

Biobank and Databank access and data sharing policy

Policy/form: #BIO001

Access

Researchers interested in accessing data or samples governed by the Autism CRC Access Committee will have registered their interest through www.autismcrc.com.au/biobank/expression-of-interest. Subsequently, the researchers will be contacted by the Biobank team, before receiving a link to access the online Application Form and this policy for their review.

Approval

The application to access specimens and/or electronic data for research projects will be reviewed by the Autism CRC Access Committee. The Autism CRC Access Committee will co-opt scientific advisers with expertise related to the specific project under evaluation where required. This Committee will assess the application against the following factors:

1. Review of the scientific merit of the project. This will be based on scientific validity; study design; technical parameters (e.g. reproducibility, sensitivity, specificity); clinical or scientific impact; practicality and feasibility (e.g. amount of tissue, number and type of samples required against the sample reserves within the Autism CRC Biobank and other prospective applications).
2. All applications will be reviewed in light of the best interests of the Autism CRC Biobank or Databanks and in keeping with the consent provided by participants.

Approval of the project by an appropriate HREC is an essential prerequisite for fulfilling approved access applications. Evidence of the ethics clearance must be provided prior to accessing samples or data.

All applications will be treated as confidential.

Researchers proposing the use of Biobank and Databank materials and/or data in a research grant application must obtain Autism CRC Access Committee approval, conditional on the grant application being successful, prior to submitting the application. Biobank material samples will generally not be held in reserve for individual projects for more than 12 months after the approval of the Access Committee.

Material Transfer Agreement

In addition to ethics approval for the research project, access to samples and/or data will be subject to the execution of Autism CRC's Material Transfer Agreement.

Samples and data are provided for specific uses, detailed in the Material Transfer Agreement. Samples and data may not be used by recipients for purposes other than specified in the Agreement. Any change in the scope and purpose of the project must first be approved by the Access Committee and be subject to the prior written agreement by Autism CRC.

Rights to any new intellectual property will be defined in the Materials Transfer Agreement, as appropriate. Regardless of the ownership rights, this policy will not affect the moral rights of researchers and acknowledgement of their work if used by others.

Acknowledgement requirements and authorship considerations

It is mandatory for investigators supplied with resources from the Autism CRC Biobank or Databanks to acknowledge Autism CRC appropriately in any published work that results from use of the material or data. The acknowledgement requirements will be specified in the Material Transfer Agreement.

If members of the Autism CRC Access Committee or Autism CRC researchers provide significant input from, over and above the supply of materials and data for a particular research project, then an agreement on authorship and/or collaboration must be entered consistently with NHMRC guide on authorship: "Authorship: A guide supporting the Australian Code for the Responsible Conduct of Research". National Health and Medical Research Council, Australian Research Council and Universities Australia. Commonwealth of Australia, Canberra (2019).

Data sharing policy

Autism CRC recognises and endorses the National Health and Medical Research Council (NHMRC) policy on data sharing <https://nhmrc.gov.au/about-us/publications/open-access-policy>.

Researchers who are provided with approval to access Autism CRC Biobank or Databank specimens or data must agree to provide Autism CRC Ltd with a copy of the curated electronic data associated with the specimens or provide links and mechanisms to enable access to the data by Autism CRC and other approved external researchers to expand the usable database for

potential future use.

If, for the purposes of publication, data are required to be deposited into a public database, a separate access request must be made to the Autism CRC Access Committee, and access approved, at least 30 days prior to the submission of the relevant publication for review. The access approval by the Autism CRC Access Committee will also include the terms upon which the public database might make the subject data available to third parties.

This policy is effective from 1 October 2014

This policy will be updated as required and the latest version of relevant documents will be available on the Autism CRC website www.autismcrc.com.au. It is the responsibility of applicants to be aware of and adhere to any changes.

Document control

Issue: Version 3, December 2022

Review: December 2024

Approved: Board approved

Responsible: Chief Research Officer (or equivalent)