

## **Participant Information Sheet/Consent Form**

### **Health/Social Science Research - Adult providing own consent**

*Turner Institute for Brain and Mental Health, Monash University*

<b>Title</b>	An investigation of genetic, psychological, lifestyle and cognitive markers of Alzheimer's disease in middle-aged adults
<b>Short Title</b>	<i>The Healthy Brain Project</i>
<b>HREC Number</b>	26855
<b>Principal Investigators</b>	<i>A/Prof Yen Ying Lim, Dr Rachel Buckley Dr Nawaf Yassi</i>
<b>Associate Investigator(s)</b>	<i>Ms Lisa Bransby Prof Paul Maruff Ms Stephanie Perin Ms Andrea Mills Ms Katherine Franks Dr Emily Rosenich Dr Laura Bird Ms Gabbi Da Costa Ms Maya Norfolk Ms Hannah Cummins</i>
<b>Location</b>	<i>Turner Institute of Brain and Mental Health, Monash University</i>

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## **Part 1 What does my participation involve?**

### **1 Introduction**

You are invited to take part in this research project, which is called The Healthy Brain Project because you are a healthy adult between the ages of 40 and 100 years who is currently living in Australia and has access to a computer or laptop.

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

Please read this information carefully. You can email us at [healthybrainproject@monash.edu](mailto:healthybrainproject@monash.edu) if you have questions about anything that you don't understand or want to know more about. We also have a Frequently Asked Questions page online ([healthybrainproject.org.au/Home/Faq](http://healthybrainproject.org.au/Home/Faq)), so please check to see if your question has been answered there. In addition, we have a forum ([healthybrainproject.org.au/forum/forums](http://healthybrainproject.org.au/forum/forums)) if you would like to see what current participants online are talking about, or post a question either to the Healthy Brain Project team or to other participants. Before deciding whether or not to take part, you might want to talk about it with a relative, friend or local health worker.

Participation in this research is voluntary. If you don't wish to take part, you don't have to.

If you decide you would like to take part in this research project, you will be asked to sign the consent section. By signing it you are telling us that you:

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

You can download a PDF version of the Participant Information and Consent Form to keep when you first log in. Once you have created a profile and consented to the study, there is also a copy of the PDF on your profile page on our website ([healthybrainproject.org.au](http://healthybrainproject.org.au)).

## **2 What is the purpose of this research?**

The main purpose of this study is to track the cognitive, lifestyle and psychological markers of a large group of community-based middle-aged adults (40-100 years inclusive) over ten years, in relation to biological factors that are consistently shown to increase risk of Alzheimer's disease (AD) dementia in older adults.

Our research aim is to determine when the earliest signs of AD appear, with the ultimate long-term outcome from our findings to inform primary and secondary prevention measures (both pharmacological and non-pharmacological). This study will primarily focus on genetic risk of Alzheimer's disease and memory decline using a range of genetic candidates. We will monitor your memory and thinking changes over ten years and try to determine how these changes might relate to normal ageing processes or other medical conditions. In particular, we are interested to determine whether we can detect extremely subtle signs of memory and thinking changes in individuals who have elevated risk for Alzheimer's disease (AD) dementia. We consider an individual to be at elevated risk for AD dementia if they have a family history of dementia and/or they have genetic signs of the disease. A gene that is associated with the greatest risk for AD dementia in the population is the apolipoprotein (APOE) gene, which we will measure in each person within the study. Our study will be one of the first of its kind to attempt to detect the earliest signs of AD dementia in middle-aged adults. This study is also unique because we will monitor your progress entirely online through your responses to memory and thinking tests, and a range of psychological and lifestyle questionnaires.

This research has been initiated by A/Prof Yen Ying Lim, Dr Rachel Buckley, and Dr Nawaf Yassi. The Healthy Brain Project ([healthybrainproject.org.au](http://healthybrainproject.org.au)) is funded by the National Health and Medical Research Council (GNT1158384, GNT1147465, GNT1111603, GNT1105576, GNT1104273, GNT1158384, GNT1171816), the Alzheimer's Association (AARG-17-591424, AARG-18-591358, AARG-19-643133), the Dementia Australia Research Foundation, the Bethlehem Griffiths Research Foundation, the Yulgilbar Alzheimer's Research Program, the National Heart Foundation of Australia (102052), and the Charleston Conference for Alzheimer's Disease.

## **3 What does participation in this research involve?**

Before you can begin this study, you will be asked to electronically consent by typing your full name on the consenting screen and ticking the checkbox that says you understand the information presented here, and that you agree to participate in this study. You will not be able to participate in the study if you do not give informed consent. Eligibility criteria for this study require you to be living in Australia to take part in this study, however, you do not need to be an Australian resident or citizen. After you have consented, you will create an online profile on the site. We will ask for your email address so that we can contact you for reminders about the study, for example, yearly follow-up reminders, reminders if you have forgotten to complete all the surveys. We will also ask for your mailing address so that we can send you a saliva DNA collection kit.

After you have consented and created a profile, you will be able to log into the Healthy Brain Project website and fill out some surveys on mood, lifestyle, medical history and motivation and engagement in research, and completing some memory and thinking tests. You will be invited to

do this each year; filling out all the surveys should take between approximately 1.5-3 hours, but they do not need to be completed in one session. You can log back into the website when you have time (over the period of a month).

The surveys will pertain to your medical history (and that of your immediate family), mood, personality, cognitive activity, sleep quality, sexual habits, social interactions, physical activity, diet, feelings and knowledge about Alzheimer's disease, and motivation and engagement in research. The surveys will be grouped broadly into 6 different sections. These will include the Basics (i.e., your demographics), Health History (i.e., your medical history and your immediate family's medical history), How You Feel (i.e., anxiety/depressive symptoms, stressful events, extroversion/introversion), and How You Live (i.e., your diet, physical activity levels, sleeping habits, cognitive activity). The final two sections will query your feelings and knowledge about AD dementia (i.e., your beliefs, attitudes, and fears around AD) and Motivation and Engagement in Research (i.e. what motivates you to participate and remain engaged in research, what you are willing to undergo for medical research). It should take approximately 10-30 minutes to complete each survey (some are shorter, and others are longer), and there are 30 surveys in total. All these surveys do not need to be completed in one sitting, but when you start one survey, we recommend completing it so that you do not leave mid-way and forget to go back and finish it.

In addition to these surveys, you will also be asked to complete a series of memory and thinking tests. These tests will measure your memory (short-term and long-term), visuospatial skills, cognitive flexibility and organisational abilities. The thinking tests will take approximately 1 hour to complete. Before you commence each of the thinking tests, more detail will be provided, and you will also be given the opportunity to practise before you start. You will need to finish the memory and thinking tests in one sitting, and you will need to ensure that you are located in a quiet environment, with minimal to no distractions (because distraction is not good for accurately gauging mental performance).

It is only after you have completed all the surveys and memory tests online that we will send you the DNA kit. In the kit, you will be sent instructions on how to deposit saliva in the receptacle, package it properly and send it back (via reply-paid registered postage) to our institute. If you have any questions about how to do this, you can email us at [healthybrainproject@monash.edu](mailto:healthybrainproject@monash.edu). After returning the kit with your saliva in it, you will not have to do this again in the study. That is, the DNA collection will be a one-time component of the study.

Using your saliva sample, we will test for several genes, including some that are known to be important for memory and thinking. Firstly, the *apolipoprotein E (APOE)* gene is important because holding a particular variant of this gene (*APOE ε4*) is known to increase the risk of AD at a population level. That is, *APOE ε4* is present in about 15% to 20% of the population and in about 40% of all people who develop Alzheimer's disease dementia. A number of other genes have also been associated with AD dementia and so understanding their effects will be important in determining resilience against brain diseases.

You will be participating in this study for ten years, and each year, you will be sent reminder emails to take the same surveys and memory and thinking tests. To repeat, the DNA kit will only be sent out in the first year.

You may be invited to extend your participation if we are awarded funding to continue the study. In this case, we will ask you to re-consent to the study.

In addition, some participants will be invited to take part in an optional study where you will be asked to complete a language learning test called "ORCA". You will complete ORCA 3 times over a 12-month period. The first session will be at Baseline, the next session will be after 6 months, and the other will be after 12 months from your initial ORCA test. These follow up tests with ORCA will test your memory for the language that we teach you. To do the ORCA test on our website will require 3 hours spread over 6 days (approximately 20 minutes per day). We would ask that you do the ORCA language test in one sitting in a quiet environment, with

minimal to no distractions (because distraction is not good for accurately gauging mental performance).

Please do not worry if you can't take a session of tests for some reason – we understand that you will not always have time to take tests, however, we ask that you try as best as possible to stick to the schedule over the 12 months. To help remind you to complete your testing, we will also send email or text reminders during your testing periods.

#### **4 Other relevant information about the research project**

We will aim to recruit approximately 10,000 individuals for this project. This study is focused on understanding the memory and thinking changes in middle-aged Australians over ten years. We have a specific interest in detecting the very earliest signs of AD dementia but will also have a broad focus on general healthy ageing, and how different psychological, lifestyle and genetic factors can be protective or maladaptive. This project involves collaborations with researchers from Monash University.

#### **5 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 need to tick the checkbox below this PDF (on the same webpage) to indicate that you have read this Participant Information and Consent Form. In the same area of the webpage, you will be asked to type in your name as an electronic signature to indicate that you are agreeing to become a participant in this study. You will be given an opportunity to download a PDF copy of this form on the consent page, and you will also find a copy of the Participant Information and Consent Form PDF in your profile page.

Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your routine care, your relationship with professional staff or your relationship with the Turner Institute, Monash University, or any other institutions that might become related to this study throughout the study.

#### **6 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 being given a small subset of the results from your testing as feedback of your progress.

You will also be able to participate on The Healthy Brain Project forum, which will give you access to extra information on brain health and latest published research in this area of neuroscience. You will also be able to ask questions directly of the chief investigators on the study, who will monitor the forum in conjunction with their lab administrators, and engage in discussions with other participants of the Healthy Brain Project to share tips on maintaining brain health, support each other in your individual brain health journeys, and be part of a community that is committed to promoting and maintaining healthy brains.

Finally, all participants of the Healthy Brain Project will be invited to attend any public lectures that members of the research team may conduct.

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

### Genetic testing

There are no known risks involved with the collection of a saliva sample. Although this saliva test can identify which versions of *APOE* a person has, it cannot predict who will or will not develop Alzheimer's disease dementia at an individual level, as we currently only understand the risk of this gene at a population level. As such, this is not a diagnostically meaningful measure of risk as recommended by the National Health and Medical Research Council ([https://www.nhmrc.gov.au/\\_files\\_nhmrc/publications/attachments/ps0001\\_clinical\\_utility\\_personalised\\_medicine\\_feb\\_2011.pdf](https://www.nhmrc.gov.au/_files_nhmrc/publications/attachments/ps0001_clinical_utility_personalised_medicine_feb_2011.pdf)) who state: "APOE testing has been used at population level to detect population level risk. The test is not accurate enough to predict individual risk" (p.5). We therefore will not indicate to you your *APOE* allele results. If you have any questions or concerns regarding this process, you can speak to the chief investigators for further information, or email us at [healthybrainproject@monash.edu](mailto:healthybrainproject@monash.edu).

### Psychological distress

You may feel that some of the questions we ask are stressful or upsetting. If you do not wish to answer a question, you may stop immediately. If you become upset or distressed as a result of your participation in the research project, please email [healthybrainproject@monash.edu](mailto:healthybrainproject@monash.edu) and the research team will be able to direct you to appropriate support. Any support services that we recommend will be provided in the State with which you reside and will not be provided by members of the research team. In addition, the National Crisis Support and Suicide Prevention service, Lifeline, can be reached at 24 hours a day, 7 days a week at 13 11 14.

## **8 What if I withdraw from this research project?**

If you do consent to participate, you may withdraw at any time. If you decide to withdraw from the project, please notify a member of the research team at [healthybrainproject@monash.edu](mailto:healthybrainproject@monash.edu) before you withdraw. A member of the research team will inform you if there are any special requirements linked to withdrawing. If you do withdraw, you will be asked to complete a 'Withdrawal of Consent' form and email it back to us at [healthybrainproject@monash.edu](mailto:healthybrainproject@monash.edu). The withdrawal form will be provided to you by the research team. This will allow us to discuss what you would like to do with your data that has already been collected.

If you decide to leave the research project, the researchers 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 up to the time you withdraw will form part of the research project results. If you would like all your previously collected data to be withdrawn, you must specifically inform the researchers when you withdraw from the research project.

## **9 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 loss of funding. In this event, all participants will be notified immediately and made aware of how their data will be stored before being destroyed after the 5-year duration required by HREC institutions.

## **10 What happens when the research project ends?**

As scientific papers are published from this study in scientific journals, we will post information about these papers on the website for participants to read. As research can take a long time to analyse, finalise and publish, some of these findings will be published after the study ends. In this case, we will make sure to disseminate this research to participants via email in addition to posting it up on the website. We will aim to provide participants with a summary of results each year as the project is continuing, and after the research project ends, we will send updates when new research is published from the project.

## **Part 2      How is the research project being conducted?**

### **11      What will happen to information about me?**

By signing the consent form, you consent to the research team collecting and using personal information about you for the research project and other related future research projects that the chief investigators will use to extend this research. Any information obtained in connection with this research project that can identify you will remain confidential. We will not disclose any identifying information about you, or provided by you during the research, without your written permission or as required by law. When the results of the research are published or discussed in conferences, no information will be included that could identify you.

All data will be de-identified, whether demographic, cognitive or genetic, will be kept in a password protected data file, and kept separate from any identifying information. The term de-identified means that any data that you provide to us will be given a unique study code, and that identifiable information (such as your name and email address) will be removed from that data. Any identifiable information will be stored separately and linked to the study code in a separate electronic file that is encrypted and that only the study team has access to. Questionnaire and memory testing data from this study will be stored on secure servers and managed by the investigator team at Monash University, for a minimum of 5 years after the completion of the project. When data is disposed of, the chief investigators will ensure that all electronic data is deleted.

All ORCA data submitted by participants (either from their web browser or mobile device) is 256-bit SSL encrypted using a certificate provided by QuoVadis Limited. It is stored on servers owned and operated by The University of Melbourne and reside in the main data centre on Queensberry Street at the University of Melbourne. The server room supports secure access systems and monitoring, and the data centre itself can only be accessed by authorised personnel via swipe card. The servers sit behind a firewall that can only be accessed remotely by administrators using the Secure Shell (SSH) protocol. Administrators are required to present the private key of a 2048-bit RSA (Rivest–Shamir–Adleman) public-keypair before they can access the server remotely. The operating system used is the Debian 10 distribution of Linux, and all packages and security patches are current.

A 2mL sample of your saliva will be collected from you. We will de-identify your sample to protect your privacy, and then send your sample via registered post for analyses, where geneticists will run genetic testing on your sample. With the advent of genome-wide research, and as candidate genes become available, we will keep your saliva sample for further genetic testing within the study. If you do not wish for us to store your sample for future studies, please let us know in writing at [healthybrainproject@monash.edu](mailto:healthybrainproject@monash.edu).

It is anticipated that the results of this research project will be published and/or presented in a variety of forums including academic journals, conferences and student theses. In any publication and/or presentation, information will be provided in such a way that you cannot be identified, except with your express permission. Specifically, any data will be presented at a group level, and at no time will your data be identifiable.

In accordance with relevant Australian privacy and other relevant laws, you have the right to request access to the information about you that is collected and stored by the research team. You also have the right to request that any information with which you disagree be corrected. Please inform [healthybrainproject@monash.edu](mailto:healthybrainproject@monash.edu) if you would like to access your information.

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

### **12      Who is organising and funding the research?**

This research project is being conducted by A/Prof Yen Ying Lim, Dr Nawaf Yassi, and Dr Rachel Buckley. The Healthy Brain Project ([healthybrainproject.org.au](http://healthybrainproject.org.au)) is funded by the National Health and Medical Research Council (GNT1158384, GNT1147465, GNT1111603, GNT1105576, GNT1104273, GNT1158384, GNT1171816), the Alzheimer's Association (AARG-17-591424, AARG-18-591358, AARG-19-643133), the Dementia Australia Research Foundation, the Bethlehem Griffiths Research Foundation, the Yulgilbar Alzheimer's Research Program, the National Heart Foundation of Australia (102052), and the Charleston Conference for Alzheimer's Disease. No member of the research team will receive a personal financial benefit from your involvement in this research project (other than their ordinary wages).

### 13 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 Monash University. 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.

### 14 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 problems which may be related to your involvement in the project, you can contact us at [healthybrainproject@monash.edu](mailto:healthybrainproject@monash.edu) or at 0491714377.

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 can contact the following people:

#### Reviewing HREC approving this research and HREC contact details

Reviewing HREC name	Monash University HREC
Telephone	+61 3 9905 2052
Email	<a href="mailto:muhrec@monash.edu">muhrec@monash.edu</a>



**Associate Professor Yen Ying Lim**

## **Consent Form** - *Adult providing own consent*

**YOUR CONSENT TO THIS STUDY INVOLVES A CHECKBOX AT THE END OF THE WEBPAGE THAT YOU WILL NEED TO TICK IN ORDER TO TAKE PART IN THIS RESEARCH STUDY. YOU WILL ALSO BE REQUIRED TO TYPE IN YOUR FULL NAME AS AN ELECTRONIC SIGNATURE TO INDICATE THAT YOU ARE ABLE AND WILLING TO PARTICIPATE AND THAT YOU HAVE READ THROUGH THIS INFORMATION FORM.**

**Title** *The Healthy Brain Project: tracking midlife cognitive, physical and psychological trajectories*

**Short Title** *The Healthy Brain Project*

**HREC Number** *26855*

**Principal Investigators** *A/Prof Yen Ying Lim, Dr Rachel Buckley, Dr Nawaf Yassi*

**Associate Investigator(s)** *Ms Lisa Bransby  
Prof Paul Maruff  
Ms Stephanie Perin  
Ms Andrea Mills  
Ms Katherine Franks  
Dr Emily Rosenich  
Dr Laura Bird  
Ms Gabbi Da Costa  
Ms Maya Norfolk  
Ms Hannah Cummins*

**Location** *Turner Institute of Brain and Mental Health,  
Monash University*

### **Declaration by Participant**

**IF YOU AGREE WITH THE STATEMENTS BELOW, PLEASE TICK THE CHECKBOX AT THE BOTTOM OF THE WEBPAGE AND TYPE IN YOUR NAME AS AN ELECTRONIC SIGNATURE. THIS WILL ALLOW YOU TO PROCEED AND BECOME A PARTICIPANT IN THIS STUDY.**

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 care.

I understand that I will be able to download a PDF of this document to keep.



## Form for Withdrawal of Participation - *Adult providing own consent*

**Title** *The Healthy Brain Project: tracking midlife cognitive, physical and psychological trajectories*

**Short Title** *The Healthy Brain Project*

**HREC Number** *26855*

**Principal Investigators** *A/Prof Yen Ying Lim, Dr Rachel Buckley, Dr Nawaf Yassi  
Ms Lisa Bransby  
Prof Paul Maruff  
Ms Stephanie Perin  
Ms Andrea Mills  
Ms Katherine Franks*

**Associate Investigator(s)** *Dr Emily Rosenich  
Dr Laura Bird  
Ms Gabbi Da Costa  
Ms Maya Norfolk  
Ms Hannah Cummins*

**Location** *Turner Institute of Brain and Mental Health,  
Monash University*

### **Declaration by Participant**

**THIS FORM NEEDS TO BE SENT TO HEALTHYBRAINPROJECT@MONASH.EDU IN ORDER TO PROCESS YOUR WITHDRAWAL FROM THE STUDY.**

I wish to withdraw from participation in the above research project and understand that such withdrawal will not affect my routine care, or my relationships with the researchers or Monash University.

ELECTRONIC SIGNATURE OF PARTICIPANT:

\_\_\_\_\_ (Please type your name in here including the date)