Australian Dementia Network

REGISTRY. CLINICS. TRIALS.

Participant Information Sheet/Consent Form

Non-Interventional Study - *Adult providing own consent*

Title	The Australian Dementia Network (ADNeT) Volunteer Portal
Short Title	ADNeT Online Portal
Protocol Number	62252
Principal Investigator	Professor Christopher Rowe
Location	Online

Part 1 What does my participation involve?

1 Introduction

You are invited to take part in this research project, The Australian Dementia Network (ADNeT) Volunteer Portal, as a means of indicating your interest in being involved in future dementia research and trials. This project aims to establish a large group of Australians aged 50 and over who are happy to be contacted about future studies in which they may be eligible to enrol, based on their answers to online questionnaires.

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

If you decide you want to take part in the research project, you will be asked to sign the consent section electronically at the end of this form. By signing it you are telling us that you:

- Understand what you have read
- Consent to take part in the research project
- Consent to the tests and research that are described
- Consent to the use of your personal and health information as described.

2 What is the purpose of this research?

Alzheimer's disease affects one fifth of our population by age 75. Our society is also witnessing a rapid growth in Alzheimer's disease prevalence and we anticipate the number of sufferers will triple by the year 2040. The slow build-up of two toxic proteins called amyloid and tau, are believed to be the cause of Alzheimer's disease. Positron emission tomography (PET) is a scanning technique that uses tiny doses of radioactively tagged compounds to give pictures of brain and body chemistry. These PET scans have shown that the amyloid build-up begins years before the development of symptoms. It is also the current thought that amyloid may speed up the formation of the other toxic protein called tau. Amyloid brain scans can detect the onset of Alzheimer's disease 15-20 years before symptoms first appear. The earlier that drugs designed to slow the build-up of amyloid or to clear it from the brain are given, the greater the chance of preventing dementia.

The purpose of this project is to allow participants to express interest in being involved in dementia research and intervention trials. Based on your answers to questionnaires presented online you will be contacted by researchers running studies or trials that you might be eligible to enrol in. Any study or trial to whom your details are provided will have their own approval from a Human Research Ethics Committee. It is hoped that by developing a large online register of 5000 participants that recruitment into research studies and trials will be improved.

3 What does participation in this research involve?

Participation in this study involves providing information about yourself by completing online questionnaires. You will be asked about:

- Your contact details
- The type of research you would like to be involved in
- Whether you are worried about your memory
- Your family history of dementia
- Your level of education and fluency in English
- Your medical history

You may be asked to provide a saliva sample via post, which will be tested for genetic risk factors for dementia. The results of this test will help us better match you to future research studies. You will not find out the results of the genetic testing. You may also be asked to complete an online memory test.

The questionnaires presented in this study are all online. You will be asked to complete them once only. You can complete them in your own home in your own time. You do not need to visit any study site to participate in this project. There are no costs associated with participating in this research project, nor will you be paid.

4 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. You can withdraw by declining to complete online questionnaires, or by contacting study staff listed at the end of this form. If you do decide to take part, you will be asked to sign this Participant Information and Consent Form electronically. A copy will be emailed to you 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 any of the institutions where this research is taking place.

There will be no charge to you for your participation in this study.

5 What are the possible benefits of taking part?

Participation in this project may help identify further research and trials that you may be eligible to participate in. This is because the researchers running this study collaborate with many other dementia researchers, who will use this cohort of participants to source people for their projects.

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

This research does not involve any interventional treatment. Thus, it is not expected that there are any significant risks of enrolling in this study. There is a small chance that you might be distressed by questions regarding your medical or family history. If you become upset or distressed as a result of your participation in the research, study staff will be able to arrange for counselling or other appropriate support. Any counselling or support will be provided by qualified staff who are not members of the research project team. This counselling will be provided free of charge.

7 What will happen to my test samples?

You may be asked to provide a saliva sample as part of the research project. If you are asked and agree to providing a saliva sample, it will be deidentified and coded using a unique study number and then sent to an external service provider to analyse for known genetic risk factors for dementia. These results will be sent back to the staff working on this project, who can re-identify the results as yours and use them to better match you to future research studies. The sample and result will be used for only this purpose, and then destroyed. You will not be informed of the results of the genetic testing.

8 Can I have other treatments during this research project?

This study does not have any specific treatments or restrictions on medications your doctor has prescribed for you.

9 What if I withdraw from this research project?

If you withdraw your consent during the research project, no additional personal information will be collected from you from the time you withdraw. 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 up to the time you withdraw will form part of the research project results.

Note that once you have submitted your responses to the online survey, you will be unable to return to the survey to indicate that you no longer consent to participating in the project. If you decide after completing the questionnaire that you no longer wish to participate (that is, to be contacted about future research studies) you can email ADNET-screening@unimelb.edu.au to advise the study team of this. Alternatively, direct contact details for relevant study staff are provided at the end of this form.

10 Could this research project be stopped unexpectedly?

This research project may be stopped unexpectedly for a variety of reasons. Such reasons may include:

- Decisions made in the commercial interests of the sponsor, or by local regulatory/health authorities

11 What happens when the research project ends?

Once you have completed the study, no further follow-up is required.

Part 2 How is the research project being conducted?

12 What will happen to information about me?

By signing the online consent form you consent to the study investigators 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. It will be disclosed only with your permission, or as permitted by law.

Any information obtained during the study is subject to inspection (for the purpose of verifying the procedures and the data) by the relevant authorities and the organisations relevant to this Austin Health Participant Information and Consent Form or as required by law. By signing the consent section, you authorise release of, or access to, this confidential information to the relevant study personnel and regulatory authorities as noted above.

Your data will be stored indefinitely on a secure password-protected server maintained by CSIRO. All identifying information such as your name will be removed and replaced with a code number that can be used to link your results together but not to identify you. CSIRO will hold the code in a secure database kept separately to other study data to ensure you cannot be identified, except by personnel working directly on this study, so that they can advise you of future research projects in which you might like to participate.

In accordance with relevant Australian and/or state 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.

13 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.

14 Who is organising and funding the research?

This research project is being conducted by Professor Christopher Rowe, the Principal Investigator of the Australian Dementia Network (ADNeT). Staff working on this study will be based at Austin Health or the University of Melbourne. ADNeT is being partially funded by a research grant from the National Health and Medical Research Council (NH&MRC). ADNeT may benefit financially from this project if, for example, it assists in boosting recruitment into sponsored pharmacological trials.

You will not benefit financially from your involvement in this research project, even if the project proves to be of commercial value. No member of the research team will receive a personal financial benefit from your involvement in this research project (other than their ordinary wages).

15 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 Austin Health.

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.

16 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 concerns which may be related to your involvement in the project, you can contact the principal study doctor, Professor Christopher Rowe, on (03) 9496 5183 or the national study coordinator:

Name: Dr Joanne Robertson
Position: ADNeT Screening and Trials coordinator
Telephone: (03) 9389 2937 or (04) 0850 8121
Email: jo.robertson@unimelb.edu.au

Details of the local site complaints person at Austin Health are:

Position: Complaints Contact Officer
Telephone: (03) 9496 4035 or (03) 9496 4090
Email: ethics@austin.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:

Austin Health Human Research Ethics Committee

Name: Ms Lisa Pedro
Position: HREC Executive Officer
Telephone: (03) 9496 4035
Email: ethics@austin.org.au

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Consent Agreement

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 consent to the use of my saliva sample to be tested for genetic information as indicated in section 3 and section 7 of this PICF.

I understand that I will be given a copy of this document to keep, via email.