... making sense of your genes

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Guidance

Title	**Protection of Human Genetic Information held in the Clinical Setting**
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The information provided below is current at date of publication.

The HGSA draws attention to existing legislation, policies and guidelines on privacy and protection of personal/health information in Australia and New Zealand that are likely to impact on privacy requirements for genetic information. As at date of this publication, current legal and policy requirements include, but are not limited to, items in the table below. This guidance is aimed at health professionals handling genetic information in any form (eg paper or electronic) such as medical records, personal history, family history or test results should make themselves aware of the up-to-date local regulatory context in which they function. The scope of this guidance applies to genetic information that is clinically generated or reported, such as results of tests accredited by the National Association of Testing Authorities (NATA), Australia, and genetic information held by clinical genetic services, but excludes genetic test results generated from research.

The shared nature of genetic information

By virtue of inheritance, genetic information is often not unique to an individual. The shared nature of genetic information raises specific privacy issues. Consequently, the protection of information arising from testing procedures and practices on germline (inherited) material requires special consideration.

Information collected in a genetics consultation often includes an extensive family tree with information about the health status of the client/patient’s relatives without their knowledge or permission. Further, the nature of genetic inheritance means that a diagnosis in one member of a family raises implications or health risks for other family members. Genetic information includes family history as well as genetic testing results.

For the purposes of this document, genetic testing is defined as tests which reveal mutations or variants in a person's germline irrespective of the technology used to detect them.

Types of genetic information

Genetic testing can reveal the following information about an individual

their carrier status, where the implications are usually for reproduction options

- The cause of a condition in a person who is already symptomatic or for whom treatment is required,
- The likely response of a person to specific medications or treatments
- The presence of a specific mutated gene which means the person is almost certain to develop the condition during their lifetime (if they live long enough), and
- The presence of a mutated gene or combination of variants which increases risk increased risk but may never develop the condition unless other factors are present.

Privacy implications in genetic testing

The HGSA recognises that genetic testing of genetic material raises complex issues for the individual being tested, particularly in relation to information relating to the risk of developing a condition in the future. Additionally, the presence of a mutation may indicate risk for that condition in other family members. Members of the HGSA hold a special position as providers of clinical genetics, counselling and testing services, and wish to make the following points in relation to genetic testing.

Genetic testing should be:

- offered in the context of genetic counselling
- based on provision of full and relevant information about the test and its implications
- based on provision of full and relevant information about what personal information is held, how the person can access their information and purposes for which it may be used or disclosed
- based on informed choice in relation to the above, without coercion/compulsion, and
- performed for the benefit of the person tested

Use and disclosure of personal genetic information

Genetics professionals should explain to clients/patients how their information is used or disclosed. Information can be disclosed to health professionals for reasonably expected purposes that are directly related to treatment or care such as diagnostic test results or carrier testing in the reproductive context. Although the client/patient should be told this will occur, their consent to disclosure for this purpose can usually be implied.

The presence of mutations predicting future disease or reproductive risks is considered to be particularly sensitive information. Divulging of this information in identified form to third parties will require the patient's permission in most instances.

Sharing of de-identified information is desirable when it benefits other family members or the accurate annotation and interpretation of test results (e.g contribution to national or international databases for this purpose). TheOffice of the Australian Information Commissioner states: *De-identification of personal information can enable information to be shared or published without jeopardising personal privacy. This enables organisations to maximise the utility and value of information assets while safeguarding privacy and confidentiality.* The APPs [Australian Privacy Principles] do not apply to de-identified information or statistical data sets, which would not allow individuals to be identified. : In New Zealand, the Health Information Privacy Code does not apply to anonymous or aggregated statistical information where individuals cannot be identified.

In cases where the Privacy Act 1988 (Cth) and thus the Australian Privacy Principles (APPs) do not apply—e.g. State departments, bodies and agencies— it is necessary to determine the extent to which the desired level of disclosure complies with the relevant legislation or administrative guideline they operate under. Generally speaking, these schemes make use of similar definitions of personal information and have similar allowances for secondary use of data if directly related to the primary purpose or related to the quality of the health service received by the consumer.”] In New Zealand, the Health Information Privacy Code (HIPC) applies to all agencies (public or private) providing personal or public health or disability services from the largest hospitals through to sole health practitioners. The HIPC also applies to some agencies that do not provide health services to individuals but that are part of the health sector, such as the Accident Compensation Corporation (ACC), Ministry of Health, Health Research Council of NZ, health insurers and professional disciplinary bodies.

Third party access – family members

Where a health care provider anticipates a situation where information will be obtained from a client/patient which may be of interest or potential benefit to other family members, he or she should discuss this with the client/patient prior to treatment being commenced or as part of protocols for ordering tests. Through counselling, individuals should be encouraged to engage with their responsibilities towards genetic relatives with regard to their information needs and rights.

Amendments to the Commonwealth Privacy Act 1998 (2006)[1] provided for guidelines to be developed by the National Health and Medical Research Council and approved by the Privacy Commissioner, *to allow the use and disclosure of genetic information to lessen or prevent a serious threat to the life, health or safety (whether or not the threat is imminent) of an individual who is a genetic relative of the individual to whom the genetic information relates*. See particularly Section 95AA and Schedule 3, Australian Privacy Principle 6.2(d). These guidelines have been developed and amended to be consistent with 2013 amendments to the Privacy Act. They provide detailed information and guidance as to when genetic information might permissibly be disclosed. However the guidelines have the same scope as the Commonwealth Privacy Act and to this end do not apply to state-based health providers. They do apply to private sector health workers.

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[1] Commonwealth Privacy Act 1998 (December 2006) http://www.comlaw.gov.au/Details/C2015C00089

The HGSA notes that as yet few Australian states or territories have enacted mirroring regulation and that there have been called for a nationally consistent approach.[2] Health professionals handling genetic information in any form (eg paper or electronic) such as medical records, personal history, family history or test results should make themselves aware of the current local regulatory context in which they function.

The Commonwealth Privacy Act, also provides helpful interpretive definitions in Part II, Interpretation, ie:

- ***genetic relative of an individual*** *(the first individual) means another individual who is related to the first individual by blood, including but not limited to a sibling, a parent or a descendant of the first individual*
- ***health information*** *means: (d) 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*
- ***sensitive information*** *means: (c) genetic information about an individual that is not otherwise health information.*

In New Zealand, the Privacy Commissioner consulted but did not proceed with a proposed amendment similar to that passed in Australia. The Commissioner was of the opinion that disclosure to at-risk relatives can be made under the existing Rule 11(1)(c) of the Health Information Privacy Code which allows health information to be disclosed if disclosure is one of the purposes for which the information was collected in the first place. Hence, health professionals will have to be prepared to discuss with the patient, prior to testing, the possibility that disclosure of the patient's genetic information could potentially be made directly to at-risk relatives. In practice, it would be appropriate to raise issues about disclosure to at-risk relatives during pre-test counselling or when seeking informed consent from the patient.

Third party access – insurers, employers or law enforcement authorities

If access to genetic test results is requested by third parties, such as insurers, employers or law enforcement authorities, client/patient consent must be sought prior to disclosure. Except if required by law or a court order, there is no obligation on a health professional to disclose information to such a third party. In Australia there is a non-binding Genetic Testing Policy, put in place by the Financial Services Council (2003, 2005).

Genetics records

Genetic health records hold detailed family tree information of potential value to other family members, particularly following generations. For this reason the HGSA recommends that genetic health records relating to a family should be stored securely, indefinitely and preferably separately from other health records.

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[2] Otlowski MFA (2015) "Disclosing genetic information to at-risk relatives: new Australian privacy principles, but uniformity still elusive" *MJA* 202(6): 335-337.

Health Privacy Regulation in Australia and New Zealand.

The following table has been adapted from the Australian Law Reform Commission (ALRC) Review of Privacy[3] with additional information on state policies.

Jurisdiction	**Laws and policy affecting public sector agencies**	**Laws affecting private sector agencies**
Commonwealth	• *Privacy Act 1988* (Cth)	• *Privacy Act 1988* (Cth) • Guidelines approved under Section 95AA of the Privacy Act 1988 (Cth), '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' (Issued by NHMRC, 27 October 2009)
New South Wales	• *Health Records and Information Privacy Act 2002* • *Privacy and Personal Information Protection Act 1998* • *NSW Health Privacy Manual Version 2, June 2005* • *http://www.health.nsw.gov.au/policies/manuals/Pages/privacy-manual-for-health-information.aspx* • *Ethical Code Governing the Provision of Genetics Services* http://www.health.nsw.gov.au/pubs/1998/pdf/gen_code.pd • NSW Genetic Health Guidelines: *Use and Disclosure of genetic information to a patient's genetic relatives: Guidelines for Organisations in NSW.* http://www.ipc.nsw.gov.au/nsw-genetic-health-guidelines	• *Health Records and Information Privacy Act 2002* (NSW) • *Privacy Act 1988* (Cth)
Victoria	• *Health Records Act 2001* • *Information Privacy Act 2000* http://www.health.vic.gov.au/privacy.htm	• *Health Records Act 2001* (Vic), *Privacy Act 1988* (Cth)
Queensland	• Queensland Health Privacy Site http://www.health.qld.gov.au/privacy/	• *Privacy Act 1988* (Cth)
Western Australia	• *Code of Ethical Practice for the Provision of Genetic Services in Western Australia* http://www.genomics.health.wa.gov.au/publications/docs/Code_of_Ethical_Practice.pdf	• *Privacy Act 1988* (Cth)
South Australia	• *Code of Fair Information Practice* http://www.sahealth.sa.gov.au/wps/wcm/connect/d001ee004cc5dfa1ad1bbda496684d9f/CodeOfFairInformationPractice-PIGR-1206.pdf?MOD=AJPERES&CACHEID=d001ee004cc5dfa1ad1bbda496684d9f&CACHE=NONE • *Health Care Act,* s93(3)(c) & (e)	• *Privacy Act 1988* (Cth)
Tasmania	• *Personal Information Protection Act 2004* (Tas),	• *Privacy Act 1988* (Cth)

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[3] http://www.austlii.edu.au//cgi-bin/disp.pl/au/other/alrc/publications/issues/31-32_Overview/1.html?query=31%20&%2032%20overview

	Schedule 1, Clause 2(d)	
ACT	• *Health Records (Privacy and Access) Act 1997* (ACT), *Privacy Act 1988* (Cth)	• *Health Records (Privacy and Access) Act 1997* (ACT) • *Privacy Act 1988* (Cth)
Northern Territory	• *Information Act 2002* (NT)	• *Privacy Act 1988* (Cth)
New Zealand	• *Privacy Act 1993* • *Health Information Privacy Code 1994 (and subsequent revisions)* • *Office of the Privacy Commissioner New Zealand* https://opcwebsite.cwp.govt.nz/ • *Health and Disability Commissioner Act 1994* • *Code of Health and Disability Services Consumers' Rights 1996 (and subsequent revisions)* • *Office of the Health and Disability Commissioner* http://www.hdc.org.nz • *Retention of Health (Retention of Health Information) Regulations 1996 (SR 1996/343)* http://legislation.govt.nz/regulation/public/1996/0343/latest/whole.html	*(similar to the left column, where relevant and applicable to private sector agencies)*
Other Information	• ALRC 96 Essentially Yours: The Protection of Human Genetic Information in Australia http://www.alrc.gov.au/publications/report-96	