The LINEAGE consortium and the GUARDIANS ELSI team - Submission to Privacy Reform – Consultation on Exposure Draft legislation

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On behalf of the LINEAGE project consortium and the GUARDIANS ELSI team, thank you for the opportunity to comment on the Privacy Amendment (Personal Data Protection) Bill 2026 – Exposure Draft Bill. Overall, we support the simplification and certainty that the proposed reforms offer, as well as their recognition of emerging technologies**.** Below are our comments, which focus on operational compliance issues as indicated in the Consultation Paper.

1. Definitions

We support the proposed definitional reforms. From the perspective of genomic data and research, we make the following observations.

'genomic information'

We support the amendment of the term 'genetic information' in current s 6FA to 'genetic or genomic information', and the corresponding amendments to the definition of 'sensitive information' in s 6FF.

We note that Sections 16B(4) and 95AA of the current Act, which have been maintained under the reforms, use the terms 'genetic information'. Given that 'genomic information' is now included in the definitions of 'health information' and 'sensitive information', and will trigger the applicable safeguards, we suggest that ss 16B(4) and 95AA should likewise be expanded to apply to 'genetic or genomic information'.

'***disclosure***'

The proposed definition of disclosure provides welcome certainty. However, because disclosure occurs whenever information is made accessible to another entity, APP 8 may apply to some overseas research-sharing arrangements (such as remote access to secure research environments that prevent any extraction or download of personal information) that previously relied on retaining organisational control. The proposed

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reforms will require clarification of whether these requirements of APP 8 be waived in view of the new proposed s 94B.

2. The 'human research' exception

The new broad exception for ethically approved human research in proposed s 94B represents a welcome simplification for the genomic research community. The provision has the potential to reduce complexity and improve consistency between privacy regulation and established research governance frameworks, particularly the *National Statement on Ethical Conduct in Human Research*. However, several aspects of the proposed framework would benefit from further clarification.

Oversight and governance

The operation of s 94B will depend significantly on the content of the human research guidelines, yet to be released.

Under the National Statement, 'human research' encompasses both higher risk projects, requiring full Human Research Ethics Committee (HREC) review and lower risk projects, which can be reviewed via internal institutional committees. Both would fall within the s 94B exception. This raises questions about whether the proposed framework provides sufficient safeguards for all forms of human research. Similar questions arise in relation to research undertaken by commercial entities, which may raise different privacy considerations from research undertaken in public or not-for-profit settings.

Relationship between APPs, consent and s 94B

Although s 94B is presented as an exception to the APP framework, we suggest it may be conceptually clearer to frame the provision as a mechanism for compliance with privacy obligations in the context of research conducted in accordance with the National Statement. In our view, privacy obligations should continue to apply to human research, with s 94B providing an approved pathway for meeting those obligations where research is conducted in the public interest, and in accordance with appropriate ethical guidelines.

We also welcome proposed s 6AAB(2), clarifying that consent relied upon for human research need not be 'current and specific' where the research complies with the National Statement. This provides important recognition of the role of broad consent in genomic and longitudinal research. However, the interaction between s 6AAB(2) and s 94B is unclear. If research meeting the requirements of s 94B is exempt from consent requirements, it is not apparent in what circumstances s 6AAB(2) is intended to operate.

Enforcement and Accountability

The manner of enforcing compliance with the proposed human research framework is unclear. It is not apparent whether failure to comply with the human research guidelines would constitute an interference with privacy under the Act or otherwise give rise to regulatory consequences.

Greater clarity regarding enforcement would facilitate consistent implementation by both researchers and institutions.

Interaction with permitted health situation provisions

We are concerned that the interaction between proposed ss 13(3A), 16B(2A) and 94B is unclear and may create uncertainty for health and genomic research. Where it is impracticable to obtain consent, the collection and handling of health information for research may appear to fall within both the retained permitted health situation exception in s 16B(2) and the new human research exception in s 94B.

Proposed s 16B(2A) would require organisations relying on a permitted health situation to take reasonable steps to de-identify health information before disclosing it for research, with non-compliance constituting an interference with privacy. At the same time, proposed s 94B permits the collection, use and disclosure of health information for human research conducted in accordance with the National Statement on Ethical Conduct in Human Research. The National Statement permits waivers of consent for the use and disclosure of identifiable health and genomic information in limited circumstances (see paragraphs 2.3.9-2.3.10 and 3.3.24).

We suggest it should be clarified that research conducted under proposed s 94B is not subject to the de-identification requirement in s 16B(2A).

3. Transparency

We support the requirement that collection notices be clear, accessible and understandable, and welcome efforts to streamline notification requirements. However, proposed APP 5.1(a) may not provide sufficient information to enable genuine choice, or, in cases where consent is required, to ensure that consent is adequately 'informed' (as required under proposed s 6AAB). We view certain points currently required under APP 5, but excluded in the proposed amendment, to be important for compliance with consent requirements, and to ensure that individuals have genuine choice regarding providing their personal information. For example:

- the consequences of not providing the information;
- the types of entities to which their personal information is routinely disclosed, including overseas recipients; and
- the name and contact details of the collecting entity, necessary to support the exercise of other Privacy Act rights, including requests for access, correction, erasure (where applicable), and complaints.