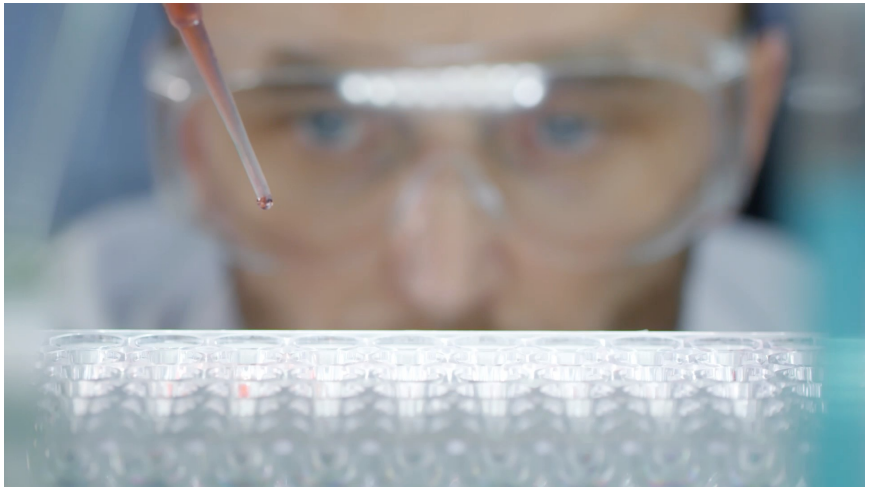
Strengthening the Public Interest Test in Commercial Genomic AI Research: Trustworthiness-Based Disclosure Requirements for Consent Waiver Applicants



LINEAGE Project

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Outline

Problem
Genomic data + AI risks; gaps in consent & public interest test.

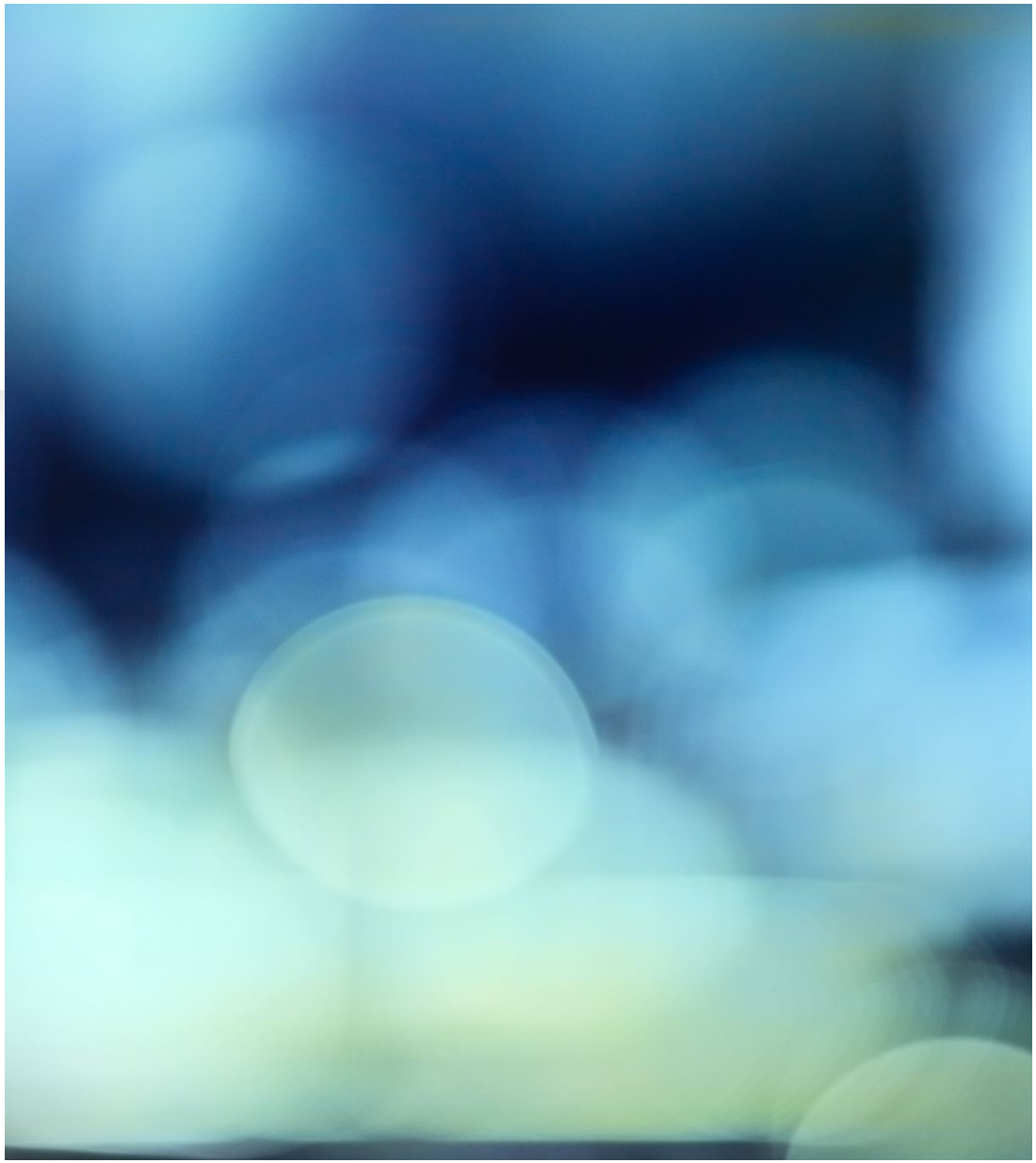
Public Interest Test
Three dimensions: substantive, distributional, relational.

Trustworthiness Framework
Ability • Benevolence • Integrity.

Disclosure Requirements
What commercial AI applicants must show.

Australia (s 95A)
Key gaps and consequences.

Recommendations
A trustworthiness-based public interest test.



PART I – PROBLEM SETUP

Genomic data: high sensitivity, high re-identification risk, group harms

AI introduces new risks: opacity, scale and bias

Rapid growth of commercial AI in medical research

Regulatory Challenge

Consent models strained by:

- secondary uses
- cross-institutional data flows
- algorithmic opacity
- Many jurisdictions (AUS/NZ/SG): consent may be **waived** on **public interest** grounds

Public interest test in Australia (s 95A Privacy Act):

- Requires disclosure
- No guidance for commercial AI-based research
- Leaves room for: inconsistent HREC decisions, strategic framing by applicants and erosion of public trust

Key Question: How should the public interest test be strengthened so that commercial AI-based genomic research warrants consent waivers and maintains public trust?

PART II – PUBLIC INTEREST TEST

What Public Interest Should Mean?

Literature suggests 3 normative dimensions:

1. **Substantive**
   Demonstrable health benefit, proportionate to risk
2. **Distributional**
   Benefits flow to groups warranting special attention.
3. **Relational**
   Affected communities have reason to accept data use.

From Principles to Practice: The Key Question

1. The three public interest dimensions offer a conceptual foundation—but their practical application to commercial AI research remains unclear.

2. Genomic data introduces distinct ethical, social, and legal implications that heighten this challenge.

3. How can clearer disclosure standards better support oversight bodies (e.g., HRECs) in assessing public-interest claims?

PART III – TRUSTWORTHINESS AS A FRAMEWORK

Why Trustworthiness?

- Required when data use exposes people to risk
- Trustworthiness = *ability* + *benevolence* + *integrity*
  (Mayer, Davis & Schoorman)
- A normative minimum for public interest justifications (Taylor)
- Translates public expectations into actionable criteria

Trustworthiness → Disclosure Requirements

- Each pillar maps onto public-interest dimensions:

Trustworthiness Pillar	Public Interest Dimension	What Must Be Disclosed
Ability :Demonstrable Capability	Substantive + Relational	Technical competence, AI explainability, AI risk governance
Benevolence: Acting for Public Benefit	Distributional + Relational	Benefit-sharing, anti-monopoly safeguards, community protection
Integrity: Principles and Consistency	Relational + Substantive	Transparency, traceability, public engagement, alignment between claims and conduct

PART V – APPLICATION TO AUSTRALIA

Australia's Section 95A Framework

Limits:

- No AI explainability requirement
- No requirement for traceability or third-party audit
- No distributional or community-benefit expectations
- No expectation of public engagement
- Focuses on risk minimisation → not residual risk justification

CONCLUSION

- Current consent-waiver framework is not fit-for-purpose for commercial AI research.
- Public interest test must be strengthened through trustworthiness-based disclosure.
- Embedding ability, benevolence, integrity into disclosure requirements:
  ✓ Constrains arbitrary use of “public interest” by commercial actors
  ✓ Allows HRECs to assess AI-based proposals with rigour
  ✓ Supports fair benefit distribution & prevents monopoly lock-in
  ✓ Reinforces public trust in genomic-AI research
  → A more legitimate and accountable consent-waiver system