



[REDACTED]  
Policy Officer  
[REDACTED]

Dear [REDACTED]

Further to your correspondence of 27 May 2021, please see below information regarding the data sharing policies and procedures of Australian Genomics.

Authorised researchers with projects that have gained ethical approval by a Human Research Ethics Committee may apply for access to Australian Genomics datasets via the process as detailed on our website. The type of data shared will depend on the specific requirements of the ethically approved research project, and the data is shared according to each participants' specified consent preferences and data use permissions. Personally identifying information is not provided for these purposes.

The external data sharing phase has not commenced in Australian Genomics, as the data are under embargo until next year, however approved projects will be publicly listed on the Australian Genomics website.

Sharing of genomic data is only permitted for ethically-approved projects or clinical care, data sharing for other purposes is not permitted unless required by *law* under the *Australian Privacy Act*. Australian Genomics does not sell its data.

Data breach prevention processes are in place at each organisation handling our data as part of the program. These include strict industry and organisational standard procedures for controlling physical access to servers, operational access controls to data and computing systems, auditing, monitoring, penetration testing and protection against malicious attack.

The coded, de-identified genomic data is stored in separate infrastructure to the participants personally identifying information.

The consent forms adopted by the different clinical research studies across Australian Genomics, are each modelled on the National Clinical Consent form, which is publicly available on our website. Participants provide consent for genomic testing and participation in the Australian Genomics research program, as well as separate, *optional* consent to further share their genomic and clinical data other ethically-approved research projects that are not be part of our program.

Participants also have the option to use the online Dynamic Consent participant portal (see below), where they can select what type of organisations they consent to sharing their data with, what type of research is permitted on their data, and can change their preferences at any time. Participants may withdraw at any time, and at this point they may choose whether their data is deleted from our databases.



Australian Genomics Data policies, practises and projects are reviewed by a registered Human Research Ethics Committee, a Community Advisory Group of patient advocates, a National Implementation Committee, and is required to meet the standards of Australian National Statement on Ethical Conduct in Human Research, and the Australian Code of Conduct for Responsible Research. They are developed to align with and meet international best practice around genomic data sharing under the Global Alliance for Genomics and Health.

We note your intention to review Australian Genomics policies and processes, and provide this information and your commentary public.

In turn, and in the interest of transparency, we request additional information about GeneWatch International, which is not clear from the GeneWatch UK website:

- GeneWatch International's internal processes and governance around your organisation and these intended activities;
- The basis of, and evaluation framework you apply, to your critique on policies and practices of organisations in other jurisdictions;
- The personal / professional liability of GeneWatch for the accuracy of represented information you publish;
- The basis for independently publishing Australian Genomics processes that are already publicly available.

We also are interested in whether your organisation participates in the activities of the Global Alliance for Genomics and Health, and if not, why not? The Global Alliance for Genomics Health (GA4GH) is developing and promoting standards to enhance participant privacy, empowerment and improve genomic practice. Australian Genomics leads and contributes activities in the GA4GH, and it is an excellent forum to collaboratively and internationally converge on standards to ensure the ethical and appropriate application of genomics, in the public interest.

We request the opportunity to review and contribute to any content you publish on Australian Genomics, including but not limited to information already available on our website, in the interest of ensuring transparency, accuracy and public understanding.

Further information is provided below for your interest.

Regards,

Managing Director,  
[REDACTED]



#### **FURTHER INFORMATION**

<https://www.australiangenomics.org.au/about-us/governance/>

**Our Community Advisory Group** brings together experienced patient advocates providing counsel on our research activity. The Group advises on the design and language of patient surveys, digital health and data management strategy, and ethical, legal and social analyses of genomics. The group is instrumental in the development of our online participant portal and Genomics in the Community initiative.

**Our National Implementation Committee** works in conjunction with the National Steering Committee to inform appropriate strategies and facilitate the implementation of Australian Genomics research outcomes into the Australian health system. Members of the Committee apply their expertise in health system planning, policy development and translation. The Committee members and Australian Genomics share a commitment to ensure the efficient, effective, ethical and equitable implementation of genomic healthcare under Australia's National Health Genomics Policy Framework.

#### **Australian Genomics National Clinical Consent Form:**

[\(https://www.australiangenomics.org.au/resources/for-professionals/national-clinical-consent/\)](https://www.australiangenomics.org.au/resources/for-professionals/national-clinical-consent/)

#### **Australian Genomics Dynamic Consent Participant Platform:**

[\(https://www.australiangenomics.org.au/resources/for-patients/your-personal-platform/\),](https://www.australiangenomics.org.au/resources/for-patients/your-personal-platform/)

#### **GLOBAL ALLIANCE FOR GENOMICS AND HEALTH**

**Ethics and Regulatory** (consent clauses for genomic research, familial consent clauses, ethics review recognition, machine readable consent, consent clauses for rare disease research)

<https://www.ga4gh.org/genomic-data-toolkit/regulatory-ethics-toolkit/>

**Data Security** (Data Security Policy, Data Security Infrastructure Policy, Authentication and Authorisation infrastructure)

<https://www.ga4gh.org/genomic-data-toolkit/data-security-toolkit/>

**Genomic Data Tools for Secure Data Sharing** (includes Passports, Data Use Ontology, Beacon, Tool Registry Service)

<https://www.ga4gh.org/genomic-data-toolkit/>