



**SCHIZOPHRENIA
RESEARCH
BANK**

PARTICIPANT INFORMATION

Prepared by Carmel Loughland
Version date (1.3): January, 2007.

Introduction

You are invited to participate in the establishment of the Australian Schizophrenia Research Bank (ASRB). The ASRB is a unique and important Australian medical research facility, established in collaboration with the Schizophrenia Research Institute (SRI), the University of Newcastle, the Centre for Mental Health Studies, the Medical Genetics Laboratory, Hunter Area Pathology Service (HAPS), the Centre for Rural and Remote Health, the University of Queensland, the Queensland Centre for Mental Health Research, the University of Western Australian and the Centre for Clinical Research in Neuropsychiatry.

The aim of the ASRB is to collect and link genetic, neuroanatomical, cognitive and clinical information from people with and without schizophrenia. The blood samples and information stored by the ASRB will be used in genetic research with the aim of developing better diagnosis, treatments and preventative strategies for people with schizophrenia.

Voluntary participation

Participation in the ASRB is completely voluntary. You may withdraw your consent at any time without disadvantage or adversely affecting your treatment. You do not have to give a reason for you to withdraw your consent. If you decide to withdraw, your request will be respected and upon receipt of a written request, your stored personal information and genetic material will be destroyed.

What will I be asked to do?

If you agree to participate in the ASRB, you will be invited to do the following:

- 1) To complete a 2 hour interview and a 1 hour set of neuropsychological assessments.
- 2) To give a 40ml blood sample (approximately 2 tablespoons of blood).
- 3) If suitable, participate in a 30-40 minute Magnetic Resonance Image (MRI) brain scan.

What if I am already a volunteer with another database?

Volunteers registered with one or more of the following databases will be invited to join the ASRB:

- Schizophrenia Research Register
- Hunter DNA Bank,
- “Gift of Hope” Brain Donor Program
- Virtual Brain bank
- WA Family Study of Schizophrenia,

If you wish to have existing information stored on these databases transferred to the ASRB, please tick the Option 1 box on the Consent Form attached. This will mean that you will not have to repeat some of the procedures conducted by the ASRB, particularly if you have participated in a clinical assessment, MRI scan or donated a blood sample previously.

You can still remain a member of the other databases and also be a member of the ASRB. The only exception to this is for people registered with the Hunter DNA Bank. This database will be subsumed into the ASRB and no longer exist after 1 May 2007.

What if I have more than one family member affected by schizophrenia?

In some families, more than one person can be affected by schizophrenia. To fully understand the genetics that underlie the development of schizophrenia within such families, it is important to collect blood samples from as many of the first-degree family members (i.e., parents, brothers/sisters, children over the age of 18 years) as possible, including the affected and non-affected relatives. This could allow researchers to reach some conclusions about whether particular genes are related to the development of schizophrenia. If more than one member of your family is affected by schizophrenia, you may be asked to provide information about the ASRB to other members of your family.

What are the risks of participating?

While the risk associated with participation on the ASRB are small, the insertion of the needle to take blood from your arm might cause slight discomfort and/or minor bruising at the needle site. There is a slight chance that you may also feel dizzy or faint. However, this risk is very small and will be further reduced by having trained Pathology Service Technician perform the blood collection.

A MRI scanner uses a strong magnetic field to measure brain structure and brain function. There are no known health risks associated with MRI scanning, provided you do not have any metal objects in your body (e.g. cardiac pacemakers, prostheses etc) and/or you are not pregnant. A radiographer will help assess whether it is safe for you to have a scan. People with claustrophobia (fear of enclosed spaces) are unable to do this task. Some people may feel uncomfortable during the scanning procedure however, you will be able to interrupt the scanning at any time. If you are not sure whether you have any metal objects in your body or are pregnant or not, we advise you to consult your family doctor before you consent to participate in the MRI scan. If there are any unexpected findings from the MRI scan, which require further investigation, these will be discussed with yourself and your treating doctor.

What are the possible benefits?

You will not benefit directly from the research conducted using your data, nor will you receive either now or in the future any royalty or any other financial benefit, which might result from genetic research into schizophrenia.

While the information stored by the ASRB is not diagnostic in nature, should research using your samples lead to new insights into mental illness, then you will be advised of the nature of the discovery and, if necessary, directed to independent genetic counselling to determine if this discovery is of value to you and your family.

How much time will I have to consider the invitation to participate?

You can take as long as you like to consider participation on the ASRB. However, if we do not hear back from you (either positive or negative) within one month about this invitation, then a representative from the ASRB will contact you either by telephone or mail to ensure that:

- (1) you have received the information, and
- (2) you are provided with an opportunity to ask questions about participation.

If you require more time to consider the invitation to participate, this will be granted without question.

Who has access to my data?

ASRB management and committee members will have access to your data. The ASRB permits researchers to access non-identifiable data for use in genetic research into schizophrenia but no identifiable information such as your name or address will be provided. Data from the ASRB may also be provided to regulatory authorities, if requested by law. Personally identifying information will not be released without your written consent.

How will my data be used?

The ASRB is a non-profit medical research initiative established to facilitate genetic research in schizophrenia. Australian researchers will be able to apply to the ASRB to access the data. All researchers must have ethic approval for their project prior to approaching the ASRB. No identifiable information (i.e., name address or date of birth etc) will be provided to researchers, ensuring the privacy and confidentiality of your data. Nor will the ASRB use the genetic samples to determine your entire genetic make-up.

Will my privacy and confidentiality be protected?

The information and samples you provide will be stored on the ASRB using a unique ID number. This number will be used to protect your privacy and confidentiality. All personal information that identifies you will be kept strictly confidential, and for security purposes will be stored separately from your MRI and blood sample data using this unique identification code. Nor will personal information such as your name and address be passed on to a third person without prior consent. Your data will not be sold or placed on a mailing list. Only anonymous (de-identified) data will be made available to approved researchers or presented at conferences or in manuscripts.

What happens to my samples if the ASRB closes?

The material stored by the ASRB is a precious and scientifically valuable resource. If in the future the ASRB was no longer be viable, then the stake-holders would seek to transfer your samples and clinical data to a third party willing to undertake the responsibility of maintaining the resource. The third party would have to adhere to the current guidelines as set out by the ASRB and the *National Statement on Ethical Conduct in Research Involving Humans (1999)*. Volunteers will be notified of any changes in 'ownership' of the ASRB and be given the opportunity to review their on-going involvement.

Should no third party exist, or if funding for this initiative ceased, then the ASRB will no longer operate. You (or if you are deceased, your nominated next of kin) will be contacted by mail and notified of the ASRB closure. Records and files pertaining to your participation

will be returned to you or your next of kin upon written request, and all your genetic samples will be destroyed.

What if I have any questions?

A toll free number has been established so that you can contact the ASRB from anywhere in Australia. If you have any questions about participation in the ASRB and would like to speak to one of our trained representatives, please call toll free on **1800 639 295**. This information sheet is for you to keep.

What do I do next if I want to participate?

To become a volunteer on the ASRB, you (or your legal representative) must sign and date the attached Consent Form. You may also select various options on the Consent Form regarding next of kin, transfer of information from other databases and participating on other databases or research projects.

Yours Sincerely,

Dr Carmel Loughland

Manager, Australian Schizophrenia Research Bank

The proposal to establish this bank have been reviewed and approved by the Hunter New England Human Research Ethics Committee (Reference No 06/05/24/5.11)

Issues of complaint

Should you have concerns about your rights as a participant on the ASRB or you have a complaint about the manner in which this initiative is conducted, it may be given to the ASRB Manager, or, if an independent person is preferred you can contact one of the following persons:

ASRB Manager

Dr Carmel Loughland 1800 639 295

Professional Officers

NSW

The Secretary, Ethics Review Committee (RPAH zone) Sydney South West Area Health Service, Level 8, Building 14, Royal Prince Alfred Hospital, Camperdown NSW 2050, Telephone: (02) 9515 6766, lesley.townsend@email.cs.nsw.gov.au

Human Research Ethics Committee – Northern Network, South Eastern Sydney Area Health Service, Room G71, EBB, Corner High and Avoca Streets, Randwick NSW 2031, Telephone: (02) 9328 3587.

In Newcastle, the Professional Officer, Hunter New England Human Research Ethics Committee, Hunter Health, Locked Bag 1, New Lambton N.S.W. 2305, Telephone: (02) 49214950, Nicole.Gerrand@hnehealth.health.nsw.gov.au

Queensland

Human Research Ethics Committee, The Prince Charles Hospital Health Service District, Rode Road Chermside QLD 4032, Telephone: (07) 3350 8500, Leep@health.qld.gov.au

Victoria

Stacey Gabriel, PO Royal Melbourne Hosptial Parkville Victoria 3050
Telephone: (03) 9342 8530, Research.directorate@mh.org.au

Western Australia

Pam Mikus, The Secretary North Metropolitan Area Mental Health Service HREC, Private
Mail Bag No 1, Claremont, WA 6010, Telephone (08) 9 347 6600
Pam.Mikus@health.wa.gov.au



**SCHIZOPHRENIA
RESEARCH
BANK**

PARTICIPANT CONSENT FORM

Prepared by Carmel Loughland

Version date April, 2007.

I,.....
(print name)

of.....
(print address)

Telephone: (h) (w) (m)

Have been diagnosed with schizophrenia

I am a control person without a personal or family history of schizophrenia

1. Agree to participate as a volunteer on the Australian Schizophrenia Research Bank (ASRB) as described in the participant information statement set out above.
2. I acknowledge that I have read the participant information statement, which explains why I have been selected, the aims of the ASRB and the nature and possible risks of the investigation, and the statement has been explained to me to my satisfaction.
3. Have been given the opportunity to ask any questions relating to any possible physical and mental harm I might suffer as a result of my participation and I have received satisfactory answers.
4. Understand that I can withdraw from the ASRB at any time without prejudice my relationship with any health professional or treating organisation, or any of the ASRB personnel involved.
5. Agree that research data gathered from the results of the study may be published, provided that I cannot be identified.
6. Understand that if I have any questions relating to my participation in this research, I can contact the ASRB and speak to one of their representatives on the toll free telephone number 1800 639 295 or on one of the local telephone numbers provided.

7. Acknowledge receipt of a copy of this Consent Form and the Participant Information Sheet.

Option for family member disclosure

In the event of my death, I consent to the information obtained from studies using my DNA / RNA / cell lines being revealed to the following nominated family member(s), upon their written request to the ASRB Access Committee. If yes, please nominate two family members you wish the information to go to in the event of your death.

- YES NO

Name: _____
Address: _____ _____
Telephone Number: _____

Name: _____
Address: _____ _____
Telephone Number: _____

Option 1: For volunteers registered with the Schizophrenia Research Register, Hunter DNA Bank, “Gift of Hope” Brain Donor Program, Virtual Brain Bank, and WA Family Study of Schizophrenia.

I consent to the ASRB having access to my assessment records stored with the following research facility (please tick one or more), which include demographic, diagnostic and other research data including MRI brain scans or genetic material stored on these databases, for the purposes of cross-referencing this information with that data collected by the ASRB.

- YES NO

Please indicate which volunteer database you are currently registered with (please tick one or more).

- Schizophrenia Research Register
- Hunter DNA Bank for Schizophrenia and Allied Disorders
- “Gift of Hope” Brain Donor Program
- Virtual Brain Bank
- WA Family Study of Schizophrenia

- OPTION: I am unsure which database(s), if any, I am registered with but I give my consent for the above databases to check my details and provide the ASRB with access to my data stored on these databases.**

Option 2: to join one of the following volunteer databases

I am interested in participating in future research projects. Please send me information about other Schizophrenia Research Institute and affiliated volunteer databases:

- Schizophrenia Research Register (a volunteer medical research databases of people interested in participating in schizophrenia related research at a future time)
- “Gift of Hope” Brain Donor Program (a human brain donation bank)
- WA Family Study of Schizophrenia (a study investigating genetic influences in families of people with schizophrenia)
- OPTION: I would like information about all the above databases.**

Option 3: to agree to be contacted in the future about follow-up research by the ASRB

I am interested in participating in future research projects associated with the ASRB data collection. I have ticked the following box to indicate my willingness to be contacted by an ASRB representative and provided with information about follow-up research being conducted by the ASRB. I understand this research will have prior ethics approval before I am contacted, and that I am free to withdraw my consent to participate in this research at any time.

- I wish to be contacted about any future follow-up data collection or research project being conducted by the ASRB.**

Signature of volunteer: _____ Date: _____

Please PRINT name



REVOCAION OF CONSENT

Prepared by Carmel Loughland

Version date April, 2007.

ONLY COMPLETE THIS FORM IF YOU WISH TO WITHDRAW FROM THE AUSTRALIAN SCHIZOPHRENIA RESEARCH BANK.

RETAIN THIS FORM IN CASE YOU WISH TO WITHDRAW FROM THE AUSTRALIAN SCHIZOPHRENIA RESEARCH BANK AT A FUTURE DATE.

I hereby wish to **WITHDRAW** my consent for the following information (please tick below) to be stored by the Australian Schizophrenia Research Bank. I understand that such withdrawal **WILL NOT** jeopardise any treatment or my relationship with any health profession
(including hospitals or my medical attendants).

- Personal information (name and address etc)
- Anonymous clinical data
- Anonymous MRI brain image data
- Anonymous genetic sample

Signature: _____ Date: _____

Please PRINT Name:

This Revocation of Consent should be forwarded to:

The ASRB Manager
PO Box 833
Newcastle 2300 NSW Australia