

Participant Information Sheet

Project Title: AusGDB: An Australian genetic database study of functional genetic variants and environmental factors in major depression

Researchers:

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This is an invitation to participate in a genetic study of major depression. We are asking two groups of people to participate in this study: 1) Healthy people who do not have any serious medical or mental health problems, and 2) People who have been told by their doctors that they have major depression and need treatment for that condition, and who are otherwise relatively healthy. These two groups of people are needed because our study will compare their results.

We wish to see how genetics can help us understand the causes major depression and course of this condition. We are asking you to donate a sample of your blood or saliva and hair for testing, and to agree to provide us with some information about you and your family.

This project is carried out under the guidelines set out by the National Statement on Ethical Conduct in Human Research and there is certain information we are required to give you. If you do not understand this explanation, please talk to the research staff. You may want to discuss this information and your involvement with family, friends or your usual doctor. Once you understand the research and agree to take part, you will need to sign a Consent Form. If you sign you are saying that you understand and agree to participate in this research. You will be given a copy of this information sheet and your signed Consent Form for your records.



If you agree to participate in this study we will take a blood sample 10 ml (2tbs) during your interview at our research clinic located at the South Australian Health and Medical Research Institute (SAHMRI), Level 4, North Terrace, Adelaide, SA 5000.

We will also ask that you attend a single interview of about 4 hours with a member of the research team to discuss your health and/or your history of major depression. We will obtain vital signs (blood pressure, heart rate and breathing rate), anthropometric measures (height, weight and waist/hip circumference), and body composition. The body composition test lasts 1 minute, participants will be requested to stand bare feet on the bioimpedance InBody 170 device and small harmless electrical signals will be emitted to the feet and hands, and resistance of body tissues to the flow of electrical signals will be measured. Participants who have pacemakers will not be submitted to body composition analysis. We will use research questionnaires for i) the diagnosis of depression and to exclude other important psychiatric conditions; ii) assessing your mood and anxiety levels; iii) assessing drinking, smoking and food habits. The interview will be conducted by a member of our research team, who is familiarised with the questionnaires we use.

If you have a history of major depression we will ask your permission to obtain information from your medical records in relation to your diagnosis, and any existing test results, only if that information is important to understand your diagnosis. You will answer if you agree or not agree to provide consent for your previous medical records to be requested from your usual doctor(s). If you agree to provide information, this information will be used to clarify past significant events, medications or tests that could help us better understand your diagnosis.

What is genetic research?

The cells of your body contain deoxyribonucleic acid, DNA for short. DNA is passed down from your parents. It carries the genes that determine physical features such as the colour of your hair and eyes. Differences in our genes help explain why we all look different. The DNA in most cells in your body is the same. The instructions for physical features are contained in your DNA.

This project will study the differences in the participants' DNA to better understand major depression and who may be more likely to develop it.

What will the sample be used for?

If you agree to take part in the DNA testing, you are giving permission for the research team to use your samples to be tested for genetic markers that may be relevant to major depression. A "code key" will link your personal information and your research data and samples for a minimum of thirty calendar days. As this link will be temporary, after that period the link between your research data and samples and your personal information will be removed, and we will not be able directly identify your results. If you change your mind and withdraw your permission before the removal of the, "code key" your research data and samples will not be used. If you change your mind after the "code key" is removed we will not be to identify individual research data and samples, therefore, your research data and samples will be tested. The "code key" is a list of codes and the participants to whom they have been assigned. After that code key is removed we will not be able to give any individual results to participants. So the samples and research data will effectively be anonymous.

Your unique DNA, once the identifying link has been removed, can only be identified if there is another sample of your DNA to compare it with.

General information about your age, sex and state of health will be kept with the information about your sample, but this information will not be specific enough to identify you.

The samples and data collected for this study will be enough for the two phases of our research: 1) Phase 1 study will be an immediate study in relation to major depression, and 2) Phase 2 study will be future studies. We will store your sample and research data for future research. There are different parts to this research, and you can agree to any or all of them, by marking that you 'agree' or 'disagree' on the consent form before you sign it. Phase 1 study is for this specific project and phase 2 study involves storing your sample for research in the future, as we find out more about major depression.

We will also collect hair sample from the scalp for the measurement of long-term lead exposure.

Phase 1 study: Testing DNA in major depression for immediate study



In this part of the project, we will use the DNA from your blood/saliva in a DNA chip to test for gene variations that may cause variations in proteins or that may influence the levels of proteins. We will also obtain the sequence of the whole genome in some samples. This study intends to find and/or study genes related to major depression. No other testing will be done on your DNA sample in this part of the research. Some information from your medical history and research questionnaires may be provided in coded form, so that the results of the testing can be looked at in relation to the diagnosis of major depression. No information that could identify you will be given to anyone outside of the local research team, except for particular inspection and quality control purposes as explained below.

Phase 2 study: Storage of blood sample / DNA / general clinical information for future research

In this part of the project, you may agree that part of your sample and some general clinical information will be stored for any kind of future research by the research team. If you agree to this part of the research, part of your sample and research data information will be stored at Flinders University/South Australian Health and Medical Research Institute for use in future research. All research for which your sample will be used will have the approval of a Human Research Ethics Committee in Australia or in other countries, but it will not necessarily relate to major depression.

Confidentiality

These tests will be done at Flinders University/South Australian Health and Medical Research Institute, the Australian National University or the Australian Genome Research Facility. Samples may also be sent to other research sites in Australia or overseas for tests and analyses.

For phase 1 and phase 2 studies your stored blood, saliva, DNA, plasma, and hair samples will be labelled only with a code number and that code will not be linked to your personal information. Samples and research data will effectively be anonymous after the "code key" is removed.

In phase 1 study your trial doctor will send your samples for testing.

In phase 2 study your DNA extracted from blood or saliva will be stored and available for future research.

Information collected as part of the research study will be accessed only by staff members of the hospital/clinic who would normally have access to the records, and no information that could identify you will be passed on to anyone who is not either an employee of Southern Adelaide Health Service or a member of the research team.

Your trial doctor will keep your signed consent forms. These will be kept separate from your medical and research records. Representatives of the research team, SA Health, Flinders University, South Australian Health and Medical Research Institute, the ethics committee or health authorities [such as the Therapeutic Goods Administration, the European Medicines Evaluation Agency or the US Food and Drug Administration], may at times access the records at our local research site to ensure that the research is being done correctly. Your results and samples will be kept securely at all times. Anyone who has access to your identified records is bound by law and by professional codes of conduct to keep your information confidential.

Results from this research will be published in various ways, including conference papers and journal articles, and if you agree to phase 2 study your data and samples may in future be used in the development of treatments for major depression including new drugs. Results will not be published in a form that could identify you.

Your results may be sent to research partners in countries other than Australia only in a coded format. Some of these countries may not have the same levels of privacy protection as in Australia, but the researchers will ensure that your information is protected. Unless the law requires it, your information will not be given to employers, insurance companies or the public.

What if I change my mind later?

If you change your mind, you may ask for your samples to be destroyed. This can be done at any time before the "code key" is removed from your samples and research data, as after that point there will be no way to tell which results are

yours. The temporary link between your personal data and your research data and samples will last for a minimum of thirty calendar days, after which that link will be removed and the samples and research data will effectively be anonymous.

If you withdraw your samples we will ask that you allow the results of any tests done so far to remain as part of the research, to ensure that the results are as useful as possible. However, you are free to require that all information that can be linked to your identity be removed from the project.

What are the benefits?

There is unlikely to be any benefit to you from taking part in this testing, but it may help other people with major depression later on. The results of the trial are only for research, and can't be used directly to assist your medical treatment.

What are the risks?

The risks are the same as for any standard blood sampling. There may be some pain and bruising, and (very rarely) infection. Some people faint when blood is drawn.

Taking part in DNA testing is not expected to affect your employment or health / life insurance as results will not be given to any third parties. Because the samples and research data will effectively be anonymous we will not be able to give individual results to participants.

Compensation

If you suffer injury as a result of participation in this research project, compensation might be paid without litigation. However, such compensation is not automatic and you may have to take legal action to determine whether you should be paid.

What are the implications for me and my family?

This study is not intended to provide information about your individual health, and we will not be able to give the participants their individual results because samples and research data will effectively be anonymous after the "code key" is removed from their data and samples.

How will my samples be stored?

All samples will be stored in a secure facility. Only authorised people from the research team will be able to access them.

Will I get my DNA test results?

No. Your identity will not be linked to your research data and samples; therefore, you will not be able to receive your individual DNA or biochemical results.

Will I be paid for taking part?

You will not be paid for taking part in genetic testing or for the use of your samples or information, even if the results of the study are profitable for the research team or their organisation/s. The results of the testing and any information that come out of it are owned by the research team and their organisation/s.

Re-imbusement for parking/travel

Participants will receive a \$25 gift card for their participation in this study.

For further information

If you would like more information about this study, now or later, you can contact

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This study has been reviewed and approved by the Southern Adelaide Clinical Human Research Ethics Committee. Should you wish to discuss the study with someone not directly involved, in particular in relation to matters concerning policies, your rights as a participant, or should you wish to make a complaint, you may contact the Executive Officer on (08) 8204 6453 or email research.ethics@fmc.sa.gov.au.