Response to Discussion paper, Review of Human Tissue Laws 2025

Submission by: Prof Jennifer Byrne

Bio: Jennifer Byrne is Director of Biobanking- NSW Health with NSW Health Pathology, and conjoint Professor of Molecular Oncology at the University of Sydney. She leads the PRIMeR group (Publication and Research Integrity in Medical Research) within the University of Sydney's Faculty of Medicine and Health and is based at the NSW Health Statewide Biobank in Camperdown, Sydney. Prior to her current biobanking role, Jennifer had extensive experience in biobanking, from both the perspective of a researcher who has employed biospecimens for research, and through establishing, overseeing and networking cancer biobanks. She was awarded the 2025-2026 Australasian Biospecimen Network Association's award for achievement in biobanking, and she holds the 2025-2026 Australian Academy of Science's Professor David Vaux Research Integrity Fellowship award.

Please note that I have responded to questions according to my knowledge and experience. The lack of response to questions could indicate that I am unable to provide an informed response, or that I do not have a strong opinion.

Glossary

The definition provided for a **biobank** (page iv) should align with the definition of a **tissue bank** (page iv), in that a biobank is a facility that stores one or more collections of biological materials/ biospecimens with associated data for the purpose of supporting research. Biospecimens are generally only useful in research if they are linked with reliable data. The term "biobank" as defined is singular, in contrast to "tissue banks".

I understand the need to use different terms for research biobanks and collections of tissues that are intended for medical purposes. Nonetheless, "tissue bank" is very frequently used to denote a research biobank. I therefore suggest using the term "**clinical tissue bank**" to avoid potential confusion. "Tissue banks" as defined is plural, in contrast to "biobank".

Question 1

*Do you agree with the objects listed in **Proposal 5** for human tissue legislation?*

Response: I suggest also including "quality improvement" as an additional purpose. Quality improvement activities are essential for the responsible use of human tissue, and yet can sometimes fall outside definitions of medical care, research, etc.

Question 7

Should any of the following materials be excluded from human tissue laws, or excluded from the operation of human tissue laws for particular purposes, circumstances, or provisions of the new human tissue legislation?

- *Cell lines.*

Response: Commercially-available cell lines should be excluded from regulation.

Commercially-available cell lines have been in research use and circulation in Australia without restrictions for periods of up to 50-70 years, without the need for human research ethics approval or other oversight. Further regulation of non-modified commercially-available cell lines seems neither desirable nor practical.

Proposal 33

New human tissue legislation should provide that:

2. *If consent for future research uses is withdrawn, any unused tissue must be discarded.*

Response: The discarding of unused tissue may be culturally unacceptable for some research participants in Australia. Some donors may request the return of tissue to family members such that the tissue can be buried on country, for example in the case of some Aboriginal donors. Any new human tissue regulation should recognize this requirement.

Section 8.7. *Problems with broad and unspecified consent "does not accommodate a change in research participants' preferences, should they choose to alter or withdraw their consent." (page 93)*

Response: From my experience, this statement is factually incorrect in the state of NSW. The type of consent (ie broad/ unspecified versus restricted) is unrelated to the opportunities and capacity for participants to withdraw consent from participating in a research study. All participants giving consent for use of biospecimens and data in research, regardless of whether consent is broad or specific, are provided a participant information sheet that includes instructions as to how to withdraw consent. Opportunities to withdraw from research studies are therefore unrelated to whether the consent model is broad/ unspecified or restricted.

Proposal 36

New human tissue legislation should provide that:

1. *An adult may give valid consent to the removal of tissue from their body after their death for the purpose of research*;

   Response: I suggest that "adult" be defined.

2. *If an adult is close to death and does not have decision-making capacity, or dies without having provided valid consent, the adult's authorised decision-maker may give valid consent to the removal of tissue from the adult's body for the purpose of research.*

   Response: I suggest that the categories of individuals who can serve as "authorised decision-maker" be defined.

4. *If a child is close to death or has died, the child's authorised decision-maker may give valid consent to the removal of tissue from the child's body after death for the purpose of research.*

   Response: I suggest that the categories of individuals who can serve as "child's authorised decision-maker" be defined. For example, does this person need to be an adult?

Proposal 37

New human tissue legislation should provide that:

2. *If consent for future research uses is withdrawn, any unused tissue must be discarded.*

Response: As per my response to Proposal 33, the discarding of unused tissue may be culturally unacceptable for some research participants in Australia.

10.3 *We are considering whether new human tissue legislation should require consent to use human tissue samples for purposes that are different from what the person who provided the sample originally consented to. If a consent requirement is created, we are also considering whether there is a need for an exception to it, to enable researchers to access these samples in some circumstances. Options to consider for an exception may include:*

- *the size of the sample;*

Response: The size of a tissue sample should not represent an exception to any requirement for participant consent. Sample size can be easily manipulated (ie a large sample could be easily divided into several smaller samples, to avoid any requirement for participant consent).

Question 31

Are legal rules needed to regulate the storage, access, transfer, and disposal of human tissue used in research biobanks?

Response: I agree that legal rules needed to regulate the storage, access, transfer, and disposal of human tissue used in research biobanks. That said, the oversight and regulation of biobanks needs to be proportionate to risk. Applying a higher standard of regulation to biobanking versus that applied to research involving human tissues could have unintended consequences. For example, this could incentivize the concealment of biobanks within research studies or clinical trials. Once tissue has been supplied by a biobank to a research team, the tissue is then stored, transferred and potentially disposed of by the research team. Regulation needs to consider where the responsibilities of biobanks begin and end.

Question 32

Would it be beneficial to have national regulation, guidance and oversight for:

a. *research biobanks that store and/or distribute human tissue or human bodies;*

Response: National regulation, guidance and oversight would benefit research biobanks by providing greater recognition of the importance of biobanking, and supporting the standardization and harmonization of biobanking practices and activities across the country. In the absence of national regulation, numerous local or state-based biobanking resources have been developed, such as the education-focussed NSW Biobank Certification programme (https://nsw.biobanking.org/) and the associated NSW biobank locator (https://nsw.biobanking.org/locator) that have been operating since 2016, and are currently supported by the NSW Health Statewide Biobank. National regulation could allow national scaling of these and other state-based initiatives.

Question 33

If you think it would be beneficial to have national regulation of research biobanks or educational collections of human tissue:

a. *what aspects of tissue collection, storage, use, transfer or disposal need to be regulated?*

Response: National regulation of research biobanks should include every stage of biospecimen and data collection, from collection to disposal. National regulation should however recognize that not all biobanks undertake all of the activities above.

b. *what types of collections should be regulated?*

Response: Biobanks that provide human biospecimens and data for research should be regulated, with the exception below.

c. *are there types of collections that should not be regulated?*

Response: Facilities that only provide commercially-available cell lines for research should not be regulated as biobanks.

Question 34

Should new human tissue legislation provide that individuals have a right to access their stored tissue? If so, what should 'access' entail in this context and who should be granted the right?

Response: This is a complex issue. In my opinion, research participants should not be able to withdraw tissue samples for private storage or use, which could result in the storage of research samples in private homes. An exception should be made to individuals wishing to dispose of their unused tissue samples according to cultural practices. Many research participants will lack the training or infrastructure required to safely and appropriately store tissue samples. For example, most research participants will not have access to liquid nitrogen or -80C freezers which are used to store many human samples in biobanks. The withdrawal and then inappropriate storage of tissue samples could lead to research samples being wasted, which would be unethical. Research participants could potentially request that their sample be withdrawn from a biobank such that it could be sent for research or testing at another facility, which might be required for their participation in a clinical trial. In these cases, the biobank would facilitate any approved sample and data transfer, as opposed to the research participant.

Proposal 44

The National Regulator (or alternative) should be authorised to provide guidance about what expenses, costs, loss or damage can be reimbursed or recovered by persons that retrieve, process, use, and/or distribute human tissue.

Response: National guidance would assist biobanks to cover a proportion of their costs, which is important for biobank sustainability.