

45 and Up Study Participant Information Sheet

Maintain Your Brain (MYB) – Genetics Research

October 2022

This research project is in addition to the main 45 and Up Study. Participation is voluntary. Participation in this project does not change your involvement in the main 45 and Up Study. Information collected by this research project will become part of the 45 and Up Study in future.

1. Why am I receiving this invitation?

We are inviting 45 and Up Study participants who joined Maintain Your Brain to consider providing a biospecimen (blood or saliva sample) for genetic analysis and inclusion in the 45 and Up Study Biospecimen Collection (45 and Up Biobank).

2. Why is genetic analysis needed in Maintain Your Brain?

DNA carries the hereditary information (genes) that underlies the physical and behavioural characteristics of all living beings. Genetic research tries to identify the genes and genetic variants that may be linked to health measures, traits and diseases, such as cognitive performance and dementia. Analysis of the DNA in your blood or saliva sample will allow us to investigate if there are any genetic variants that influence the response to the MYB interventions on health, other risk factors, cognition and dementia.

3. If I provide a blood sample, what's involved?

For Maintain Your Brain, a blood sample (up to 3ml – less than 1 teaspoon) will be collected by an experienced technician. Additional samples (up to about 30ml) will be collected at the same time for the 45 and Up Biobank. Your samples can be collected at selected NSW Health Pathology centres (click [here](#) for list). DNA will be extracted and analysed for genetic information. The remainder of your sample will be stored in a secure biorepository managed by the 45 and Up Study for future analysis.

4. What if I want to provide DNA but don't want to donate blood?

Blood collection is the preferred sample to collect as it gives a higher yield and quality DNA compared to saliva. In addition, collection of the other blood samples by 45 and Up may be useful

to MYB in the future to examine other questions (e.g. proteins, metabolic profile) in the future.

However, if you would prefer not to donate blood or there is no collection centre nearby but you are still happy for us to investigate your genes, you can instead provide a small amount of saliva in a special vial mailed to you by the MYB team. You then return this by reply-paid post. DNA from your saliva sample will be extracted and analysed for genetic information. Any identifying information will be removed before analysis.

5. Why should I consider submitting a sample for DNA extraction?

Human DNA is now routinely collected by many studies investigating a range of traits and diseases. Your sample will provide important information that will help increase our understanding about the role of genetics in cognitive ageing and dementia. This research will lead to increased knowledge and potentially lead to new diagnostic tests, treatments, and novel ways to prevent cognitive decline and dementia.

6. Will this project help determine my risk of any diseases?

Your blood or saliva sample is for research purposes only and does not constitute clinical genetic testing. Our project will not identify results of potential importance to your health. It is possible that future research using your sample may result in new information about your risk of getting a disease. It is your choice whether or not you wish to be contacted by the 45 and Up Study if a future project finds some results relevant to you or your family's health. If desired, you can nominate a contact person to receive this information if these results are identified following your death. You can select these preferences on the consent form. We will not contact you about any results without your permission.

7. Arrangements for protection of your identity

We will take full measures to protect the privacy of all participants. Your specimen will be given a unique identification number to protect your privacy. We will not give out any personal information that can identify you to the scientists who are approved to receive the samples. Some information such as age and gender will be made available to enable the medical research to proceed. Any information that is obtained in connection with your sample and that can be identified with you will remain confidential and will be disclosed only with your permission or except as required by law.

8. How will my DNA be used with information already provided as part of the Maintain Your Brain trial?

Your DNA will be stored under an identification number that allows it to be connected with:

- Existing data you provided as part of Maintain Your Brain such as cognitive testing or responses to questionnaires
- 45 and Up Study records and records held at other organisations such as Medicare and Pharmaceutical Benefits Scheme ('linkage data').

Only authorised personnel will have access to this information. Electronic records will be stored for at least 15 years by MYB. The information (electronic records and genetic material) will also be provided to the Sax Institute to be included with your existing 45 and Up Study data where it will be stored for the life of the Study plus a further 7 years.

9. How will the blood sample for the 45 and Up Biobank be used?

The samples for the 45 and Up Biobank will be stored securely for future research at the NSW Health Statewide Biobank at 67 Missenden Rd, Camperdown NSW. These samples will be stored indefinitely and may be used in additional health-related research either nationally or internationally that is in the public interest, only after receiving approval from the 45 and Up Study and an Australian Human Research Ethics Committee.

10. How will my DNA be used in future research?

All researchers wishing to access the genetic material stored by UNSW must first have approval

from the relevant Human Research Ethics Committee for their project. Those researchers also must apply in writing to the MYB Governance Committee describing the intended use of the samples for approval to access the samples. It is not possible to foresee all the potential projects that may use the genetic material, now or in the future. Researchers may be from non-profit research institutes such as universities or from commercial organisations from Australia or overseas. The material will also be provided to the 45 and Up Study to be included with your existing data.

Researchers using samples obtained from MYB may make discoveries which may be subject to patent applications or commercialisation. However, in this regard such discoveries only arise from the analysis of pooled de-identified samples. Therefore, there will not be any benefits for individual participants. No payment, compensation, royalty or any other financial benefit will be made to you. The storage and use of all genetic material will be conducted in accordance with the National Health & Medical Research Council's Guidelines for Genetic Registers and Associated Genetic Material (1999), the Human Tissue Act (1984, amendments 2003), the National Statement on Ethical Conduct in Human Research (2007) and relevant Australian Legislation.

11. Benefits and risks

By agreeing to participate, you are making a generous contribution to research that may benefit society by resulting in new tests or treatments, or may help to prevent or cure cognitive ageing and dementia. You will not receive any direct benefit from participating in this type of research. Participants in this or any related studies cannot claim ownership rights, payment, compensation, royalty or any other financial benefit to any medical or scientific product that results from research with their samples.

The medical risks of providing these specimens are minimal.

Currently in Australia, genetic research does not affect your ability to obtain private health insurance. Is it however possible that in the future, the fact that you have taken part in a study involving genetics might affect you or your family if you want to take out a new health, disability, or life insurance policy. We will not pass any information about you to anyone, including your family members, without your written permission unless obliged to by law.

12. Confidentiality and disclosure of information about me

By providing your electronic signature and submitting the consent form you consent to the research team collecting and using information about you for the research project and to the inclusion of your sample in the 45 and Up Biobank. Each sample given for research is precious. Careful security measures are used to ensure that both sample and donor confidentiality are strictly protected. All samples collected will be stored under code numbers. We may provide some of your anonymised DNA sample, to approved researchers for use in future as-yet unidentified research studies. Any samples that are released to other scientists will contain no identifying information, only code numbers. We will not share individual DNA results with anyone participating in the study. Confidentiality, data security and anonymity will be maintained according to National Health and Medical Research Council (NHMRC) guidelines. Finally, all results of the research will be published in a form that will not allow individuals to be identified.

To maximise the benefits to medical research we may store your non-identifiable data in a databank on secure, encrypted computers and servers in order to provide the anonymised data to approved researchers for use in future as-yet unidentified research studies. Any requests to access the study data by qualified researchers will require approval by the Maintain Your Brain Governance Committee. If requested, the study's monitors, auditors, regulatory authorities, or Institutional Review Board will be granted direct access to your original records for verification of trial procedures and/or data.

We will undertake to protect your privacy within the limits of the law and follow State and Federal Government guidelines.

For samples and information held in the 45 and Up Biobank and by the 45 and Up Study, your information is protected under the *Privacy and Personal Information Protection Act 1988* (NSW) and the *Health Records and Information Privacy Act 2002* (NSW). The 45 and Up Study, the NSW Health Statewide Biobank, and any researchers accessing the 45 and Up Biobank, must adhere to these laws and their ethics approvals.

13. How and when will I find out what the results of the research study are?

The research team intend to publish and report the results of the research study in a variety of ways. All information published will be done in a way that will not identify you nor will any individual results be reported.

A summary of research findings will be published at the completion of the research on the MYB website (www.maintainyourbrain.org).

14. What if I want to withdraw from the research study?

If you do consent to participate, you may withdraw at any time by contacting the 45 and Up Study or the research team and telling them you no longer want to participate. Your decision not to participate or to withdraw from the research project will not affect your relationship with the 45 and Up Study, the Sax Institute, UNSW Sydney or any partner organisations. It may not be possible to destroy material that has already been processed or information that has already been used for research.

15. What should I do if I have further questions about my involvement in the research study?

If you require further information regarding this research project, please **call the 45 and Up Study Infoline 1300 45 11 45** or email 45andUp@saxinstitute.org.au

If you have any problems relating to your involvement in the research, for example about how to donate your sample, you can also contact the research team at maintainyourbrain@unsw.edu.au

16. What if I have a complaint or any concerns about the research study?

If you have a complaint regarding any aspect of the research project or the way it is being conducted, please contact the UNSW Human Research Ethics Coordinator:

Telephone +61 2 9385 6222
Email humanethics@unsw.edu.au
Ethics MYB: HC220670
Reference 45 and Up Study: HC210602

About the 45 and Up Study

The 45 and Up Study is the largest general-population program of health-related research ever conducted in Australia. More than 267,000 people aged 45 and over are participating in the Study, and they are being followed over time through routine follow-up questionnaires and linkage to health and other records.

The 45 and Up Study has been approved by the University of New South Wales Research Ethics Committee. Study participants have also given permission to be invited to participate in further research projects. Each of these research projects has been through a stringent review process prior to approval. Participation in these research projects is optional.

Study governance

The 45 and Up Study is owned and managed by the Sax Institute in collaboration with major partner Cancer Council NSW, and partners the Heart Foundation and NSW Ministry of Health.

About the Sax Institute

The Sax Institute is an independent, not-for-profit organisation that improves health and wellbeing by driving better use of evidence in policies, programs and services.

The Institute is a registered charity that works with governments, health organisations, research organisations and a network of experts nationwide to analyse policy problems and find the best evidence-based solutions.

Contact the Sax Institute about the 45 and Up Study

For any questions, comments, or complaints about the 45 and Up Study or this research project, to withdraw consent for participation or for further communication, please contact us:

Telephone: 1300 45 11 45 (toll-free Study Infoline)

Email: 45andUp@saxinstitute.org.au

In writing to:

Dr Martin McNamara, Chief Investigator,
45 and Up Study, GPO Box 5289,
Sydney NSW 2001

Confidentiality

The 45 and Up Study, and any research projects associated with it, are bound by Commonwealth and State privacy legislation and guidelines: the *Privacy Act 1988* (Cth), *Health Records and Information Privacy Act 2002* (NSW); and the NSW Health Privacy Manual for Health Information. The 45 and Up Study has strict procedures and systems in place to safeguard participant confidentiality. The Study is also bound by strict scientific ethical accountability to the University of New South Wales:

Ethics Secretariat
University of New South Wales
Sydney NSW 2052

Telephone: (02) 9385 6222

Email: humanethics@unsw.edu.au

Thank you. We could not conduct the 45 and Up Study without the generosity of our participants. We are immensely grateful to all of you.