

# 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 part of the Study and 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 also gave permission to be invited to participate in further research projects. All of these research projects have been through a stringent review process prior to approval. **Participation in these research projects is optional.**

## Study governance

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



## Sax Institute

The Sax Institute is an independent, not-for-profit organisation whose mission is to improve health, health services and programs by increasing the use of research in policy making. We want to achieve wiser decisions for a healthier Australia.

The Sax Institute's objectives are to: generate new research for use in policy; improve policy makers' access to existing research; and develop and test innovative new ways to increase the use of research evidence in policy making. See [www.saxinstitute.org.au](http://www.saxinstitute.org.au)

## Confidentiality

The 45 and Up Study, and any research projects from it, are bound by Commonwealth and State privacy legislation and guidelines: 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 to safeguard 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](mailto:humanethics@unsw.edu.au)

## 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, including withdrawal of your blood samples or for further communication, please contact us by:

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

**Email:** [45andUp@saxinstitute.org.au](mailto:45andUp@saxinstitute.org.au)

In writing, addressing your correspondence to:

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

## For more information on the NSW Statewide Biobank

For details on storage of blood samples, biospecimen data, and the return of incidental findings, please refer to <http://biobank.health.nsw.gov.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.

This information sheet is for you to keep.

SaxInstitute 

45 and Up  
Study

# Information for Participants



## NeuRA Research Project

Genetic contributors, clinical  
course and pharmacogenomics  
of Bipolar Disorder



## Genetic contributors, clinical course and pharmacogenomics of Bipolar Disorder

This research project is in addition to the main 45 and Up Study.

Participation is voluntary. Participation in this research 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 the future.

### Purpose of this research

The research project is looking to identify the genetic risk factors for bipolar disorder, examine why people with this condition tend to have higher rates of general medical illness (such as cardiovascular disease, diabetes and asthma), and to determine whether genetic information (or specific DNA sequence differences) could be used to identify people who are likely to respond positively to particular medicines, potentially enabling personalised treatment for bipolar disorder in future.

### Eligibility for participation

You have been invited to participate in this research project because our records indicate that you may have received one of the medicines which are typically used to treat bipolar disorder, and/or you may have received a diagnosis from a doctor of bipolar disorder, acute mania, cyclic schizophrenia, schizoaffective disorder or psychosis.

If this is incorrect, please let us know.

### What participation involves

If you choose to take part in this research project you will be asked to do the following things:

- Complete a questionnaire about your moods, physical and mental health, medication use and responsiveness to treatment
- Provide a blood sample at a NSW Health Pathology service centre for biomarker analysis and/or genetic testing, which may include whole genome sequencing of your DNA.

### Information and document storage

All paper forms are scanned and the information saved as data files on a password-protected computer server with access restricted to authorized researchers. The forms are stored securely by the Sax Institute for seven years, after which they are shredded.

Blood samples will be stored securely at the NSW Statewide Biobank, 67 Missenden Road, Camperdown, NSW; and Neuroscience Research Australia, 139 Barker St, Randwick, NSW. Blood samples and research results will become part of the 45 and Up Study Biobank and will be stored indefinitely, and may be used in additional health research that is in the public interest. Information from your blood sample will be stored securely in de-identified form, with access restricted only to authorized researchers.

### Risks for participants

The project is of low risk to participants, however you may feel that some of the questionnaire items are upsetting and there may be some discomfort from having blood collected. Rarely, some bruising at the site of blood collection may occur.

### Impact of genome sequencing for participants

Genome sequencing may incidentally find results of potential importance to your future health or your blood relatives' health. Clinically significant results are defined as genetic findings that will have a serious impact on your health and for which there are medically actionable interventions, such as hereditary breast cancer, some colorectal cancers and cardiomyopathies. If that occurs, you will be contacted to receive these results, which would be provided to you, at the research team's expense, via a genetic counsellor or health professional via your local NSW Health Genetics Service.

Note that discovery of incidental findings may enable access to early treatments to improve your health, but also have negative implications for life insurance cover for you and your blood relatives. If you do not wish to receive incidental findings, please decline to participate.

### Additional information, advice or referral options

If required please contact our **Infoline 1300 45 11 45**, or by **email 45andUp@saxinstitute.org.au** for advice.

### Costs and payments

Participation in this research project will not cost you anything and you will not receive any payment for your involvement in the research project.

### Benefits of the research project

There will be no immediate personal benefit to you from your participation in this research project. This research may however improve the understanding of the causes of bipolar disorder, and that may help improve the treatment and outcomes for people with bipolar disorder in future.

### Information the researchers will receive from the Sax Institute

By agreeing to be a part of this research project, you agree to the Sax Institute providing the researchers with:

- Information relevant to this research project that you have previously provided to the 45 and Up Study
- Information that you have already allowed the 45 and Up Study to combine from health and other records
- Questionnaire data and/or information that you provide as part of this research project
- Your contact information (name, telephone number and email address) which may be used to invite you for a more in-depth interview in future.

### Research project management

This research project is being conducted by Neuroscience Research Australia and The University of New South Wales. The lead investigators of this research project are:

- Associate Professor Janice Fullerton; Professor Philip Mitchell; Professor Peter Schofield.

Questionnaire data collection is being managed by the Sax Institute, blood collections are managed by NSW Health Pathology, and genome sequencing performed at the Kinghorn Centre for Clinical Genomics.

### Ethics approval and contact information

This research project has been approved by the New South Wales Population Health Research Ethics Committee (HRE1203) and The University of New South Wales Human Research Ethics Committee (HC180485). Any person with concerns or complaints about the conduct of this research should contact the Ethics Coordinator on 02 9385 6222 or by email at [humanethics@unsw.edu.au](mailto:humanethics@unsw.edu.au)