Genomic Data & Privacy Law

A Summary of Health Legal's Report for Australian Genomics

Australian Genomics Health Alliance

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Report summary

In late 2016, Health Legal were commissioned to advise Australian Genomics on:

- *The ownership of genomic information;*
- *How privacy law obligations apply to sharing genomic information for clinical and research purposes, and;*
- *The requirements for informed consent when collecting genomic information.*

(The views expressed in this report are those of Health Legal, on the above brief, and do not necessarily reflect the views and opinions of Australian Genomics).

Background

The privacy rights of individuals are regulated by legislation which has been enacted by the Commonwealth Parliament and the Parliaments of the States and Territories.

The Privacy laws place individual autonomy at their centre. Accordingly, the Privacy laws recognise that individuals may consent to the ways in which their information may be collected, used, and disclosed, and such dealings with an individual's personal information will be lawful.

Genomic information which is about an individual, or from which an individual's identity may be reasonably ascertained, is regulated by the Privacy laws.

Information presented in aggregate and which is not linked (or 'linkable') to any individual would not be considered personal information.

Where a patient undergoes genomic testing for clinical purposes, the consent of the patient (or their representative) is always required. That is because the patient must provide their informed consent to the testing procedure and also to enable the information to be analysed.

The use of this information for medical research is secondary to the original clinical purpose and is only permitted in limited circumstances.

Key Findings

- **Australian Genomics** needs to comply with the Privacy laws in each State and Territory, and those of the Commonwealth.
- While the requirements under those laws are similar, there is no single law which will regulate and enable the lawful implementation of an Australia-wide federated model of genomic data collection and sharing.
- The common element in each Privacy law is that a person may consent to the way in which their information is collected and handled.
- Patients seeking treatment for a medical condition who are referred to genomic testing will necessarily give their consent for that purpose.

- Patients may also be asked to consent more broadly to the use and disclosure of their information for research purposes.
- There is scope to advocate for legislative change to achieve uniformity and to support any further uses of genomic information (which is identifiable) to which the individual has not consented.

Who owns genomic data?

- Under Australian law, tissue taken from a human body constitutes property.
- The law in Australia has recognised that it is possible to acquire property rights over tissue where there has been work or skill applied to preserve them, and a person exercising such work and skill acquires a right to retain possession of the tissue [*Doodeward v Spence* (1908) 6 CLR 406].
- If the tissue constitutes property, it follows that the property may have an owner.
- In the case of genomic testing, the pathology testing service will have the strongest claim on ownership of the property since (in most cases) it is the pathology service that has arranged for the collection of the sample and 'worked' on it by preparing the sample in a form which can be analysed.
- Similarly, Health Legal considers that the pathology service will also have the strongest claim in the genomic data produced.
- The patient would not have a claim in the tissue, nor the genomic information derived from its analysis.
- While these conclusions rest on settled legal principles, they may not accord with public expectations.
- Given that the information represents intellectual property, such property may be assigned. That means that rights in the genomic data could be transferred to another entity.
- To the extent that the genomic data is commercially valuable, entities with an interest in that data may seek to exploit it. For example, the information may be used in the development of diagnostic procedures and treatments.
- The owner of the genomic information may be entitled to exploit any discoveries; however, that does not mean that such discoveries will be protected from exploitation by other entities. Such broad protection would only apply if the discovery (called an invention for patent law purposes) was capable of being patented.
- Following the *D'Arcy v Myriad Genetics Inc* [2015] HCA 35 case, determined in the High Court, the law is settled in Australia that merely isolating a gene does not give rise to a patentable invention. However, genuine inventions which go further in terms of treatment or diagnostic tools would be patentable.

How do the Privacy Laws apply to genomic data?

- The collection, use or disclosure of *personal information* must be permitted by the relevant Privacy law in order to be lawful.
- *Personal information* means information which is 'about an identified individual, or an individual who is reasonably identifiable'.
- Information which is not about an individual and which does not identify the individual is not subject to the Privacy laws.
- Consequently, information which once was personal information may be rendered 'non-personal' through a process of de-identification.
- The *Privacy Act 1988* (Cth) ('Privacy Act') defines 'health information' (in section 6FA(d)) as including 'genetic information about an individual in a form that is, or could be, predictive of the health of the individual or a genetic relative of the individual'.
- Further, 'sensitive information' (which includes health information) is defined in that Act more expansively as including 'genetic information about an individual that is not otherwise health information'.
- The definition of 'health information' in the *Privacy Act 1988* includes three other types of health information (section 6FA(a), (b) and (c)) and in each case, the definition is qualified by the requirement that the information also be 'personal information'. However, that qualification has not been applied in relation to genetic information (in section 6FA(d)) and so genetic information which does not identify any individual patient may still be 'health information' if it is about an individual and must be treated accordingly.

- Therefore, the question becomes "Is the information about an individual?" Health Legal's view is that record- level variant information is about an individual patient (especially if the information remains linked to the patient) and is therefore health information. However, if the information becomes aggregated it is no longer about an individual.
- The collection of health information is governed by Australian Privacy Principles (APPs) 3 and 5. The use of patient information is governed by APP 6 and disclosure of patient information is generally governed by APP 6.
- Collection of health information may generally only occur with individual's consent, and only where the information is reasonably necessary for the collecting organisation's functions or activities.
- The Privacy laws permit the use and disclosure of personal information for the primary purpose for which it was collected.
- Use or disclosure of patient information for other purposes (such as research) will be considered use for a 'secondary purpose'. APP 6 prohibits the use of patient information for secondary purposes unless an exception applies. Relevant exceptions include where the patient consents to the use of their information for the secondary purpose or if the conditions for a 'permitted health situation' (under the '*Privacy Act'* if applicable) are satisfied.
- An example of a permitted health situation would be where information is required for research relevant to public health or public safety, for a purpose that could not be served by de-identified information, where it is impracticable to obtain the individual's consent, and when an ethics committee has given its approval.
- The Privacy laws apply to an entity to the extent that the entity 'holds' the personal information. For this purpose, 'holding' information means having 'possession and control' of the record which contains the information and the possession or control of the record does not need to be exclusive.
- The Data Custodian may or may not be subject to the Privacy laws depending on the extent to which it can access the information. If the Data Custodian is purely providing a hosting service, it may not be subject to the Privacy laws with respect to the hosted information.

Privacy Laws regulate certain dealings in personal information. In the Australian Genomics context:

- *Collection* will occur when the entity comes to hold personal information. Generally, the subject of the information needs to be made aware when an entity has collected information about them;
- The personal information will be *used* when it is analysed as part of a research project or considered for clinical purposes; and
- *Disclosure* of the personal information will occur when the information is shared with another entity. This could be by transmitting the information to another entity or if another entity is given access to the information, even without the transmission of information.
- In determining whether to regard the genomic information as identifiable information, Australian Genomics needs to consider the context in which the information is held. The information is identifiable even if only the individual, and no one else, could identify themselves from the information.
- De-identification of personal information requires the manipulation of the personal information so that it does not identify an individual. For example, this could involve removing identifiers or generalising the information. The same legal principles apply to de-identified information that is: is it reasonably practicable for the entity concerned to discern the identity of an individual from the information available to the entity?

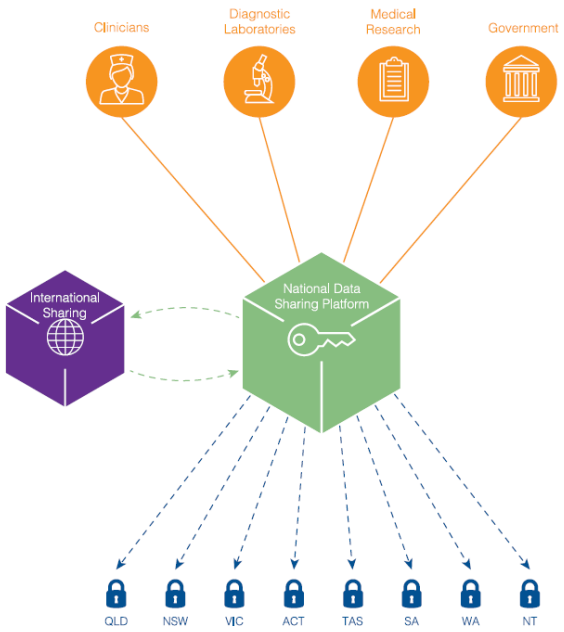
- While genomic information may itself not be identifiable, Australian Genomics will also need to consider whether the information may be re-identified. This can occur where the information could be linked with data contained in another

database (which could be publically accessible or accessible to an Australian Genomics member only) or if a 'linkage key' is used to provide a manner by which the patient may be re-identified.

- If a linkage key system is implemented, the entity having access to the key is considered to hold identifiable patient information; which must be treated in accordance with the Privacy laws.
- Genomic data collected during the course of a patient's lifetime may continue to be of use after they die. The APP Guidelines explain that 'personal information' refers to information about an 'individual' and that means 'a natural person'. This does not include deceased persons. Accordingly, the *Privacy Act 1988* does not extend to deceased persons. (In Victoria, the *Health Records Act 2001* excludes from the definition of 'personal information', 'information about an individual who has been dead for more than 30 years'). However, as the APP Guidelines continue to explain, care should be taken in terms of dealing with information that may relate to another person for example, a hereditary medical condition.
- There are limited exceptions under the Privacy laws when it is lawful to disclose information *without* obtaining the consent of the patient, and where the purpose is not for clinical or research purposes such as: emergency situations (although the laws differ with respect to the threshold to be met); to certain 'locating bodies' such as the Australian Federal Police; and when compelled to do so (i.e. in response to a valid subpoena).
- Generally, transfer of information interstate is permitted under the Privacy laws if the information will remain in a jurisdiction which has equivalent privacy protections. Transfers of information within Australia meet this requirement.
- In the event data was transferred outside Australia the requirements of the *Privacy Act 1988* would need to be considered and specifically APP8 which governs the disclosure of personal information overseas. The key question would be whether there is actual disclosure of patient information to a third party.

Implications for Australian Genomics' Proposed Data sharing model

- There is no single Act of Parliament which governs the exchange of genomic information on a national basis and accordingly there is no single Act which is capable of enabling the research purpose on a national basis.



- For consent based collection, under the Privacy laws, personal information may be collected, used and disclosed with the consent of the individual. Therefore, if the Australian Genomics consent model covers all of the purposes for which the information is to be collected, used and disclosed, including secondary use in research the Privacy laws do not impede the Alliance's activities and no legislative amendments are required.
- For non-consent based collection, use and exchange of de-identified information for research the Privacy laws do not regulate dealing in information which does not identify any individual and is not about individuals. Therefore, if the research purposes may be achieved by de-identified and aggregated information, the Privacy laws do not impede those activities and do not require amendment.
- For non-consent based collection, use and exchange of identified information, the Privacy laws permit the exchange of identified information for research purposes; however, the requirements are not uniform. Under the Privacy Act 1988 (where applicable) the Australian Genomics member would need to satisfy the requirements

for a 'permitted health situation' while in other jurisdictions there is no express exemption for research.

- If all States, Territories and the Commonwealth reached consensus about adopting a uniform set of requirements to enable genomic research involving identifiable information, such research activities would need to be authorised by all jurisdictions. If Australian Genomics members were of the view that the Privacy laws inhibit such research, the case could be made that a uniform exemption should apply. For example, that could be consistent with the 'permitted health situation' already recognised in the Privacy Act 1988.

Consent and the exchange of information

- Patients must give their consent when undergoing genomic testing – consent can be express or implied, and written or verbal. However express, written, consent if preferable for evidentiary and record keeping purposes.
- Medical practitioners have a duty to provide patients with sufficient information about the material risks inherent in the proposed procedure.
- Health Legal regard the following risks to be material, which must therefore be discussed with each patient:
  - *Any psychological risks associated with the testing; and,*
  - *Whether the results will reveal information about the health status of the patient's family.*
- As part of the informed consent process, patients should be informed of who their genomic test results will be reported to.
- The law is not clear on whether clinicians have a duty to disclose to (or a 'duty to warn') genetic relatives if a patient's genomic testing reveals an illness that the genetic relatives may be at risk of developing and the patient has not consented to disclose that information to their relatives.
- Case law suggests that any such duty may be satisfied by a clinician giving appropriate advice to the patient on the implications of the test results for the affected third parties and this is consistent with National Health and Medical Research Council (NHMRC) publications concerning disclosure of genetic results, which recommend that doctors advise patients to tell their relatives so that relatives can take any action to reduce the risk or severity of any disease.
- There is a relevant exception to disclosure of a patient's genetic information without consent which only applies in some jurisdictions. In these jurisdictions, organisations are permitted to disclose a patient's genetic information to a genetic relative without consent where they reasonably believe that the disclosure is necessary to lessen or prevent a 'serious threat to the life, health or safety' of a genetic relative of the patient, and the disclosure is in accordance with specific guidelines approved by the Commonwealth Information Commissioner under section 95AA of the Privacy Act 1988.
- The genomic testing may give rise to incidental findings. If such incidental findings are impossible to exclude, then patients should be informed that this is an inherent risk in undertaking genomic testing and they must agree to accept this risk as a condition of undertaking the genomic testing. If these findings can be excluded, then patients may be asked to decide whether they wish to be informed of such findings.
- Patients should also be made aware that their results (including any incidental findings) may have an impact on their ability to obtain life insurance and the terms of that insurance. Life insurers may request that individuals provide all their genetic test results for the purposes of their application. Therefore, the fact that the results of genomic testing may jeopardise a patient's eligibility for life insurance needs to be clearly explained as part of the informed consent process.
- Because consent is voluntary, a patient may also withdraw or limit their consent at any time. The systems developed should enable a patient to do so with the result that limitations should be applied to any identifiable patient information.
- Blanket or 'bundled' consent for patient information to be used for multiple purposes may undermine the voluntariness of the consent and also the specificity which is required. Health Legal recommend that the systems developed include the option of providing time-limited consent or alternatively patients may opt-out at any time or at least be reminded that they may do so.

- Obtaining consent via an opt-out mechanism is unlikely to comply with the clinical requirements and also, the voluntary nature of consent which is required by the APP Guidelines. Further, the Consultation Draft for the public consultation on Section 3 (Chapters 3.1 & 3.5), Glossary and Revisions to Section 5 National Statement on Ethical Conduct in Human Research, 2007 most recent updated to the National Statement on Ethical Conduct in Human Research states that an 'opt-out approach should not be used in genomic research'. However, an opt-out model of consent may be appropriate where consent relates to the collection and exchange of de-identified information. For example, for research purposes.

References

Doodeward v Spence (1908) 6 CLR 406

D'Arcy v Myriad Geneics Inc [2015] HCA 35

Privacy Act 1988

Australian Privacy Principles (APPs) are contained in Schedule 1 of the Privacy Act 1988 (Australian Government Office of the Australian Information Commissioner Privacy fact sheet 17: Australian Privacy Principles)

Health Records Act 2001 (Vic)

Use and disclosure of genetic information to a patient's genetic relatives under Section 95AA of the Privacy Act 1988 (Cth) – Guidelines for health practitioners in the private sector. 2014 National Health and Medical Research Council

Public Consultation on Section 3 (Chapters 3.1 & 3.5), Glossary and Revisions to Section 5 National Statement on Ethical Conduct in Human Research, 2007

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Full Report: Health Legal

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Appendix A. Privacy Laws that apply in each State and Territory

State or Territory	Privacy law which applies to private sector entities		Privacy law which applies to public sector health services
New South Wales	*Privacy Act 1988* (Cth)	*Health Records and Information Privacy Act 2002 and HPPs*	*Health Records and Information Privacy Act 2002 and HPPs*
Queensland			*Information Privacy Act 2009 and NPPs; Hospital and Health Boards Act 2011; and Public Health Act 2005*
South Australia			*Health Care Act 2008* and *Information Privacy Principles Instruction*, Cabinet Administrative Instruction 1/89, Premier and Cabinet Circular 12.
Tasmania			*Personal Information Protection Act 2004 and PIPPs*
Victoria		*Health Records Act 2001 and HPPs*	*Health Services Act 1988; and Health Records Act 2001 and HPPs*
Western Australia			*Health Services Act 2016;* Information Management Policy Framework (PF2016_01); Guidelines for the Release of Data; and Information Use and Disclosure Policy – MP 0015/16