



Aboriginal Genetics and Health Studies Data Access Committee

Access to DNA Variant Data

1. General principles

The Telethon Kids Institute (hereafter referred to as The Institute) Aboriginal Genetics and Health Studies Data Access Committee will consider applications for access to de-identified DNA variant data generated from studies based at The Institute, including studies carried out in collaboration with The Menzies School of Health Research, Darwin, NT. Access to data will be granted to qualified researchers for appropriate health-related uses. A qualified researcher refers to a scientist who is employed, or a student enrolled at, or legitimately affiliated with an academic, non-profit or government institution, or a commercial company performing Aboriginal health-related diagnostic services.

The data is deposited in the European Genome-phenome Archive (EGA) and access is by application to the Telethon Kids Institute Aboriginal Genetics and Health Studies Data Access Committee (AGHS_DAC). Access to data will be granted to researchers for appropriate use and will be governed by the provisions laid out in the associated informed consent for each cohort or collection, and the terms contained in the Data Access Agreement.

The AGHS_DAC is concerned only with access to the core, de-identified, DNA variant data generated by each study. The only phenotypic information held by the AGHS_DAC is that which is implied by membership of a particular trait or disorder under investigation, case or control group as entered in the EGA repository and associated publications. Data will be accompanied by information on the sex, age and broad geographical region of collection. The Committee will **not** consider requests for more detailed demographic or phenotypic information.

Access is conditional upon availability of data and signed agreement by the researcher(s) and the responsible employing Institution to abide by policies related to publication, data disposal, ethical approval and confidentiality.

2. Application procedure

Applicants requesting access to data from the AGHS_DAC will be asked to complete a basic application form and to agree to the terms and conditions laid out in the Data Access Agreement (DAA). The DAA must be signed by both the applicant and the relevant Head of Department, Head of Institute, or equivalent. Where the applicant is the Head of Department, a countersignature from another officer authorized to sign material transfer agreements on behalf of the institution must be provided.

Successful applicants who have access to data will be designated "Registered Users" and will be issued with a username and password by the EGA to enable access to the database.

The Committee will consider applications that include named collaborators, but each Institution must sign a separate Data Access Agreement. Should you wish to share the data with additional collaborators not previously approved, **they must make a separate application for access to the Data.**

Applicants agree to use the data for the approved purpose and project described in the application; use of the data for a new purpose or project will require a new application and approval.

Details of the application procedure, along with the relevant forms, can be found at <https://www.telethonkids.org.au/aghs> under the 'Access to Data' tab.

3. Membership of TKI_AGHS Data Access Committee

Associate Professor Gareth Baynam, (Chair), Genetic Services, WA Health

Mr Glenn Pearson, Head Aboriginal Research Development, Telethon Kids Institute

Dr Heather d'Antoine, Associate Director for Aboriginal Programs, Menzies School of Health Research

Associate Professor Kristen Novak, Office of Public Health Genomics, WA Health

Professor Elizabeth Davis, Consultant Endocrinologist, Princess Margaret Hospital

Ms Denise Anderson, Biostatistician, Telethon Kids Institute

Dr Carrington Shepherd, Postdoctoral researcher, Aboriginal and Torres Strait Islander Health, Telethon Kids Institute

Dr Sarra Jamieson, Project Manager, Telethon Kids Institute (*ex officio*)

email: Sarra.Jamieson@telethonkids.org.au

4. Assessment Criteria

Each application will be assessed to determine if:

- it has been submitted by a qualified researcher or researchers, embedded in a recognised institution that can provide institutional responsibility for appropriate research governance
- the project described constitutes 'biomedical health-related research' in the context of the consent process, and is likely to be understood as such by the sample donors

- it breaches any of the ethical permissions or restrictions in the consent forms for any component cohort or collection
- it has the potential to produce information that will enable identification of individual participants
- that PhD students include details of their research supervisors

In considering applications, the AGHS_DAC have clarified their policies in regard to specific data access requests. The Committee has agreed that:

- AGHS_DAC does NOT attempt to peer review the scientific quality of proposals. However, it does ask for a brief summary of the research to be undertaken, in order to judge whether it falls within the scope of the consents. It also considers that grossly inadequate research is ethically questionable, and reserves the right to refer back for clarification those requests that do not appear to attain even a minimal standard of competence
- the use of data by commercial companies for commercial purposes is **NOT** permitted

5. Data Available

Please visit <https://www.telethonkids.org.au/ags> to view the project-specific datasets available under Telethon Kids Institute Aboriginal Genetics and Health Studies. Individual-level genotypes for all genetic variants typed or identified in the course of these studies will be accompanied by:

- chromosome position
- age at onset or collection
- broad geographical region of collection
- sex

6. Availability of DNA samples

DNA samples are **not** available through the Data Access Committee.

7. Publications arising from projects approved by the Data Access Committee.

A PDF reprint of all publications arising from projects approved must be sent to the Data Access Committee.

8. Northern Territory-based study

Applicants requesting data from studies where sample collection was based at the Menzies School of Health Research will additionally be required to comply with Key Principles and Statements in the Living Protocol drawn up by the Governance Committee for those studies:

Key Principles and Statements in the Living Protocol

Principles	Statements
<p>1. Comply with guidelines for ethical conduct in Aboriginal and Torres Strait Islander health research. These guidelines are on the NHMRC website. http://www.nhmrc.gov.au/guidelines-publications/e52 .</p>	<p><i>The Recipients granted access to DNA variant data will comply and act within the parameters of the project’s ethics approval.</i></p>
<p>2. Respect consent of collectives and individuals.</p>	<p><i>The Recipients granted access to DNA variant data will only operate within the parameters of the consent provided for the use and application of collected human DNA samples. Original project consent forms are made available on the AGHS_DAC web site at https://www.telethonkids.org.au/aghs</i></p>
<p>3. Data will be represented in ways that support community. Publications will be checked by the AGHS_DAC on behalf of the Aboriginal Governance Group.</p>	<p><i>The Recipients granted access to DNA variant data must not publish details or a description of the materials or the results of the research in any form without written consent of the AGHS_DAC.</i></p>
<p>4. Obligation to inform the participating Aboriginal communities about requests for secondary usage of data.</p>	<p><i>The AGHS_DAC will inform the Aboriginal Governance Group at the Menzies School of Health Research of all data sharing projects approved.</i></p>
<p>5. If the data have been used by an external organisation/institution to generate new information, those data must be made available for community use.</p>	<p><i>The Recipient institution to return all derived data, via the AGHS_DAC, to the Menzies School of Health Research upon completion of their project.</i></p>