal Investigator]*
Associate Investigator(s)	*[Associate Investigator(s)]*
Location	*[Location]*

Part 1 What does my participation involve?

1 Introduction

You are invited to take part in this research project. This is because you have (or are likely to have) moderate to severe depression and are not currently taking antidepressant medication. The research project is testing a new approach to selecting antidepressant medication for the treatment of depression. The new approach is called pharmacogenomic testing. Pharmacogenomics is the study of how a person's genes affect the way their body responds to medications.

This Participant Information Sheet/Consent Form tells you about the research project. It explains the tests and treatments involved, what information is collected and how it is used as part of the project. 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.

Your participation in this research project is completely voluntary and there will be no cost to you. If you do not want to take part in this project, you do not have to. You should feel under no obligation to participate in this project. Choosing not to take part in this project will not affect your current and future medical care in any way.

If you decide you want to take part in the research project, you will be asked to sign various consent forms. By signing them you are telling us that you:

- Understand what you have read
- Consent to take part in the research project

- Consent to have the tests and treatments 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 and Consent Form to keep.

You are under no obligation to continue with the research project. You may change your mind at any time about participating in the research. People withdraw from research projects for various reasons and you do not need to provide a reason.

You can withdraw from the research project at any time by completing and signing the 'Participant Withdrawal of Consent Form'. This form is provided at the end of this document (Form '**D**') and is to be completed by you and supplied to the research team if you choose to withdraw at a later date.

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, but 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 is a new, simple genetic test, which can determine the way a person's body will respond to medication. The ALIGNED Study is a research project that is looking at how pharmacogenomics can help to find the right antidepressant medication for people with depression. Pharmacogenomic 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.

By comparing antidepressant treatment response and change in depression symptoms for participants whose antidepressant medication has been selected based upon their pharmacogenomic test results to those receiving standard antidepressant therapy, we may be able to tell whether pharmacogenomic testing provides a benefit for people with moderate to severe depression. This may lead to a quicker and greater improvement in depression symptoms.

The research project will also look at the cost effectiveness of the pharmacogenomic testing approach for selecting antidepressant therapy. One of the goals of this project is to collect data which can be used to lobby for Medicare rebate status for pharmacogenomic testing to guide treatment(s) for major depressive disorder.

The project also aims to identify biological markers that can help in antidepressant treatment selection. This will be done by carrying out a magnetic resonance imaging (MRI) scan of the brain in a sub-group of study participants (optional component of ALIGNED study).

The antidepressant medications selected as part of this research project are currently approved for depression treatment in Australia.

This research has been initiated by Associate Professor Kathy Wu, St Vincent's Hospital and the University of New South Wales, Sydney, in collaboration with psychiatrists and a team of researchers based at Universities and Healthcare Facilities throughout Australia.

This research has been funded by a Medical Research Future Fund Emerging Priorities and Consumer-Driven Research Mental Health Pharmacogenomics grant.

This research is being coordinated by Associate Professor Kathy Wu in collaboration with The George Institute for Global Health, Sydney. The Local Principal Investigator at *[Location]* is a psychiatrist.

3 What does participation in this research involve?

Participation includes 9 study sessions, carried out over 24 weeks. You will also be required to see your treating clinician/GP for initiation of antidepressant therapy as required based on current clinical guidelines, and to attend follow-up visits with your treating clinician/GP who can monitor your treatment response. All study sessions will be done remotely via telephone or videoconference. Some study sessions may comprise separate telephone and videoconference calls on the same day/over several days, depending on which approach suits your schedule best. There is an optional component where a magnetic resonance imaging (MRI) brain scan will be carried out. If you decide to participate in this research project, the study doctor or study coordinator will inform your local doctor.

After you have completed the Expression of Interest online and prior to any research assessments taking place, the relevant consent form(s) attached to this information sheet must be signed.

A detailed description of the study sessions and assessments is provided below:

Pre-Screening: The pre-screening session will be done by telephone with the study coordinator and will include basic questions to check whether it is suitable for you to take part in the research project. A link to access the Participant Information Sheet and Consent Forms online will also be provided to you at this session and the study coordinator will go through the consent process with you.

Screening: The screening session will be done by videoconference with the study coordinator and will include detailed questions about your lifestyle, general health and wellbeing and current medications. It will also include questionnaires to determine your diagnosis of depression as well as degree of depression. Your eligibility for research project participation will be determined after the screening session and will be communicated to you via telephone by the study coordinator.

Pharmacogenomic Testing: A buccal (inner cheek) swab sample kit will be sent to your home via express post. Instructions on how to collect the sample will be provided. Once the sample has been collected, the study coordinator will arrange for a courier to collect the sample kit and ship it to the laboratory for pharmacogenomic testing (located in Melbourne, Victoria).

Baseline Questionnaires and Interview: You will be provided with an online link to access questionnaires, which will ask about your quality of life, productivity, work life including income (if applicable) and depression symptoms. These questionnaires will need to be completed within 3 days of the screening session. The study coordinator will arrange for a virtual interview to take place over videoconference with an assessor within the next 3 days, who will ask about your depression symptoms and degree of depression.

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 (Consent Form '**C**'). If you provide consent for access to your MBS and/or PBS data, your signed consent form will be sent securely to Services Australia who holds MBS and PBS data. Medicare collects information on your doctor visits and the associated costs, while the PBS collections information on the

prescription medications you have filled at pharmacies. This information will be de-identified and aggregated for economic analysis and will not be shared with your doctors or a third party without your explicit consent. Data from *[date]* to *[date]* will be collected. Services Australia is not involved in the conduct of this research project other than to release your MBS and/or PBS claims information. Services Australia will not provide your personal information to the ALIGNED Study without your consent.

Hospital Admission and Emergency Department Data: With your consent (Consent Form '**C**'), the study team will link your identifying information (e.g. name, date of birth, address) to gather data from hospital and emergency records, comprising information about your health and health care you have received and was provided in hospitals and emergency departments (referred to as Hospital Data). The collection of this Hospital Data is usually required by law and is securely stored by the service or agency that collects it (the Data Custodian). This research project will collect your hospital and emergency records through electronic data linkage, which is a way to gather 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 a data linkage agency with key fields, including but not limited to your name, date of birth and address. The data linkage agency will then create a unique ID for you and send it to the Data Custodian responsible for managing the Hospital Data. Your hospital and emergency records will be linked with the unique ID and sent to the study team. This information will be de-identified and aggregated for economic analysis and will not be shared with your doctors or a third party without your explicit consent. Hospital Data from *[date]* to *[date]* from 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

If you withdraw from the research project, you will be able to choose whether the project will destroy or retain the information it has collected about you from Services Australia (Form '**F**'). You should only choose one of these options. Where both boxes are ticked in error or neither box is ticked, the project will destroy all information it has collected about you, which is in its possession.

If you withdraw from the study (Form '**D**' and '**F**'), your MBS/PBS information and Hospital Data that has already been analysed and/or included in a publication may not be able to be withdrawn or destroyed. In such circumstances, your personal information will continue to form part of the ALIGNED Study records and results; however, no publication will include any information which is able to identify you. Your privacy will continue to be protected at all times.

Study Intervention: This is a randomised controlled research project. Sometimes we do not know which treatment or approach is best for treating a condition. To find out we need to compare different treatments or approaches. We put people into groups and give each group a different treatment. The results are compared to see if one is better. To try to make sure the groups are the same, each participant is put into a group by chance (random). You will be randomised to the pharmacogenomic-informed treatment group or standard treatment group. Randomisation will occur on a 1:1 basis, where you will have a 50% chance of being allocated to one of these treatment groups.

This is also a double-blind study. This means that neither you nor your study doctor will know which treatment group you are in. However, in certain circumstances your study doctor can find out which treatment group you are in.

This research project has been designed to make sure the researchers interpret the results in a fair and appropriate way and avoids study doctors or participants jumping to conclusions.

Your treating clinician/GP will receive a Treatment Guide, which will contain recommendations for which antidepressant medication should be prescribed to you. You will be required to attend your treating clinician/GP's clinic to receive the prescription for antidepressant medication and will be asked to start taking this medication on the same day/following day. The study coordinator can assist you in arranging this appointment with your treating clinician/GP.

Magnetic Resonance Imaging (MRI) Brain (Neuroimaging): Participation in this component of the research project is optional and will depend on your location as the neuroimaging facilities are only available in select locations throughout Australia. If you live in one of the locations where this is available and provide consent to participate in the MRI brain component (Consent Form '**B**'), you will need to attend the nominated hospital/healthcare facility where an MRI scan of your brain will be done within one week of initiating antidepressant medication. The scan will take approximately 45 minutes to complete and will involve you lying quietly in the scanner with your eyes open.

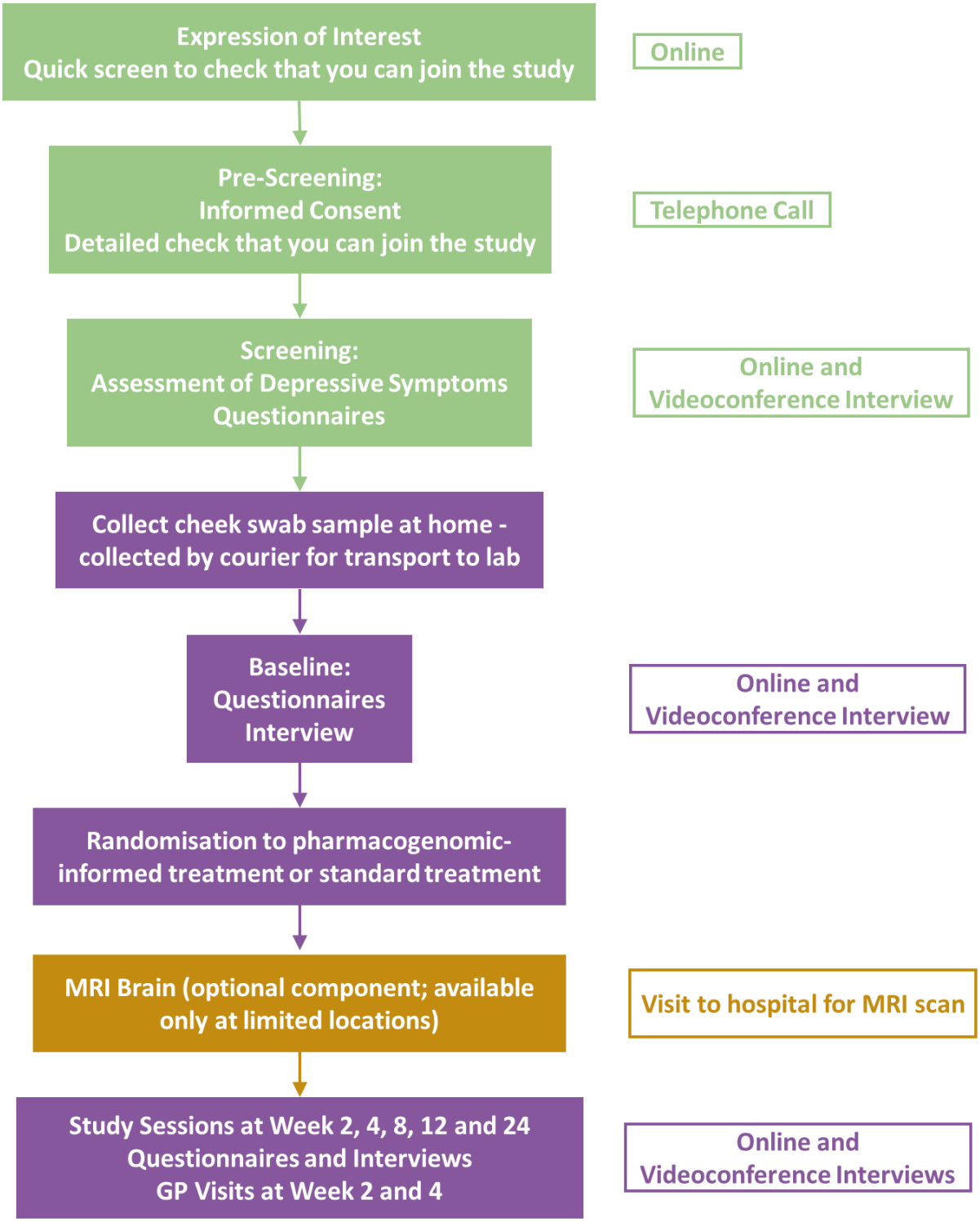
With your consent, your contact details and signed consent form (Consent Form '**B**') will be provided to the MRI booking team at iCore when arranging your MRI appointment. Your de-identified MRI data will be transferred by iCore from the neuroimaging facility to the University of Sydney for analysis. iCore is working with the study researchers at the University of Sydney to facilitate MRI scan bookings and transfer of MRI data for analysis for the ALIGNED Study.

Weeks 2: This session will be done by telephone or videoconference with the study coordinator and will include questions on your general health and wellbeing and current medications. You will also be required to attend your treating clinician/GP's clinic two weeks after starting antidepressant medication for a review of your general health and depression symptoms. The study coordinator can assist you in arranging this appointment with your treating clinician/GP.

Week 4, 8, 12, and 24: These sessions will be done by telephone or videoconference with the study coordinator and will include questions on your general health and wellbeing and current medications. The study coordinator will arrange for a virtual interview to take place over videoconference with an assessor within 5 days of the sessions, who will ask about your depression symptoms and degree of depression. You will also be provided with an online link to access questionnaires, which will ask about your quality of life, productivity, work life including income (if applicable), depression symptoms, side effects related to your antidepressant medication and your adherence to your antidepressant medication. These questionnaires will need to be completed within 3-5 days of the sessions.

At the week 12 session, you will be told which treatment group you were randomised to by the study coordinator. Your treating clinician/GP will also be sent a copy of your pharmacogenomic test results, which you can discuss with them at your next clinic visit.

An overview of the study session and assessment schedule is provided in the diagram on the next page:



There are no additional costs associated with participating in this research project, nor will you be paid. You may have to pay for medication and visits to your local doctor if these are not covered by Medicare.

You may be reimbursed for any reasonable expenses associated with attending videoconference sessions as part of the research project. Alternatively, mobile data may be provided to you to enable attendance at the videoconference sessions. Please discuss your requirement for reimbursement or mobile data with the study coordinator. The maximum amount of reimbursement will be up to $50 for the entire research project.

4 What do I have to do?

There are no dietary or lifestyle restrictions required to take part in the research project. If you have any questions about your regular medications during the study, please contact your treating clinician/GP for advice.

5 Other relevant information about the research project

A total of 776 people will take part in this research project across NSW, ACT, VIC, WA, SA and QLD, Australia. Participants can live in any part of the previously listed states; however, they will require access to a telephone, internet connection and videoconferencing equipment (e.g. smartphone, tablet, laptop computer) to be able to take part in the study sessions and assessments. Study coordinators and study doctors will be located in Sydney NSW, Melbourne Victoria, Canberra ACT and Perth Western Australia.

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 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 *[Institution]*.

7 What are the alternatives to participation?

You do not have to take part in this research project to receive treatment for depression. Other options are available; these include attending your treating clinician/GP to arrange psychotherapy (talking therapy), cognitive behavioural therapy facilitation or for prescription of antidepressant medication. Support may also be found online at Beyond Blue www.beyondblue.org.au; phone: 1300 22 4636, Black Dog Institute www.blackdoginstitute.org.au or Lifeline www.lifeline.org.au; phone: 13 11 14. Your study coordinator will discuss these options with you before you decide whether or not to take part in this research project. You can also discuss the options with your treating clinician/GP.

8 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. This research may also help to identify how we can pick the most appropriate antidepressant medication for people with moderate to severe depression in the future.

At the end of the study, your treating clinician/GP will be provided with a copy of your pharmacogenomics report. This report contains information on other medications, such as heart/blood pressure medications, pain medications, neurological medications, that you may need in the future. The report can then be used to guide the choice and dosage of future medications.

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

It is likely that your treating clinician/GP will prescribe antidepressant medication for treatment of your depression, whether you participate in this research project or not. Antidepressant medications often cause side effects. You may have none, some or all of the effects listed below, and they may be mild, moderate or severe. If you have any of these side effects, or are worried about them, talk with your study coordinator and treating clinician/GP. Your study coordinator will also be looking out for side effects.
There may be side effects that the researchers do not expect or do not know about and that may be serious. Tell your study coordinator and local doctor immediately about any new or unusual symptoms that you get.

Many side effects go away shortly after treatment ends. However, sometimes side effects can be serious, long lasting or permanent. If a severe side effect or reaction occurs, your treating clinician/GP may need to stop your treatment. Your treating clinician/GP will discuss the best way of managing any side effects with you.

Common side effects experienced when taking antidepressant medication are listed below:

- Nausea or vomiting
- Diarrhoea or constipation
- Indigestion
- Loss of appetite
- Weight gain
- Headaches
- Dizziness
- Blurred vision
- Dry mouth
- Tiredness or drowsiness
- Difficulty sleeping (insomnia)
- Sweating
- Lower sexual responsiveness

These side effects should improve over time, although some, including sexual problems, may persist.

Taking some antidepressant medication during pregnancy may cause harm to the unborn child and newborn baby. Because of this, it is important that research project participants are not pregnant or breast-feeding when starting the study. You must not participate in the research if you are pregnant or trying to become pregnant, or breast-feeding.

If you do become pregnant whilst participating in the research project, you should advise the study team and your treating clinician/GP immediately. The study doctor or your treating clinician/GP may need to adjust your antidepressant medication and advise on further medical attention should this be necessary.

If you become upset or distressed as a result of your participation in the research, the study coordinator will be able to arrange for or direct you to counselling or other appropriate support. Any counselling or support will be provided by qualified staff who are not members of the research project team.

Pharmacogenomic (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.

Optional MRI Component

MRI stands for magnetic resonance imaging. An MRI scanner is a machine that uses electromagnetic radiation (radio waves) in a strong magnetic field to take clear pictures of the inside of the body. Electromagnetic radiation is not the same as ionising radiation used, for example, in X-rays. The pictures taken by the machine are called MRI scans.

We will ask you to lie on a table inside the MRI scanner. The scanner will record information about your brain. It is very important that you keep very still during the scanning. When you lie on the table, we will make sure you are in a comfortable position so that you can keep still. The scanner is quite noisy and we can give you some earphones or disposable earplugs to reduce the noise. Some people may experience symptoms of claustrophobia from lying in a confined space. If you do experience discomfort at any time during the scan, you will be able to alert staff by pressing on a call button provided to you.

There are no known long-term risks related to MRI scans as used in this research project. MRI is extremely safe when performed at a centre with appropriate procedures. However, the magnetic attraction for some metal objects can pose a safety risk, so it is important that metal objects are not taken into the scanner room.

We will thoroughly examine you to make sure there is no reason for you not to have the scan. You must tell us if you have metal implanted in your body, such as a pacemaker or metal pins.

The scans we are taking are for research purposes. They are not intended to be used like scans taken for a full clinical examination. The scans will not be used to help diagnose, treat or manage a particular condition. A specialist will look at your MRI scans for features relevant to the research project. On rare occasions, a specialist may find an unusual feature that could have a significant risk to your health. If this happens, we will contact you and your treating clinician/GP to talk about the findings. We cannot guarantee that we will find any/all unusual features.

10 What will happen to my test samples?

Pharmacogenomic testing is a mandatory component of the research project. De-identified buccal (cheek) swab samples will be sent to myDNA Life Australia Pty Ltd for pharmacogenomic 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).

Pharmacogenomic testing will not result in information about your future health risk or genetic disease predisposition, nor having children with a genetic disorder, or information that may be relevant to the health of your family members who are not a part of the project.

Following pharmacogenomic testing, your DNA samples will be stored temporarily at myDNA Life Australia Pty Ltd for up to 2 years, to enable internal validation and satisfy NATA accreditation requirements. Following this storage, your de-identified DNA samples will be transported to St Vincent's Centre for Applied Medical Research, Sydney for storage for up to 5 years.

Your samples will be re-identifiable (only identified through a code); however, only the study coordinator, study doctor and study-specific operational staff based at The George Institute for Global Health will have access to this code and be able to identify your samples as belonging to

you. Study-specific operational staff at The George Institute for Global Health may require access to your identifying information to facilitate courier collection of your DNA samples for transport to myDNA Life Australia Pty Ltd for pharmacogenomic testing.

Additional research testing of your de-identified DNA samples may take place in the future; however, this testing will be reviewed by a Human Research Ethics Committee who will provide oversight and approval prior to additional research testing taking place. You will be asked to provide optional consent for this extended and unspecified research testing in the future (Consent Form '**A**'). Future research testing on your samples will not include any commercial use. If consent for future research testing of your DNA samples is declined, the DNA samples will be disposed of after 3 years, following completion of the ALIGNED Study. Your DNA samples will not be released for other uses without your prior consent, unless required by law.

11 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.

It is not anticipated that new pharmacogenomic information will become available during the course of this research project. In the rare event it does become available, neither you nor your study doctor will be notified of such information, as it is believed that any new information is unlikely to significantly change the interpretation of your pharmacogenomics results.

12 Can I have other treatments during this research project?

Whilst you are participating in this research project, you may not be able to take some or all of the medications or treatments you have been taking for your condition or for other reasons. It is important to tell your study doctor and the study staff about any treatments or medications you may be taking, including over-the-counter medications, vitamins or herbal remedies, acupuncture or other alternative treatments. You should also tell your study doctor about any changes to these during your participation in the research project. Your study doctor should also explain to you which treatments or medications need to be stopped for the time you are involved in the research project.

13 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. You should be aware that data collected by researchers up to the time you withdraw will form part of the research project results (apart from the data collected from

Services Australia). If you do not want them to do this, you must tell them before you join the research project.

14 Could this research project be stopped unexpectedly?

This research project may be stopped unexpectedly for a variety of reasons. These may include reasons such as:

- Unacceptable side effects
- The treatment approach being shown not to be effective
- The treatment approach being shown to work and not need further testing
- Decisions made by local regulatory or health authorities

15 What happens when the research project ends?

At the end of the research project, your local doctor will have received a copy of your pharmacogenomic test results and can discuss antidepressant treatment options with you.

It is anticipated that this project will be completed in 2024. You will be provided with a summary of the results of the project if you wish.

Part 2 How is the research project being conducted?

16 What will happen to information about me?

By signing the relevant consent forms 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 to maintain your privacy. Your 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 assigned a unique study identification number (study participant ID) when you join the research project. This study participant ID will be used to label your study documents (kept by the study coordinator) and information collected by study staff, including answers you provide when completing study questionnaires. Information will be stored in a secure electronic database in de-identified format (coded with your study participant ID and with personal identifiers removed). The same study participant ID will also be linked to the DNA sample you provide for pharmacogenomic analysis; however, only the study coordinator, study doctor and study-specific operational staff at The George Institute for Global Health will have access to the study participant ID list and be able to re-identify your study documents and DNA sample. Operational staff at The George Institute for Global Health require access to your identifiable information to arrange for courier collection of your DNA sample and provision of your Treatment Guide to your treating clinician. Under no circumstances will your identifiable information be given to MyDNA Life Australia Pty Ltd.

Identifiable information (personal information that will disclose your identity) such as your name and age will be stored separately from sensitive information (such as your health data) collected from you. This is to ensure protection of the confidentiality of project participants at all times. The research project database is access-controlled, and only delegated study staff can access the information. The type of information can that be accessed by study staff will be limited depending on their role in the research project.

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 format (coded with all personal identifiers removed). If you agree and provide consent (Consent Form '**A**'), your de-identified data may be used in the future for other related ethics-approved research.

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 (Consent Form '**A**') you agree to the study team accessing health records if they are relevant to your participation in this research project.

Your personal information specified within the consent form (Consent Form '**C**") will be sent securely to Services Australia to authorise the release of your Services Australia information to the research project. Services Australia will retain your consent form for the life of the research project as a record of your consent. A copy of your consent form will also be retained by the research project for the life of the project. Your Services Australia information will be de-identified and stored securely by the research project on servers, or hosted through secure cloud computing providers, physically located within Australian borders. Your Services Australia information will not be sent outside of Australian jurisdiction and is governed by the Privacy Act 1988. Your Services Australia information will not be used for any future unrelated research.

Your Services Australia information that has been included in de-identified databases will be securely destroyed after the final publication of the research project (15 years). However, if you withdraw from the research, 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 research project in a manner appropriate to the security classification of the record content.

Research project documents will be stored on site at *[Name of institution]* in a secure location with access provided to study staff only. Electronic study data will be stored securely on the St Vincent's Hospital network and The George Institute for Global Health network. Only delegated study staff can access the study data. Study data will be retained for a minimum of 15 years after study completion in accordance with local regulatory requirements. Following this, study data will be destroyed – standard paper destruction methods e.g. confidential disposal/shredding will be used for destruction of study documents and electronic study data will be permanently deleted.

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 and authorised representatives of the Sponsor, The George Institute for Global Health, the institution relevant to this Participant Information Sheet, *[Name of institution]*, 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 for this purpose.

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/or [Name of state/territory]* 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.

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.

18 Who is organising and funding the research?

This research project is being conducted by Associate Professor Kathy Wu, St Vincent's Hospital and the University of New South Wales, Sydney, in collaboration with [local PI] and researchers at Universities and Healthcare Facilities across Australia. The research project is being coordinated by Associate Professor Kathy Wu and The George Institute for Global Health.

The University of New South Wales (UNSW) and collaborating research institutions may benefit financially from this research project if, for example, the project assists them in obtaining approval for a new treatment approach for depression.

By taking part in this research project you agree that samples of your DNA (or data generated from analysis of these materials) may be provided to UNSW. UNSW 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 UNSW.

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

[Name of institution] will receive a payment from the Medical Research Future Fund (the National Health and Medical Research Council) for undertaking this research project.

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 *[Name of institution]*.

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.

Services Australia has confirmed that this research and any associated documents, have been approved by a HREC that is registered with the National Health and Medical Research Council (NHMRC) and operates within guidelines set out by the NHMRC.

20 Further information and who to contact

The person you may need to contact will depend on the nature of your query.

If you want any further information concerning this project or if you have any medical problems which may be related to your involvement in the project (for example, any side effects), you can contact the principal study doctor on *[phone number]* or any of the following people:

Clinical contact person

Name	*[Name]*
Position	*[Position]*
Telephone	*[Phone number]*
Email	*[Email address]*

For matters relating to research at the site at which you are participating, the details of the local site complaints person are:

Complaints contact person

Name	*[Name]*
Position	*[Position]*
Telephone	*[Phone number]*
Email	*[Email address]*

For more information about matters relating to privacy and how your personal information is handled by the Study Sponsor, The George Institute for Global Health, please refer to The George Institute's Privacy Policy (https://www.georgeinstitute.org.au/privacy-policy)

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:

Reviewing HREC approving this research and HREC Executive Officer details

Reviewing HREC name	St Vincent's Hospital HREC
Ethics reference no.	2021/ETH00806
HREC Executive Officer	Research Officer
Telephone	02 8382 4960
Email	SVHS.Research@svha.org.au

Local HREC Office contact (Single Site -Research Governance Officer)

Name	*[Name]*
Position	*[Position]*
Telephone	*[Phone number]*
Email	*[Email address]*

What do I do if I have a privacy complaint?

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 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.

[State]
Website: *[State Privacy Commissioner website]*
Telephone: *[State Privacy Commissioner phone number]*
Email: *[State Privacy Commissioner email address]*
Mail: *[State Privacy Commissioner postal address]*

Consent Form A - Main Study - *Adult providing own consent*

Title	An Australian Multicentre Double-Blinded Randomised Controlled Trial of Genotype-guided versus Standard Psychotropic Therapy in Moderately-to-Severely Depressed Patients Initiating Pharmacotherapy
Short Title	ALIGNED Study
Project Sponsor	The George Institute for Global Health
Coordinating Principal Investigator/ Principal Investigator	*[Coordinating Principal Investigator/ Principal Investigator]*
Associate Investigator(s)	*[Associate Investigator(s)]*
Location	*[Location where the research will be conducted]*

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 give permission for my doctors, other health professionals, hospitals or laboratories to release information to *[Name of Institution]* concerning my disease and treatment for the purposes of this project. I understand that such information will remain confidential.

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 the personal information I provide during the research project will be collected and used as set out in the Participant Information Sheet.

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

Name of Participant (please print) _____

Signature _____ Date _____

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.

I understand that, if I decide to discontinue the study treatment, I may be asked to attend follow-up visits/session 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 storage and use of coded DNA samples taken from me for use, as described in the relevant section of the Participant Information Sheet, for (tick as many as applicable):

☐ This specific research project
☐ Other research that is closely related to this research project
☐ Any future research

Name of Participant (please print) _____

Signature _____ Date _____

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.

By signing this consent section, I agree to the use of my coded health information and data, as described in the relevant section of the Participant Information Sheet, for (tick as many as applicable):

☐ This specific research project
☐ Other research that is closely related to this research project
☐ Any future research (please note Services Australia will not be used for any unrelated research)

Name of Participant (please print) _____

Signature _____ Date _____

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.

Consent Form B – Optional Neuroimaging Component –

Adult providing own consent

Title	An Australian Multicentre Double-Blinded Randomised Controlled Trial of Genotype-guided versus Standard Psychotropic Therapy in Moderately-to-Severely Depressed Patients Initiating Pharmacotherapy
Short Title	ALIGNED Study
Protocol Number	*[Protocol Number]*
Project Sponsor	*[Project Sponsor in Australia]*
Coordinating Principal Investigator/ Principal Investigator	*[Coordinating Principal Investigator/ Principal Investigator]*
Associate Investigator(s)	*[Associate Investigator(s)]*
Location	*[Location where the research will be conducted]*

Declaration by Participant

I have the information in the Participant Information Sheet relating to the neuroimaging study component or someone has read it to me in a language that I understand.

I understand the purposes, procedures and risks of the neuroimaging study component described in the project.

I give permission for my doctors, other health professionals, hospitals or laboratories to release information to *[Name of Institution]* concerning my disease and treatment for the purposes of this project. I understand that such information will remain confidential.

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 the personal information I provide during the research project will be collected and used as set out in the Participant Information Sheet.

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

Name of Participant (please print) _____

Signature _____ Date _____

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.

By signing this consent section, I agree to the storage and use of coded MRI data for use, as described in the relevant section of the Participant Information Sheet, for (tick as many as applicable):

☐ This specific research project
☐ Other research that is closely related to this research project
☐ Any future research

Name of Participant (please print) _____

Signature _____ Date _____

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.

By signing this consent section, I agree to being contacted by the research team in the future for other ethics-approved research projects.

Name of Participant (please print) _____

Signature _____ Date _____

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.

Alternatively, I do not wish to be contacted by the research team in the future for other ethics-approved research project: ☐

Participant Study ID: _____

Consent Form C – MBS/PBS Data Linkage (Participant Consent Form for the release of Services Australia information) - *Adult providing own consent*

Title	An Australian Multicentre Double-Blinded Randomised Controlled Trial of Genotype-guided versus Standard Psychotropic Therapy in Moderately-to-Severely Depressed Patients Initiating Pharmacotherapy
Short Title	ALIGNED Study
Project Sponsor	The George Institute for Global Health
Coordinating Principal Investigator/ Principal Investigator	*[Coordinating Principal Investigator/ Principal Investigator]*
Associate Investigator(s)	*[Associate Investigator(s)]*
Location	*[Location where the research will be conducted]*

Consent to release of Medicare Benefits Schedule (MBS) and/or Pharmaceutical Benefits Scheme (PBS) claims by Services Australia to The George Institute for Global Health for the purposes of the ALIGNED Study.

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

Any changes to this form must be initialled by the signatory. Incomplete forms may result in the research project 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 research project.
□ the results of this research may be published in articles or journals.
□ my name will never be disclosed by Services Australia, used in the research project or published.
□ my participation in the research project is completely voluntary.
□ I can withdraw my consent to release my Services Australia information to the research project at any time (refer to the participant information sheet and withdrawal of consent form) and I do not have to provide a reason.
□ the information provided to me about the research project, and I have been given the opportunity to ask questions, and any questions I have asked have been answered to my satisfaction.

Consent:
□ I consent to the disclosure by Services Australia of my MBS and/or PBS information to researchers for the purposes of the project.

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 the Services Australia to provide my:

☐ Medicare & PBS claims histories OR
☐ PBS claims history OR
☐ Medicare claims history

For the period* XX / XX / 20XX to: XX / XX / 20XX to the ALIGNED Study.
DD / MM / YYYY DD / MM / YYYY

Date range is to be completed prior to or at the time of signing the consent form.
*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.

☐ In the event that I pass away during the study period, I consent to Services Australia to continue to provide my claims information to the research project.

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**)	ATC Code	ATC Name
06/03/09	01/03/09	03133X	Oxazepam Tablet 30 mg	Concessional Ordinary	$5.30	$25.55	N05 B A 04	Oxazepam
04/07/09	28/05/09	03161J	Diazepam Tablet 2 mg	General Ordinary	$30.85		N05 B A 01	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 payments, 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 D for Withdrawal of Participation – Main Study - *Adult providing own consent*

Title	An Australian Multicentre Double-Blinded Randomised Controlled Trial of Genotype-guided versus Standard Psychotropic Therapy in Moderately-to-Severely Depressed Patients Initiating Pharmacotherapy
Short Title	ALIGNED Study
Project Sponsor	The George Institute for Global Health
Coordinating Principal Investigator/ Principal Investigator	*[Coordinating Principal Investigator/ Principal Investigator]*
Associate Investigator(s)	*[Associate Investigator(s)]*
Location	*[Location where the research will be conducted]*

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 *[Institution]*.

Name of Participant (please print) _____

Signature _____ Date _____

You can also withdraw from the research project verbally by phoning *[insert name]* on *[insert number]* who will complete the Participant Withdrawal of Consent Form on your behalf.

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, including a record of the date and time of the verbal communication of withdrawal.

Date:
Time:
Details/Comments:

The complete withdrawal form will be sent to the participant where withdrawal is communicated verbally.

Declaration by Study Doctor/Senior Researcher (for withdrawal communicated verbally)†

I declare that the above information is true and correct. I have not sought to influence the participant's decision in completing the withdrawal of consent form. I understand that providing a false declaration is a serious offence.

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 Doctor/
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.

Form E for Withdrawal of Participation – Optional Neuroimaging Component - *Adult providing own consent*

Title	An Australian Multicentre Double-Blinded Randomised Controlled Trial of Genotype-guided versus Standard Psychotropic Therapy in Moderately-to-Severely Depressed Patients Initiating Pharmacotherapy
Short Title	ALIGNED Study
Project Sponsor	The George Institute for Global Health
Coordinating Principal Investigator/ Principal Investigator	*[Coordinating Principal Investigator/ Principal Investigator]*
Associate Investigator(s)	*[Associate Investigator(s)]*
Location	*[Location where the research will be conducted]*

Declaration by Participant

I wish to withdraw from participation in the neuroimaging component of the research project and understand that such withdrawal will not affect my routine treatment, my relationship with those treating me or my relationship with *[Institution]*.

Name of Participant (please print) _____

Signature _____ Date _____

You can also withdraw from the research project verbally by phoning *[insert name]* on *[insert number]* who will complete the Participant Withdrawal of Consent Form on your behalf.

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, including a record of the date and time of the verbal communication of withdrawal.

Date:
Time:
Details/Comments:

The complete withdrawal form will be sent to the participant where withdrawal if communicated verbally.

Declaration by Study Doctor/Senior Researcher (for withdrawal communicated verbally)†

I declare that the above information is true and correct. I have not sought to influence the participant's decision in completing the withdrawal of consent form. I understand that providing a false declaration is a serious offence.

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 Doctor/
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.

Participant Study ID: _____

Form F for Services Australia Participant Withdrawal of Consent Form – MBS/PBS Data Linkage - *Adult providing own consent*

Title	An Australian Multicentre Double-Blinded Randomised Controlled Trial of Genotype-guided versus Standard Psychotropic Therapy in Moderately-to-Severely Depressed Patients Initiating Pharmacotherapy
Short Title	ALIGNED Study
Project Sponsor	The George Institute for Global Health
Coordinating Principal Investigator/ Principal Investigator	*[Coordinating Principal Investigator/ Principal Investigator]*
Associate Investigator(s)	*[Associate Investigator(s)]*
Location	*[Location where the research will be conducted]*

Declaration by Participant

I wish to withdraw my consent to release my Services Australia information to the research project effective from the date below. I request that the study handles the information they have collected about me from Services Australia in the following way (choose one option):

☐ DESTROY all information collected about me to date so it can no longer be used for research
☐ RETAIN all information collected about me to date so it can continue to be used for research

I understand that:
1. no further information about me will be collected for the research project from the withdrawal date;
2. information about me that has already been analysed and/or included in a publication by the research project, may not be able to be destroyed; and
3. choosing to withdraw from the research project will not affect my access to Health Services or Government benefits.

Name of Participant (please print) _____

Signature _____ Date _____

You can also withdraw from the research project verbally by phoning *[insert name]* on *[insert number]* who will complete the Participant Withdrawal of Consent Form on your behalf.

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, including a record of the date and time of the verbal communication of withdrawal.

Date:
Time:
Details/Comments:

The complete withdrawal form will be sent to the participant where withdrawal is communicated verbally.

Declaration by Study Doctor/Senior Researcher (for withdrawal communicated verbally)†

I declare that the above information is true and correct. I have not sought to influence the participant's decision in completing the withdrawal of consent form. I understand that providing a false declaration is a serious offence.

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 Doctor/
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.