

Genomic Data Access Information Sheet

QIMR Berghofer Genomic Data Access Committee

1. General principles

QIMR Berghofer Genomic Data Access Committee (DAC) will consider applications for access to de-identified, individual-level omics data generated from studies based at the Institute. This includes studies carried out in collaboration with other organisations, where QIMR Berghofer is legally responsible for the data.

Access to data will be granted to qualified researchers running a project with ethical approval and undertaking a research activity that aligns with participant consent for secondary use of their data. Participant consent varies between studies, and therefore, allowable data uses will also differ between datasets.

A qualified researcher refers to a scientist employed by or affiliated with an academic, non-profit, or government institution. For students to access data, a supervisor or employee of the receiving organisation will need to apply for data on behalf of the student. Sharing with qualified researchers employed by commercial entities is allowed for some datasets.

2. Application procedure

Before submitting an application, please email the DAC at dac@qimrb.edu.au. In the email, include details about your:

- proposed project,
- dataset you are requesting, and
- the sequencing and file type you need.

We'll let you know your data access options before we proceed with the application process.

If a full application and DAC approval are required, you will be asked to complete the Data Access Application form.

3. Data Transfer Agreement

A legal representative of the receiving Institute is required to sign QIMR Berghofer's Data Transfer Agreement (DTA). Use of the data is limited to the terms of the DTA and the project(s) listed in the Schedule.

The receiving organisation and any employees who work with the data must comply with the DTA clauses on publication, data disposal, ethical approval, and confidentiality.

The DAC will consider data requests that include collaborations, but each Institution that houses or works with the raw data must sign a separate DTA.

Use of data for a new project or purpose, after the DTA is executed, will require a new data request application and DAC approval. The DTA may only require an amendment to the Schedule for new projects.

4. QIMR Berghofer Genomic Data Access Committee

DAC members:

Dr Nicola Waddell, Medical Genomics Team Lead, QIMR Berghofer

Mr John Pearson, Genome Informatics Team Lead, QIMR Berghofer

Dr Miranda Vidgen, Research Officer – Data Governance, QIMR Berghofer

Dr Ross Koufariotis, Bioinformatician, QIMR Berghofer

In addition to the DAC members, individual requests may involve DAC Advisors. DAC Advisors are specialist knowledge holders who contribute when a data request involves concepts that need specific input and perspectives. For example, commercialisation, new technology, vulnerable populations or communities, or the principal investigators of a dataset.

5. Application Assessment Criteria

Each application will be assessed before DAC review to determine if:

- It has been submitted by or on behalf of a qualified researcher or researchers, embedded in a recognised institution that can provide institutional responsibility for appropriate research data governance.
- The project has appropriate ethical approval for human research.

- (*international requests only*) If Department of Foreign Affairs and Trade (DFAT) Foreign Arrangement Scheme (FAS) approval or notification is required for the organisation to receive data.
- The proposed data use involves sensitive issues (See “Limitations of Data Access” section).
- It involves computational calculation and assignment of ethnicity to participants.

When considering applications, the QIMR Berghofer Genomic Data Access Committee assess the following aspects:

- What is the scope of data sharing allowable by participant consent, project investigators and/or QIMR Berghofer for the requested dataset? Does this allowable scope align with the proposed data usage?
- Does the proposed data usage require the sharing of raw or aligned data? Would a derivative dataset suit the proposed usage? Can the Medical Genomics team offer this option?
- Are there any special considerations that are outside the scope of the DAC members’ expertise and require input from a DAC Advisor?
- Does the Applicant’s data management response for the requested dataset(s) align with organisational expectations?
- If, or how, AI will be applied to the dataset.

QIMR Berghofer Genomic Data Access Committee does NOT peer review the scientific quality of proposals or the ethics of the overall study. It asks for a summary of the research to assess whether it falls within the scope of the participant consents and organisational requirements. If the QIMR Berghofer Genomic Data Access Committee identifies any ethical concerns with the proposed data use or insufficient information to assess scope, it will request clarification before proceeding with a decision.

6. Supporting Data

Associated phenotypic and clinical data are available in the supplementary materials of the relevant peer-reviewed publication. **Please check that this supporting data is sufficient before proceeding with data request application.** No additional phenotypic or clinical data is available via the request pathway.

7. Limitation to Data Access

Whilst each dataset has different limitations based on participant consent, several limitations are applied universally to our datasets:

- Our organisation does not allow storage or management of individual-level omics data received from QIMR Berghofer on Third-party platforms (this includes Cloud data storage). This is a clause in the DTA that should be considered before signing.
- We do not allow data use that involves computational calculation and assignment of ethnicity to participants.
- Any requests for data for a use that involves a specific community will need supporting documentation to confirm support for the project from that community.
- All research activities the data will be used for require ethical approval. This includes research done by commercial entities, where commercial use is allowed by participant consent.
- No research results can be returned to participants.

8. Requests by international entities

Data requests from entities outside Australia may be affected by the Australian Department of Foreign Affairs and Trade (DFAT) [Foreign Arrangements Scheme \(FAS\)](#). As a Queensland state government entity, QIMR Berghofer must participate in this scheme.

The scheme requires our Institution to seek approval or to notify the Australian federal government if we enter into a data transfer agreement with a core or non-core foreign entity, respectively. When we receive an enquiry or request for data access, we will determine if data transfer to your organisation is affected by the scheme. If the receiving organisation is affected by the scheme, it will delay the data request process while we seek approval or go through the notification process. You and your receiving organisation will not need to do any additional work.

9. Publications

Acknowledgement of QIMR Berghofer and any relevant Third Parties as the source of the data is required for publication. It is expected that QIMR Berghofer be allowed to review a publication at least **14 days before intended submission**. A copy of the pre-submission publication can be sent to dac@qimrb.edu.au for review. The DAC also requests that you email a PDF copy of the publication once it is published.