Australian Dementia Network

REGISTRY. CLINICS. TRIALS.

Austin HEALTH

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# Participant Information Sheet/Consent Form

**Non-Interventional Study** - *Adult providing own consent*

| | |
|---|---|
| **Title** | The Australian Dementia Network (ADNeT) Volunteer Register |
| **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 The Australian Dementia Network (ADNeT) Volunteer Register, as a means of indicating your interest in being involved in future dementia research and trials. This register aims to establish a large group of Australians aged 50 and over who are happy to be considered for suitable studies.

Slow recruitment into clinical trials and research studies delay the development of treatments for dementia. We hope that by developing a large online register, recruitment into dementia studies and clinical trials will improve.

Signing up for this register is voluntary. You will receive the best possible care whether you take part or not.

If you decide you want to sign up to this register, 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 register
- Consent to the tests and research described here
- 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. Alzheimer's disease prevalence is also growing rapidly and we anticipate the number of people living with dementia will triple by the year 2040.

The purpose of this register is to allow participants to express interest in being involved in dementia research and intervention trials. Based on your answers to our online questionnaires we will assess whether you might be eligible to enrol in active clinical trials. If suitable, you will be contacted by researchers for further information.

Any study or clinical trial to which we provide your details will have approval from a Human Research Ethics Committee.

## 3 What does participation in this register involve?

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

- Your contact details – so we can contact you about participation in research and/or trials.
- The type of research you would like to be involved in – there are trials that involve lifestyle interventions and trials that involve drugs/medication. If you have a preference you can tell us via the questionnaire.
- Whether you are worried about your memory – this is simply to know how you feel about your memory, whether this is something that worries you.
- Your family history of dementia – this will help us assess your risk of developing dementia.
- Your level of education and fluency in English – this is necessary to ensure that you are able to complete the required tests. These are standardised tests that require a good understanding of English. If reading and understanding English is difficult, this may result in unreliable results or inability to complete the tests.
- Your medical history – this is necessary to ensure you don't suffer of a major health condition that might make you ineligible for clinical trials.

You may also 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 may also be asked to complete an online memory test.

We do not normally provide the results of these tests.

All questionnaires related to this register are online. You will be asked to complete them once only. You can complete them in your own home in your own time.

## 4 Do I have to take part in this research project?

Participation in this project is voluntary. You do not have to participate if you do not want to take part. 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. You can download and save a copy to keep if you want to.

Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect any treatment you may be undergoing, your relationship with those treating you or your relationship with any of the institutions where this project is taking place.

There will be no cost to you for your participation in this register and you will not be paid for your participation.

## 5 What are the possible benefits of taking part?

We are not able to promise that you will be selected for future dementia research and/or trials by participating in this register. However, participants in the register may be more likely to be selected for such studies. 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.

Selection to individual trials depends on strict criteria set by the trial or research project.

Ultimately, by participating in dementia research and trials you will help researchers who are trying to find treatments to prevent and slow the progression of dementia.

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

Being part of the register does not involve any interventional treatment. Thus, it is not expected that there are any significant risks of enrolling in this register.

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 this register, 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 provide a saliva sample, it will be de-identified and coded using a unique study number and then sent to a collaborating research institute (QIMR Berghofer) 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.. You will not be informed of the results of the genetic testing.

We will store your DNA samples for use in future Ethics Committee approved research studies that may or may not be related to this study. In the future, other doctors and scientists at this and other medical and research centres may use your samples to learn about many different diseases and conditions. This work may include de-identified DNA being shipped to an external service provider to be analysed using genotyping arrays or for sequencing. The external provider will have no access to identifying information and will return or destroy any remaining sample after analysis. Their goal is to

improve health outcomes and develop new treatments. The purpose of storing these types of samples is to answer questions in the future, so we expect to keep your samples indefinitely.

**8 Can I have other treatments while being part of the register?**

Participating in the register does not have any restrictions on specific treatments or medications your doctor has prescribed for you.

**9 What if I withdraw from the register?**

If you withdraw your consent to participate in the register, 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 project can be measured properly and to comply with law. You should be aware that data collected up to the time you withdraw, including your saliva sample, will be retained and form part of the 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 after completing the questionnaire you decide that you no longer wish to participate in the register (that is, you no longer want to be contacted about future research studies) you can email ADNET-screening@unimelb.edu.au to advise the study team of this. You can also contact relevant study staff listed at the end of this form.

**10 Could this register be stopped unexpectedly?**

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

- Decisions by local regulatory/health authorities, or
- Changes to research funding

**11 When will this register be closed?**

There is no anticipated end-date for the volunteer portal, as information will be retained to match registrants for upcoming research and trials.

## Part 2 How is the volunteer register being conducted?

**12 What will happen to information about me?**

By signing this consent form you consent to study investigators and relevant research staff collecting and using personal information about you for dementia research. Any information obtained in connection with your registration on the volunteer register that can identify you will remain confidential. It will be disclosed only with your permission, or as permitted by law.

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.

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.

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 correction of any information you deem incorrect. Please contact the team member named at the end of this document if you would like to access your information.

## 13 Complaints and compensation

This consent form relates to your registration as a volunteer for future dementia research projects and trials.

If you suffer any injuries or complications as a result of this, you should contact the volunteer register 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 volunteer register is being set up by Professor Christopher Rowe, the Principal Investigator of the Australian Dementia Network (ADNeT) as part of a larger research project looking at improving the diagnosis of dementia and participation in dementia clinical trials. Staff working on this project will be based at Austin Health or the University of Melbourne. ADNeT is being funded by a research grant from the National Health and Medical Research Council (NH&MRC) as well as philanthropic grants and commercial companies (e.g. pharmaceutical companies).

You will not benefit financially from your involvement in this register, 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 register (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
***Position:*** HREC Executive Officer
***Telephone:*** (03) 9496 4090
***Email:*** ethics@austin.org.au

# Consent Form - *Adult providing own consent*

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| **Protocol Number** | 62252 |
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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.

### Declaration by Participant

Please type your name and a valid email address in the below box. By doing so and clicking submit, you are providing consent to participate in this study.

*<Name>*

*<Email address>*

*<Submission button>*