Legal privacy protections of shared genomic data in international research collaborations – 'transplants' or 'irritants'?

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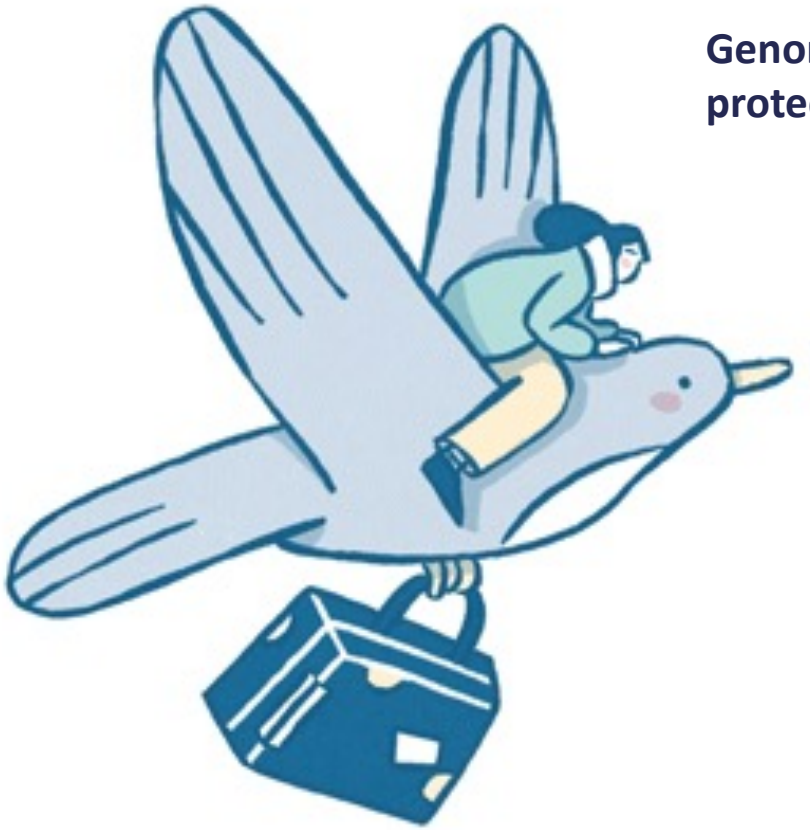
Background

- Increased genomic data-sharing for research, including in international collaborations.
- Public benefit, advances medical knowledge, precision medicine
- Privacy risks in increased sharing of genomic data.

➢ Heightened privacy risks where genomic data are shared across borders



Genomic data + privacy protections…

Legal transplants and legal irritants

Legal transplants (Alan Watson)

The importation of laws from one country to another is described as a 'legal transplant', which when successful means that the transplanted law becomes part of the recipient legal system and continues to grow and develop within that system.

Alan Watson, *Legal Transplants: An Approach to Comparative Law* (Athens: University of Georgia Press, 2nd edition, 1993), Alan Watson, 'The Birth of Legal Transplants' (2013) 41(3) *Georgia Journal of International and Comparative Law* 605, 607.

Legal irritants (Gunther Teubner)

Laws are imbued with legal meaning and function specific to the transferring jurisdiction, and also linked to legal, cultural and social processes which may be at variance with those of the receiving jurisdiction, causing 'irritation'.

While a transported rule may look the same, it has actually been altered in the process of interacting with the legal framework and social institutions in the new environment, and may have unintended consequences.

(Gunther Teubner, 'Legal Irritants: Good Faith in British Law or How Unifying Law Ends Up in New Divergences' (1998) 61(1) *Modern Law Review* 11)

Australian and Israeli privacy legislation applying to genomic data

Australia

Privacy Act 1988 (Cth) (Privacy Act)

Australian Privacy Principles (APPs) (Privacy Act, Sch 2)

Israel

Protection of Privacy Law 5741 – 1981 (Israel) (PPL)

Privacy Protection (Transfer of Databases Abroad) Regulations, 5761-2001 (Israel) (Transfer of Data Abroad Regulations)

Patient's Rights Law 5756 – 1996 (Israel) (PRL)

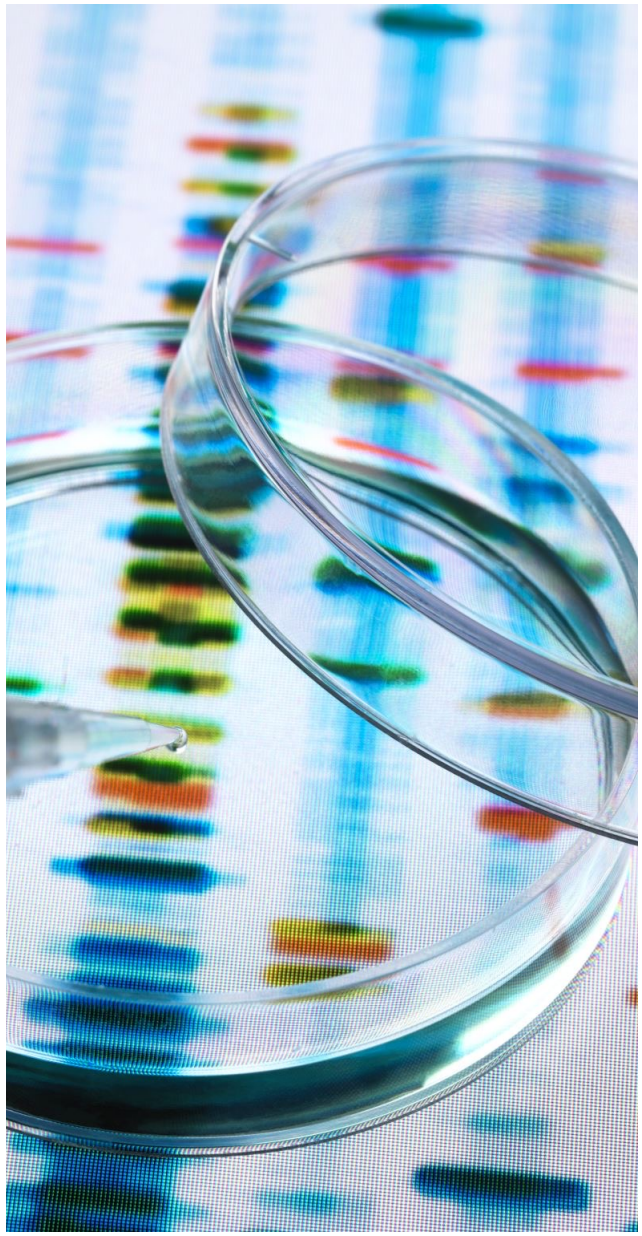
Draft Patient Rights Regulations (Use of Health Data for Research) 2019 (Israel) (Draft Regulations)

Genetic Information Law, 5761 – 2000 (Israel) (GIL)

- The right to privacy has the equivalent of constitutional status under the *Basic Law: Human Dignity and Liberty 5752 – 1992* (Israel) § 7.

Comparative analysis of privacy protection provisions -

– ***Differences in the legal bases for collecting and processing genomic data.***



Comparison of legal bases for collecting and processing genomic data

Consent is relied upon as legal basis in both Australian and Israeli law, but not exclusively**.**

- Reliance on consent as a basis for sharing genomic data in cross-border ‘big data’ research collaborations was identified as one of the key privacy challenges, and potential areas of risks.

Comparison of legal bases for collecting and processing genomic data

Other relevant legal bases for collecting and processing genomic data based on the public benefit or **public interest** in genomic research.

- e.g. Privacy Act s 16B (2)(3) - ‘permitted health situations’ applying to research

	Australia	Israel
Legal basis for collecting, using and disclosing genomic data for research	Genomic data that is personal information may be collected, used or disclosed for research purposes ▪ with consent, or ▪ without consent, where a s16B(2),(3) 'permitted health situation' applying to research exists. (Privacy Act s 16B(2), APPs 3.4(c), 6.2(d)) The 'permitted health situation' applies to collection is necessary for research or compilation of statistics relevant to public health and safety, Use or disclosure must be in accordance with the NHMRC Section 95A Guidelines The public interest in the research must outweigh requirements for data subject consent (Privacy Act s 95A, NHMRC, Section 95A Guidelines)	Israeli statute relies almost exclusively on data subject consent for collection and processing of genomic data for research (that is not de-identified) (PPL §§ 1, 3; PRL § 20; GIL § 23; Draft Regulations reg 2(E)(F)). Each new use requires fresh consent. The PPL provides a defence for privacy infringement in PPL § 18, where the infringement was justified by a matter of public interest in the circumstances ➢ Note that this is brought as a statutory defence in criminal or civil proceedings for infringement of privacy, and not as a *prima facie* permission. The Draft Regulations regs 2(5)(6) require that secondary use of health data for research is permitted only with de-identified data, unless with prior informed consent of the data subject.
Requirements of consent	Privacy Act s 6 - consent means express consent or implied consent. • Guidance adds that consent should be informed, voluntary, current and specific, APP Guidelines 10, [B.35]. However, this is not stated in the Act. • The government has agreed-in-principle to the proposal following the Privacy Act Review, to amend the definition to state that consent must be 'voluntary, informed, current, specific and unambiguous'. This is subject to further consultation.	PPL § 3 consent is 'informed, express or implied consent' (similar definition in PRL) The GIL requires that consent for collection of genomic data for research must be express and in writing. (GIL §§ 11(b) and 23.)

Differences in legal bases and privacy risks

The same conduct with the same data may be permitted in one jurisdiction but an interference with privacy in the other.

If an Australian recipient were to use shared genomic data collected for a particular research project in Israel, for any purpose other than the specific research purposes for which it was collected and consented to, this could be compliant with Australian law (if it was permitted health situation, or another APP 6.2 exception applied), however it would constitute interference with the privacy of the Israeli data subject who contributed the data

The use of the genomic data in ways to which the Israeli data subject and has not provided consent is an alteration, diminution or loss of privacy protection for the Israeli data subject.

- The data subject would also have lost their right to object (request to exit) provided under Israeli law.

Differences in legal bases and privacy risks

The same conduct with the same data may be permitted in one jurisdiction but an interference with privacy in the other.

If an Israeli organisation using or processing genomic data collected in Australia for research, in accordance with Israeli privacy laws, resulting in more restricted use of the data for research. *Is this a privacy risk for the Australian data subject? No APPs have been breached.*

This study considers an alteration to the privacy protection (or entitlement) as originally provided – a privacy risk.

Restricting the use of the data for medical research, which was permitted under Australian law, alters the domestically afforded privacy protection, which is shaped to protect both the individual and public interest in privacy, the interests of the entities involved, and the flow of information for purposes of medical research.

Statutory regulation of international sharing of genomic data

Legislative provisions

- ***In Australia - APP 8 - cross-border disclosure of personal information***
- ***In Israel – the Transfer of Data Abroad Regulations -made under the PPL***

Statutory regulation of international sharing of genomic data

Similarity of laws

Australia

- APP 8.2(a) allows disclosure on the 'reasonable belief' that Israeli privacy laws are of a standard that is 'overall', 'at least substantially similar' to that of the APPs.
- APP 8.2(a) – individuals must have access to enforcement mechanisms in the recipient jurisdiction.

Israel

- Transfer of Data Abroad Regulations (reg 1)
  - the recipient country must provide the same level of protection as provided under Israeli law – *mutatis mutandis* AND
  - must incorporate certain principles

- Note that the right of the Israeli data subject to bring direct action in court would be difficult to enforce under the Australian law, where different avenues of recourse are available.

Statutory regulation of international sharing of genomic data

Obligations of sharing entities

Obligations of sharing entities

Australia

- APP 8.1 – entity must take 'reasonable steps' to ensure the recipient does not breach the APPs.
- The APP entity is liable for any breach by the recipient (s 16C)

Israel

- Transfer of Data Abroad Regulations (regs 2(4), (3))
  - Under all circumstances, written agreements or undertakings are required. (also generally in PRL, GIL and regulations).
  - An opinion of the Privacy Protection Authority sets out mandatory written undertakings.
- Draft Regulations require signed undertakings of all researchers (reg 4), an external researcher must enter into a data sharing agreement with the health organisation sharing the data. Required terms are set out in App D.

Transporting the legal privacy protections attached to genomic data via contractual agreement

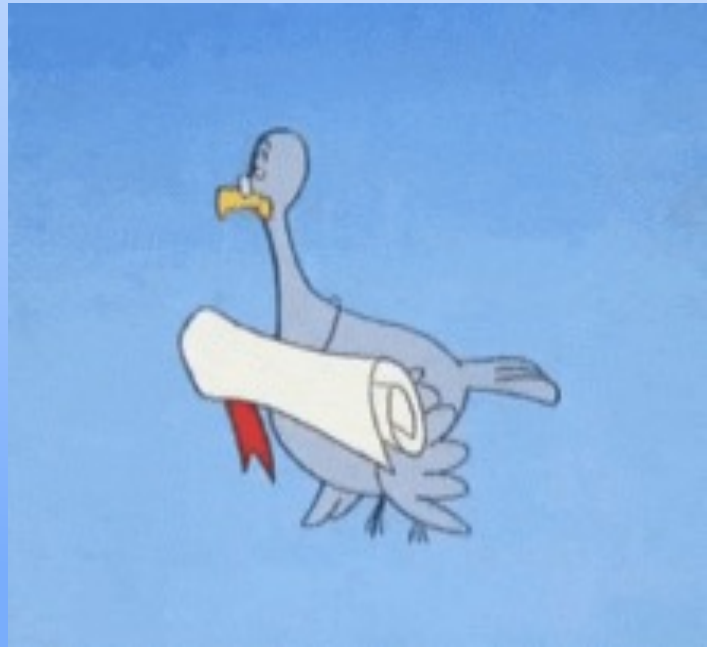
Legal transplants and legal irritants through contract

…'smuggling regulatory laws across borders' results in 'mutation, withering, or, albeit rarely, unscathed survival'.

- (Li-Wen Lin, 'Legal Transplants through Private Contracting: Codes of Vendor Conduct in Global Supply Chains as an Example' (2009) 57(3) *The American Journal of Comparative Law* 711, 713.)

Potential sources of irritation:

- interpretation and application requires reference to the privacy protection regime of the sharing country
- different import/meanings of terms
- ability to audit, monitor, ensure compliance with terms importing the laws
- how this assists the data donor in enforcing privacy entitlements



Transporting privacy protections through contract – 'private legal transplants'

- ***… include requirements for auditing systems which do not rely on regulatory authorities*** (Heike Schweitzer, 'Private Legal Transplants in Negotiated Deals' (2007) 4(1) *European Company and Financial Law Review* 79)

- ***… carefully study the similarities and differences between the borrowing country's law and the law of the borrower country. Such a study may dictate … a level of guidance needed to be incorporated into the newly enacted law to guide legal practitioners and judges to proper interpretation of the new concept.*** (Silvia Ferreri and Larry A DiMatteo, 'Terminology Matters: Dangers of Superficial Transplantation' (2019) 37 *Boston University International Law Journal* 35, 86-87.)

- ***'Guidance' may be incorporated as a 'contractual device'*** (Akio Hoshi, 'Interpretation of Corporate Acquisition Contracts in Japan: A Legal Transplant through Contract Drafting' (2021) 16(1) Asian Journal of Comparative Law 106, 110, 119.)

➢ ***Following on consideration of 'similarities and differences', guidance can be used as a contractual device to aid in interpretation of terms importing privacy protections, and assist in preserving them as provided in the originating jurisdiction.***

Steps may be taken through contract to address privacy risks and 'legal irritation' when genomic data are shared between two non-harmonised jurisdictions, such as Australia and Israel:

- understand the laws of the sharing countries and the differences between them which give rise to privacy risks caused by 'legal irritation';
- use this understanding to inform drafting of terms and definitions to best align with those of the originating jurisdiction;
- include provisions for monitoring compliance with privacy protection rules, which do not depend upon regulatory bodies which may not have authority in the recipient jurisdiction; and
- provide guidance in the form of a 'contractual device' (such as an annexed 'guidance statement') to assist in interpreting the 'transplanted' rules in the way intended in their originating privacy protection framework.

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Understanding the differences in laws between two sharing jurisdictions can inform steps to address privacy risks and enhance protection of individual privacy, while supporting international genomic data-sharing for research.

Thank you

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