24th January 2022

Attorney-General's Department
Australian Government
PrivacyActReview@ag.gov.au

To Sir or Madam,

Thank you for the opportunity to provide a submission in response to the *Privacy Act 1988* Review Discussion Paper, on behalf of Australian Genomics.

Australian Genomics is an Australian Government initiative supporting genomic research and its translation into clinical practice. Through broad engagement and a national collaborative approach, it achieves two key objectives: to improve efficiency, reach and timeliness of genomic research projects, and to support Commonwealth State and Territory health departments in the implementation of genomics research outcomes by refining and communicating evidence to inform policy development.

Australian Genomics engages with current and emerging government policy and priorities to identify gaps and opportunities, to support policy and action for integrating genomic technologies into the health system. By interfacing with consumers, governments, industry and global genomics initiatives, Australian Genomics drives change and growth in the sector.

In all contexts, Australian Genomics considers non-anonymised genomic information as personal, sensitive information under definitions of the *Privacy Act 1988* and is therefore collected, used and disclosed to protect the privacy of the individual following the guidelines of the *Privacy Act 1988*, *Australian Privacy Principles* and the *NHMRC National Statement*, among others. Individual level genetic and genomic data by its nature is not easily de-identified, but this creates a tension because at the same time, there is broadly acknowledged benefit in the sharing of genomic data for clinical and research purposes, as health genomics strives to increase our understanding of functional variation in the human genome. Thus, any changes to the *Privacy Act 1988*, such as those with the intended purpose of strengthening protections of individuals in the online environment / digital platforms, should only be done once the impact of each change has been considered with respect to genomic and health-related data, so as not to have unintended consequences that hinder the progress being made by global clinical genomic efforts in advancing health.

Here we consider some of the key proposed changes to the *Privacy Act 1988*, specifically in relation to potential impacts on the handling of genomic and health data for clinical and research purposes.

Proposal 2: The definition of personal information

1. The change in wording of the definition of personal information from "about" an individual to "relates to" an individual, may not have any foreseeable, immediate implications for whether genetic/genomic information is covered under the *Privacy Act 1988*.

- The *Privacy Act 1988* clearly articulates that genetic information is considered personal information that also falls under the narrower definition of sensitive information. We support the inclusion of genetic information in the list of examples of personal information. We do not expect the proposed changes to the definitions of personal or sensitive information to alter any categorisation of genetic/genomic data as personal and sensitive information.

2. In the context of genetic and genomic information, information relating to, and inferred information, should be protected by privacy legislation.
    - We understand that the personal information wording change to "relates to" has been proposed so that it can include technical data, such as location data. If this technical data includes metadata (as mentioned in the Discussion Paper p.24), this may have impact on data associated with or resulting from a person's genomic sequencing information. For example, one may be able to infer from the metadata associated with a person's genomic sequencing data: diagnostic or clinical service identifiers, name and location of health services accessed, or investigation type performed. If the definition of personal information also covers inferred information, then data inferred from genomic data but not the primary purpose for performing the sequencing can give information about paternity, ethnicity, susceptibility to other genetic diseases, and other genetic traits or disease associations, and combined with other health data would be able to infer more about and individual.

3. In relation to important comments raised in the Discussion Paper about direct to consumer (DTC) genetic testing (p.34-35) and the protection of personal information obtained through it, it is our view that whatever means by which genetic information is collected, it should be subject to protection under the *Privacy Act 1988*.
    - In 2020, Australian Genomics and the Genioz study made a joint submission to the TGA consultation on review of the regulation of self-testing *in vitro* diagnostics in Australia, focusing on DTC genetic tests[1]. While such DTC tests are unavailable in Australia, consumers can access those offered by overseas companies. The submission raised the data privacy issues relating to genomic testing done offshore in this context (as well as many other issues) and explored potential solutions, noting that there are no easy answers. One recommendation is that consumer education could have a key role in helping health consumers understand the implications of taking offshore tests for the privacy of their personal information.

4. It is our view that genetic data, particularly an individual's *whole genome* data, is "reasonably identifiable" even when "de-identified", because the individual could be re-identified from it by an appropriately skilled person. Whether a person is reasonably identifiable from their *genetic variant* information or short sequences of their DNA, and therefore should also be considered personal information under the *Privacy Act 1988*, has been the subject of robust discussion.
    - It will be important to reach sector agreement on this, as it has multiple impacts. For example, it impacts upon the guidelines and processes underpinning whether and how

[1] https://www.tga.gov.au/sites/default/files/submissions-received-and-tga-response-review-regulation-certain-self-testing-ivds-australia-agha-gs.pdf

genetic variant information can be shared to databases (e.g. ClinVar). The objective of many of these databases is to share genetic variant and associated health information to support the continued improvement in understanding of genetic variation and disease, and to assist in increasing genetic diagnoses for the individuals affected. They are the basis of international efforts in health genomics and the advancement of the field depends upon it. At this time, and through our own participant research genomic sequencing studies, Australian Genomics shares this information only on the basis of consent of the individual. Approaches to sharing this information when consent and testing are done in a clinical setting (rather than research) have been considered by efforts including the Australian Genomics National Consent for Genomic Testing project, which aims to harmonise approaches to patient consent and information materials. There seems to be increasing consensus in the field that variant level information is not identifiable and thus does not require specific consent.

5. There are many instances where the *Privacy Act 1988* should cover information about the deceased.
    - As this is already the case for genetic information, our submission will not expand on this proposal any further.

6. The proposal to expand protections of personal information under the *Privacy Act 1988* to include de-identified information, meaning that it must be anonymised to be no longer about an individual and thus covered under the *Act*, would not alter our current practices.
    - In relation to collection, use or disclosure of genetic/genomic information, we treat "de-identified" data (that is, personal identifiers removed and replaced with a code) as covered by the *Act* at this time. This means that individual level genetic and genomic information is anonymised by being aggregated before it is no longer managed under the *Act*. But, it is important to note that a) it is possible that not all entities involved in the handling of genetic/genomic data have the same view that individual level genomic data is not de-identifiable, and b) to reiterate that the value of genomic and other health data for use in research can be greatly diminished if it is anonymised.

Proposal 9: Consent to the collection, use and disclosure of personal information

7. We agree with the Discussion Paper in considering that consent remains essential wherever possible to the collection, use and disclosure of sensitive information, and where it is intended to be disclosed for an additional purpose (e.g. secondary purpose, p.76) for health and genomic research.

8. The proposal to amend the *Privacy Act 1988* to ensure "consent be 'informed, voluntary, current and specific, and given with capacity'" is cause for concern among health research initiatives like genomic studies. The health research sector would need clarification and an assurance that consent obtained for collection of personal information for a primary purpose can continue to include secondary purposes, for sharing to future, unspecified research projects.
    - The newly proposed definition is in line with the GDPR definition of "freely given, specific, informed and unambiguous…" and the proposed Online Privacy Code's "voluntary, informed, unambiguous, specific and current". The purpose of the "specific"

requirement is to avoid consents being broad or bundled. However, given the way large-scale health research initiatives (such as genomic research, biobanks and longitudinal studies) are currently widely conducted, the term "specific" may be cause for concern, and requires clearer definition. Many research efforts are set up with the intention to make the data they collect available to other research programs, or intend to make their data available for secondary purposes, which are *not specified at the time at which consent is obtained* from the individual. Page 78 of the Discussion Paper outlines the APP guidelines for sufficient specificity, but this does not provide clarity for the health and research sector.

9. Australian Genomics has been actively advocating for a number of years for a transition to more specific consent through mechanisms such as dynamic consent platforms[2].
    - These mechanisms require more piloting and significant sectorial cultural change, as well as better commitment to infrastructural support to deliver them, before they are more widely adopted. Relatedly, we note that of the submitters to the Issues Paper consultation who were overwhelmingly "opposed to consent playing a more prominent role", none were from the health and research sector.

10. Australian Genomics supports the development of standardised consent taxonomies (p.79).
    - Through our own work have begun to use the Global Alliance for Genomics and Health's Data Use Ontology standard, promoting unambiguous, shared understanding of genomic data access and use permissions[3]. We agree with the Discussion Paper that it is unlikely that consent templates will be applicable across sectors, but standardising elements of consent within sectors would be a major advancement benefiting individuals and APP entities.

Proposal 10: Additional protections for collection, use and disclosure of personal information

11. The definition of a 'secondary purpose' as a purpose that is "*directly related to"*, and reasonably necessary to "*support the primary purpose"* could prove problematic for the secondary use of data for unrelated health research.
    - Under the current APP6, information can only be disclosed if it is for the same purpose (primary purpose) for which it was collected, and any new purpose (secondary purpose) would require consent or an exception. There needs to be clarification of what "directly related to" means – and whether all health research is considered directly related. Our experience suggests that most secondary use of data for health research purposes would not fulfil the proposal that it is "necessary to support the primary purpose" and thus could drastically limit the ability to use collected data for secondary research purposes.

[2] Haas, M.A., et al. 'CTRL': an online, Dynamic Consent and participant engagement platform working towards solving the complexities of consent in genomic research. Eur J Hum Genet **29,** 687–698 (2021). https://doi.org/10.1038/s41431-020-00782-w

[3] Lawson J, et al.. The Data Use Ontology to streamline responsible access to human biomedical datasets. Cell Genom. 2021 Nov 10;1(2) doi:10.1016/j.xgen.2021.100028

This is in direct contrast to the broadly adhered to FAIR (Findable, Accessible, Interoperable and Responsible) data principles, as well as guidelines and standards more specific to our work, including (but not limited to) the Global Alliance for Genomics and Health's Framework for the Responsible Sharing of Genomic and other Health-related Data[4] and the US National Human Genome Research Institute's Policy on Data Standards[5]. Making participant data available for reuse also reduces the burden on participants by reducing the need to recreate study datasets.

12. If the collection, processing and disclosure personal information for health research becomes subject to "legitimate interest" and "fair and reasonable" tests, it is likely that the use of genomic and other health data for primary and secondary research purposes should pass both tests.

Proposal 11: Restricted and prohibited acts and practices

13. We agree that additional requirements could be considered for restricted practices, which include "the collection, use or disclosure of biometric or genetic data…".
    - The Privacy Impact Assessment is becoming an increasingly common tool in assessing the impact of access to health data for health research. Another approach may be to introduce the opportunity for individuals to self-manage their privacy with relation to secondary use of their information for health and research purposes, such as through digital, dynamic consent. However, it should also be kept in mind that all health research in Australia is already subject to robust, high-standard ethical review by Human Research Ethics Committees, which consider research participant privacy issues. Therefore, the introduction of any additional requirements in this review process may not further improve the quality of protection for the individuals involved, but rather have negative consequences such as slowing the pace of vital research.

14. Australian Genomics also supports the continuation of restrictions on the access to genetic and genomic test results by the life insurance industry[6], and supports the current Moratorium applied to the industry, although improvements could be made to strengthen protection for individuals.

Proposal 19: Security and destruction of personal information

15. There should not be changes to the *Privacy Act 1988* or APP 8.2b to enforce the anonymisation of stored health or genetic/genomic data. It should remain stored de-identified (personal identifiers removed and replaced with a code).
    - The proposal for entities to destroy or anonymise data that is no longer being used, rather than the current direction under the *Act*, which is to de-identify it, would limit the reuse and inherent value of data. As previously discussed in relation to Proposal 2, anonymisation of genomic data renders it far less useful for clinical and research purposes.

[4] https://www.ga4gh.org/wp-content/uploads/Framework-Version-3September20191.pdf
[5] https://www.genome.gov/about-nhgri/Policies-Guidance/Genomic-Data-Sharing/data-standards
[6] https://www.australiangenomics.org.au/wp-content/uploads/2021/09/Australian-Genomics-Health-Alliance-AGHAA%CC%82-FSC-Life-Insurance-Code-of-Practice-2.0-Submission-1.pdf

Proposal 22: Overseas data flows

16. Currently, if an individual provides their consent, their personal information can be shared to overseas countries where the privacy laws are not considered equivalent to Australia's. This proposal is to remove the consent exception. In many scenarios this may be considered a highly reasonable step, however, in the health and research sectors there are instances where it is not.
    - Australian Genomics participates in a global collaboration to advance health genomics (the Global Alliance for Genomics and Health), which includes many developing countries, which also represent great diversity in culture and government/governance structures. Closing the door on any data sharing would be an abandonment of our responsibility to collaborate with colleagues in those countries who are striving to strengthen their health systems. Therefore, there must be a way to continue to share information internationally on a case-by-case basis, and the expansion of certification schemes (p. 159) could be an important step in facilitating this.

Proposal 28: Interactions with other schemes

17. The proposal to harmonise state and territory privacy laws is an important one and relates to several key systemic issues affecting the sharing of genetic/genomic and other health information for clinical purposes as well as research.
    - In our direct experience, different privacy acts (or different interpretations of them) have led to:
        - Compounding difficulties in accessing administrative datasets (hospital and emergency department) for ethically approved health economic evaluations of the cost of diagnosing or living with rare diseases and cancers with a genetic basis.
        - Additional requirements for completion of human research ethics applications and governance approvals in some states and territories.
        - Inconsistencies in study procedures for participants in research depending on the jurisdiction they are enrolled in research from.
        - Inconsistencies in the ability to share an individual's genomic information across jurisdictional borders for research and for clinical purposes, in turn limiting opportunities for achieving a genetic diagnosis for the individual.

In addition to our responses to individual proposals:

18. We seek assurance that there will also be an appropriately consulted review of research and health-related exceptions which are the subject of the Guidelines approved under Sections 95A of the *Privacy Act 1988*.
19. The *Privacy Act 1998* s16B "permitted health situations" could be amended to more broadly apply to medical research activities to minimise the impact of the proposed changes should any form part of future privacy laws in Australia.

Thank you for the opportunity to provide our perspectives on the Discussion Paper, and we welcome any further opportunities to participate in the review.

Sincerely,

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