

Attachment 3



APPLICATION AND ACCESS AGREEMENT FORMS

The Australian Schizophrenia Research Bank (ASRB) Access Committee is responsible for approving all research applications requesting access to volunteers, samples or other data stored by the ASRB. The Access Committee aims to protect the interests of participants while assisting investigators undertaking schizophrenia research by providing access to research volunteers, genetic samples, MRI scans and clinical data¹.

Making an Application

The following information is provided to assist investigators with making an application to the ASRB to access research volunteers, stored clinical data, MRI data and genetic samples.

1. The Access Committee consists of researchers, clinicians and consumer/carer representatives, and members are appointed by the ASRB Governance Committee.
2. The ASRB Access Committee reviews and processes all applications to access research volunteers, clinical data, MRI data and genetic samples. If approved, access to research volunteers will be granted for twelve months, renewable for a further twelve month term per project. Further access for the same study beyond this time will require a new application. See *Guidelines for Researchers* document for explanation of these processes.
3. Application forms and associated documents can be obtained from the ASRB or on the ASRB web site (<https://www.neura.edu.au/sri>). Completed application forms (one electronic copy and one hard copy) and their associated documents should be forwarded to the ASRB.

Postal address: Dr Kate Johnston
NeuRA
Australian Schizophrenia Research Bank
PO Box 1165
Randwick NSW 2031 Australia

Email: k.johnston@neura.edu.au

Web Site: www.neura.edu.au/sri

Fax: +61 2 9399 1005

¹ Clinical data refers throughout to demographic, diagnostic, medical, family history, personal history, symptomatic and neuropsychological data obtained at interviews with the participants.

4. Ethics committee clearance from a properly constituted Human Research Ethics Committee should be sought before making an application to the ASRB. A copy of the full application and corresponding clearance letter is to be included with your application.
5. Funding sources for the proposed study must be disclosed and if the study is being funded on the basis of one or more competitive research grants, then a copy of each relevant research grant application will need to be submitted along with the application.
6. As part of the review process, investigators may be required to modify their applications before the project is finally approved. Investigators should note the time likely to be associated with this review process and make adequate provision for this in their research timetable. The ASRB will review all applications prior to them being considered by the Access Committee and will be able to assist researchers in finalising their application using the electronic copy of their application.
7. Once the ASRB Access Committee has reviewed the application, investigators will be informed of the Committee's decision by email. If approved, the ASRB will make arrangements with the investigator for the delivery of samples and data or facilitation of contact with research volunteers.
8. Access to genetic samples and non-identifiable information about the volunteer (i.e., clinical, neuropsychological and MRI data) is on a cost recovery basis and payment of this access fee will be required prior to provision of the genetic samples and other data. The ASRB will discuss and finalise these costs with the investigator. These costs are described in the Guidelines for Researchers and will be paid by the investigator to the Schizophrenia Research Institute, which manages funds on behalf of the ASRB. The cost associated with the packaging and transport of samples will be paid directly by the investigator to the nominated courier.
9. The ASRB has developed a relational database that permits the cross-referencing of genetic data with demographic, diagnostic, medical and family history data, as well as neuropsychological and structural MRI brain imaging data. Because research findings using these data may have important implications for the donors, it is vital that investigators accessing samples assist the ASRB by providing information about any significant research findings in relation to the samples obtained. The ASRB acknowledges that any new data acquired by investigators for a particular study belongs to the investigators. However, at the end of the study, the ASRB seeks to hold copies of the relevant raw data pertaining to the samples or participants accessed from the ASRB. Relevant raw data refers to demographic (e.g., change of address or contact details, family name, marital status etc) or clinical data (i.e., diagnostic classification, IQ score, neuropsychological performance, symptom ratings etc). ASRB requires that this data be reported back as soon as possible after a volunteer has participated in a project. Researchers should seek written permission from their participants to permit information and data transfer. These data will not be made available to other investigators, except with the written permission of the original investigators. If they so wish, the original investigators may place conditions on access to the data by third parties. Where appropriate, and with the consent of the original investigators, volunteers (or their family, if deceased) may be notified of any research findings that have direct health implications for volunteers and/or their families.
10. Investigators must seek formal approval from the ASRB before varying any agreed upon research protocol, undertaking subsequent studies, or conducting additional follow-up research which utilises the volunteers / samples and/or data provided by the ASRB (as described in the *Guidelines for Researchers* document).
11. It is a requirement that any publications or presentations arising from research that has accessed the ASRB acknowledges the contribution of the ASRB. The ASRB must be included in the author list for any publications arising from research that has accessed the ASRB, using any one of the following formats:

- a) The Australian Schizophrenia Research Bank, with the names of ASRB Chief Investigators listed in the acknowledgements at the end of the paper (see Chief Investigator list in item c) below) ;
- b) Vaughan J Carr (and/or other CIs as appropriate) on behalf of the Australian Schizophrenia Research Bank;
or
- c) Individually listing the CIs and ASRB Manager: Carr V, Schall U, Scott R, Jablensky A, Mowry B, Michie P, Catts S, Henskens F, Pantelis C, Loughland C.

The following statement must be included in the acknowledgements (or other appropriate section of the publication):

This study was supported by the Australian Schizophrenia Research Bank (ASRB), which is supported by the National Health and Medical Research Council of Australia, the Pratt Foundation, Ramsay Health Care, the Viertel Charitable Foundation and the Schizophrenia Research Institute.

The ASRB requires one hardcopy reprint or PDF file of all publications be forwarded to the ASRB Manager.

12. Any deviations from the above must be approved in each instance by the ASRB Access Committee.



**SCHIZOPHRENIA
RESEARCH
BANK**

Access Agreement

“**ASRB**” means the Australian Schizophrenia Research Bank (providing the Research Volunteers or Materials under this agreement). “**Research Volunteers**” means those ASRB volunteers and associated clinical data provided to the recipient.

The Recipient Organisation and Recipient Scientist identified below (“**Recipient**”) agree that the supply of Research Volunteers or Materials described in the Access Agreement, including any modification of the materials (“**Material**”) by the ASRB will be governed by the following terms and conditions.

1. The Recipients acknowledge they have received, read and understood the “Guidelines for Researchers” (attached hereto).
2. The Recipients will be responsible for complying with all applicable legislation and regulations in relation to the use of the Materials and Research Volunteers. In the agreement, the Materials include any progeny, modification or improvements to the Materials that the Recipients develop, directly or indirectly while using the Material supplied by the ASRB.
3. The Recipients will only use the Research Volunteers or Materials for research and experimentation in connection with the Research Project (“**Project**”) identified on the *ASRB Resource Access Application Form* and not for any profit making or commercial purposes involving human subjects without the prior written consent of the ASRB. The Recipient will seek written approval from the ASRB, using the established processes, before varying any agreed upon project protocol, undertaking subsequent studies, or conducting additional follow-up research.
4. The Materials and any intellectual property subsisting in or in relation to them are the property of the ASRB. The ASRB grants the Recipients a non-exclusive right to use the Materials within the terms of this agreement. Consistent with this non-exclusive right, the Recipients must not sell, loan or otherwise provide the Materials to any other party for any purpose without the prior written consent of the ASRB.
5. The Recipients’ right and licence to use the Research Volunteers and Materials are not transferable. The Recipients agree that the Materials may only be used at the Recipient Organisation and only in the Recipient Scientists’ laboratories under the direct supervision of the Recipient Scientists. The Recipients agree that the Research Volunteers may only participate in the approved Project at the Recipient Organisation and only in the Recipient Scientists’ laboratories under the direct supervision of the Recipient Scientists.
6. If approved, access to Research Volunteers will be granted for twelve months, renewable for a further twelve month term per project. Further access for the same study beyond this time will require a new application. Research Volunteers will be contacted by the ASRB on behalf of the Recipients. If they agree to participate in the Project, the Research Volunteers’ contact details will be forwarded to the Recipient in a password protected document. The ASRB attempts to ensure that Research Volunteers’ records are accurate. However, the ASRB accepts no responsibility for the inadvertent provision of incorrect information or for the withdrawal of Research Volunteers from the Project.

7. The Recipients acknowledge that the Materials are or may be the subject of a patent or patent application. Except as provided in this agreement, the Recipients agree that they have no express or implied licence or other right to any patents, patent applications, trade secrets or other proprietary rights of the ASRB. In particular, no express or implied licence or other right is provided to use the Materials for commercial purposes.
8. If the Recipients desire to use Research Volunteers or license the Materials for commercial purposes, the Recipients agree, in advance of such use, to negotiate in good faith with the ASRB to establish the terms of a commercial licence agreement. The Recipients acknowledge that the ASRB will have no obligation to grant such a licence to the Recipients, and may grant exclusive or non-exclusive commercial licences to others, or sell or assign all or part of the rights in the Materials to any other party.
9. The fact that the Recipients have used the Research Volunteers and Materials for research and experimentation pursuant to this agreement will not give the ASRB any right, title or interest in any product or process that is developed or invented by the Recipients in the course of that research and experimentation. However, if that product or process incorporates or uses information or Materials which are confidential or proprietary to the ASRB or any patented or patentable invention which is the subject of a registration or application in the name of the ASRB then nothing in this agreement will give the Recipients the right to use such information or inventions in the commercial exploitation of the said products or processes.
10. The Recipients must treat as confidential, information on any Research Volunteer and Materials or other information provided by the ASRB which the ASRB regards as being confidential to it, and must take all reasonable and necessary precautions to restrict access to researchers who are directly involved in the Project and who are placed under an obligation to observe the terms of this agreement. The Recipients' obligations of confidentiality will survive termination of this agreement and will continue until the confidential information disclosed by the ASRB lawfully becomes part of the public domain.
11. The Recipients must return to the ASRB or, at the ASRB's request, arrange the disposal or destruction of all remaining or unused Research Volunteers' details and Materials once (i) this agreement terminates; (ii) the Project for which the Research Volunteers and Materials have been supplied discontinues; or (iii) there is no further need for the Research Volunteers and Materials in connection with the Project. In addition, the Recipients must also provide to the ASRB copies of any reports and outlines of any discoveries or results in relation to the research and experimentation conducted on the Materials.
12. Nothing in this agreement prevents the ASRB from exploiting, distributing or otherwise making the Research Volunteers and Materials available to any other parties at any time.
13. The ASRB has taken all reasonable precautions to screen the Materials for infectious diseases. However, the ASRB accepts no responsibility for the transmission of any disease as a result of the use of any Materials supplied by the ASRB. The Recipients acknowledge that they will use the Materials at their own risk and agree to accept sole responsibility and liability for the conduct of the Project. To the extent permitted by law, the ASRB supplies the Materials without any warranties, express or implied, including any warranties of merchantability or fitness for a particular purpose.
14. Research Volunteers are not screened for HIV, Hepatitis B or Hepatitis C. Standard precautions relating to physical contact with humans, particularly in relation to bodily fluids, as recommended by the NHMRC, should be undertaken by the Recipients to prevent possible infection. The ASRB will take no responsibility for injury or illness that may occur to researchers and their staff as a result of ASRB volunteers participating in the project.

15. The Recipients agree to indemnify the ASRB and its staff and agents against any and all damages, expenses (including without limitation legal expenses) claims, demands, suits or other liability arising from the Recipients' acceptance, use or disposal of the Materials or Research Volunteers.
16. The Recipients agree to acknowledge the ASRB in any publications or presentations which result from the use of the Materials or Research Volunteers. During and after the term of this agreement, the Recipients must provide the ASRB with copies of all manuscripts submitted or published. The Recipients must also promptly provide the ASRB with copies of all details or results of research derived from the Materials or Research Volunteers which have been published. The ASRB must be included in the author list for any publications arising from research that has accessed the ASRB, using one of the following formats:
 - a) The Australian Schizophrenia Research Bank, with the names of ASRB Chief Investigators listed in the acknowledgements at the end of the paper (see Chief Investigator list in item c) below;
 - b) Vaughan J Carr (and/or other CIs as appropriate) on behalf of the Australian Schizophrenia Research Bank; or
 - c) Individually listing the CIs and ASRB Manager: Carr V, Schall U, Scott R, Jablensky A, Mowry B, Michie P, Catts S, Henskens F, Pantelis C, Loughland C. The following acknowledgement must appear on all publications and presentations that have resulted from accessing tissue from the ASRB:

This study was supported by the Australian Schizophrenia Research Bank (ASRB), which is supported by the National Health and Medical Research Council of Australia, the Pratt Foundation, Ramsay Health Care, the Viertel Charitable Foundation and the Schizophrenia Research Institute.

17. The ASRB makes no representation and provides no warranty that the use of the Materials will not infringe any other party's intellectual property or other rights which will interfere with the Recipients' ability to use the Materials for the purposes contemplated by this agreement.
18. The ASRB may terminate this agreement any time by giving 30 days' written notice to the Recipient Organisation.
19. A notice given under this agreement must be in writing and signed by a person duly authorised by the sender and must either be by hand, post, fax or electronic mail to the address last notified by the intended recipient to the sender. A notice sent by post will be deemed given after 3 days if posted locally or 10 days if posted internationally. A notice sent by fax will be deemed given on receipt of a transmission control report from the dispatching machine. A notice sent by electronic mail will be deemed given on receipt by the sender of an acknowledgement indicating that the mail item was read by the recipient.
20. The Recipients must provide the ASRB with regular reports on the progress of work undertaken using the Materials or Research Volunteers and any subsequent findings, and must abide by the conditions outlined in the Guidelines for Researchers document and those set from time to time by the ASRB for the frequency of progress reports (every twelve months unless otherwise specified) and their format.
21. Any failure by a party to compel performance by the other party of any terms and conditions of this agreement will not constitute a waiver of those terms or conditions or diminish rights arising from their breach.
22. This agreement may only be amended in writing, signed by the parties. If any provision of this agreement is invalid or unenforceable, it will be deemed deleted but the remaining provisions of this agreement will remain in full force and effect.
23. This agreement contains the entire understanding between the parties concerning its subject matter and supersedes all prior communications between the parties.

24. Each party will execute all documents and perform all acts necessary to give full effect to this agreement.
25. This agreement is governed by the laws of New South Wales and the Commonwealth of Australia. Each party submits to the non-exclusive jurisdiction of courts exercising jurisdiction in New South Wales and the Commonwealth of Australia in connection with all matters concerning this agreement.
26. The recipients will pay the costs associated with accessing the ASRB as described in the Guidelines for Researchers booklet, following discussion with the ASRB Manager. Samples and data will not be provided until payment has been provided.



**AUSTRALIAN SCHIZOPHRENIA RESEARCH BANK
ACCESS AGREEMENT**

Recipient Organisation: _____

Recipient Scientist(s): _____

Project ID / Name: _____

Resources being accessed (please tick):

- Genetic samples (DNA or genotyping)
- Clinical (socio-demographic, diagnostic) data (excluding neuropsychological data)
- Neuropsychological performance (IQ, RBANS, Executive functioning, working memory) data
- MRI or DTI data
- Research participants (volunteers)

Signed by the Recipient Scientists:

I / we (the undersigned) have read, understood, and agree with the above conditions of use associated with the Australian Schizophrenia Research Bank (ASRB). All scientists directly involved in the project must sign the agreement.

Signature of recipient scientist

Signature of recipient scientist

Print name and date

Print name and date

Signature of recipient scientist

Signature of recipient scientist

Print name and date

Print name and date

* Add more if required

Institutional Head

I, the undersigned as Institutional Head, have the authority to execute this agreement on behalf of the institution detailed below.

Signature of Institutional Head: _____ **Date:** _____

Full Name: _____

Institution Name: _____

Contact address / details: _____



Resource Access Application Form

Office use only:

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| | | | | | | | | | |
|--|--|--|--|--|--|--|--|--|--|

1. TYPE OF APPLICANT/APPLICATION

Please indicate which type of application is being submitted (choose one only)

External Researcher Study

Please choose one of these options if your study **does not** include an ASRB CI on the application.

- Australian Study
 - Research undertaken at an Australian academic/not-for-profit institution with an Australian Chief Investigator
 - Can include international collaborators
 - Accessing ASRB volunteers only
- Australian Study
 - Research undertaken at an Australian academic/not-for-profit institution with an Australian Chief Investigator
 - Can include international collaborators
 - Accessing ASRB data/samples
- International Study
 - Research undertaken at an overseas academic/not-for profit institution.
 - Some restrictions apply on sample access.
- Commercial Study
 - Research undertaken by for-profit commercial company

Internal ASRB Researcher Study

Please choose one of these options if your study **does** include an ASRB CI on the application.

- ASRB Chief Investigator Local Study
 - Research undertaken by ASRB Chief Investigator(s) accessing locally collected ASRB data/samples only
- ASRB Chief Investigator Local Study
 - Research undertaken by ASRB Chief Investigator(s) accessing locally recruited ASRB volunteers only
- ASRB Chief Investigator National Study
 - Research undertaken by ASRB Chief Investigator(s) accessing data/samples/volunteers collected from multiple ASRB sites

Have you accessed the ASRB for this project previously? YES / NO

If YES, please specify dates of access

If YES, please provide a justification for seeking further access. This should include details of progress against objectives of the project.

Will you also be applying to the Western Australia Family Study of Schizophrenia for this project? YES / NO

2. APPLICANT DETAILS

Chief investigator or project supervisor: (include title, name, position, qualifications; please attach brief ~2 page CV including recent publications relevant to the current application)

Other investigator(s) (include title, name, position, qualifications)

Administering department and institution

Contact details (include name of contact person, mailing address, telephone, facsimile and e-mail details)

3. RESEARCH PROJECT

Short title of project

One paragraph lay description of project

Brief overview of project including background, aims, methodology, significance of project and specific hypotheses (please provide 1-2 pages of information)

List funding support for this project (please attach proof of funding)

Brief background of research environment in which study is to take place (facilities and/or technical expertise available). If students are to be involved in the study, please describe supervision arrangements.

4. OVERVIEW OF REQUEST

Indicate what element of the ASRB you are requesting access to (select as many as are required)

- Genetic Samples or genotyping (proceed to question 5)
- MRI Scans (proceed to question 5)
- Clinical Data (proceed to question 5)
- Neuropsychological Data (proceed to question 5)

Recruitment of ASRB volunteers for other research studies (proceed to question 6)

5. DETAILS OF MATERIAL BEING REQUESTED

Provide details of the material(s) being requested, including the number of samples required and any other specification information as necessary (see ASRB web site for details of data that can be requested – <https://www.neura.edu.au/sri>).

Please provide justification for your request with reference to the hypotheses described in 3. RESEARCH PROJECT above. Include power analyses where necessary and justification for access to specific assessment item subscales if relevant.

Please note that genetic or imaging samples/data only come with a core dataset of socio-demographic information (including age, gender, diagnosis, race/ethnicity) unless otherwise requested.

When completed proceed to question 9

6. SELECTION CRITERIA FOR RESEARCH PARTICIPANTS

Number of people with schizophrenia and/or healthy controls being sought from the ASRB

List recruitment sources being accessed other than the ASRB

ASRB volunteers can be approached using the following criteria (please tick if required):

- Age range. Specify age range in years.....
- Gender. Specify gender or gender distribution.....
- Region (PLEASE NOMINATE POST CODE RANGE)

List any other criteria (e.g., IQ range, GAF score range)

Are you also requesting access to participant's clinical data (if available)? YES / NO

If yes, please tick which clinical data you require (if available):

- Confirmed diagnosis using the Diagnostic Interview for Psychosis (DIP)
- Complete Diagnostic Interview for Psychosis (DIP) data
- IQ measures (i.e., WASI vocabulary and performance scores)
- Repeatable Battery for the Assessment of Neuropsychological Status subtests and total score (RBANS)
- Other (please specify).....

7. APPROACH AND FOLLOW UP PROCEDURES FOR RECRUITING PEOPLE FOR SCHIZOPHRENIA RESEARCH PROJECTS

Once you have been granted access, the ASRB will make initial contact with suitable volunteers and invite them to participate in your project. Their contact details will be forwarded to you in a password protected document. Once you have received this information, what procedures do you have for contacting volunteers to participate in your study (i.e., contact them by phone, mail etc)? Explain how you will deal with volunteers that do not show up or withdraw from the study.

8. PROTOCOL INFORMATION

List questionnaires and/or assessments, tests, and tasks that will be administered to ASRB volunteers.

Will any of the following be used? YES / NO

If YES, please mark the box next to the procedure(s) being used.

| | |
|---|---|
| <input type="checkbox"/> Drugs | <input type="checkbox"/> Special diets or modified foods |
| <input type="checkbox"/> Chemical compounds | <input type="checkbox"/> Needles, electrodes or other sharp instruments |
| <input type="checkbox"/> Ionizing or non-ionizing radiation | <input type="checkbox"/> Blood or tissue sampling |
| <input type="checkbox"/> Other biological agents | <input type="checkbox"/> Any other invasive procedure (please state) |

If yes, please give details emphasising any adverse consequences and potential risks, and what safety precautions are in place for participants.

List the type of data being collected and the method of analysis.

Is any financial remuneration or other compensation being offered to participants for reimbursement of their time, travel expenses, or any other inconveniences incurred? YES / NO

If YES, state how much will be offered and why?

Confidentiality of records:

How will the confidentiality of the ASRB volunteers' personal information and test results be maintained during and after the study?

Are ASRB volunteers' records to be preserved after the study is complete? YES / NO

If YES, how will the confidentiality of the ASRB volunteers' records be maintained during the period of their preservation? (*Please note: you are not permitted to re-contact ASRB volunteers for any future project without first obtaining permission from the ASRB Register*)

In order to ensure the ASRB database is accurate and up-to-date, researchers are required to provide personal and clinical information about ASRB participants participating in their study. What procedure do you have for fulfilling this requirement?

When completed proceed to question 10

9. PROTOCOL INFORMATION

List the type(s) of analysis you will be performing on the material(s)

Will genetic material or other data be preserved after the study is complete? YES / NO
If YES, why will this material be preserved and how will it be stored?

When and how will genetic material or other data be destroyed?

10. PLEASE ATTACH THE FOLLOWING DOCUMENTS

All applications must attach the following documents:

Outline of the research protocol (2 pages maximum)

Attached

Evidence (if any) of funding support available for project, including relevant grant application(s)

Attached

Full Ethics Application and Approval document Attached

Brief CV (~2-pages) of chief investigator or project supervisor Attached

Applications to recruit participants for other research must also attach the following document:

Participation Information statement for study Attached

SIGNATURES:

I certify that the above information is correct and that the proposed research will not vary from that outlined above without prior approval from the ASRB Access Committee. The proposed research conforms to the general principles set out by the NHMRC.

Chief Investigator: **Date:**.....

COST RECOVERY (OFFICE USE ONLY)

Shipping Charges (to be paid by researcher directly to courier):

Sample Costs (to be paid by researcher to the Schizophrenia Research Institute):

Additional Processing Fee (to be paid by researcher to the Schizophrenia Research Institute):