NSW Health Pathology

Submission to ALRC re Issues Paper 51 : Review of Human Tissue Laws

NSW Health Pathology (**NSWHP**) welcomes the opportunity to provide the following submission in relation to the Issues Paper. The submission reflects observations by NSWHP primarily relating to the NSW human tissue framework and access to residual diagnostic tissue.

1. Residual tissue held by pathology laboratories

The Issues Paper and human tissue legislation focusses on organ donation/transplantation and anatomical/post mortem examinations. NSWHP considers it may be helpful for there to be additional focus on residual diagnostic tissue, noting this type of tissue is frequently requested for ethically-approved research studies.

Subject to retention requirements, residual diagnostic tissue is retained by pathology laboratories following pathological assessment – it ranges from small biopsies to removed whole organs (e.g. thyroid, uterus, lung). Typically, residual diagnostic tissue includes:

- small samples in formalin fixed paraffin embedded (FFPE) tissue blocks, cores and slides;
- larger samples that are formalin fixed but not in tissue blocks;
- (occasional) fresh unfixed tissue; and
- blood, saliva and excreted tissues such as urine and stool samples.

These types of tissue are routinely sought for research purposes. NSWHP submits it may be helpful for the definition of tissue[1] to more expressly reference the types of residual human tissue held by pathology laboratories.

2. Exemption for consent under s34(1)(b1) HTA for small samples of tissue

S34 of the Human Tissue Act (NSW) (NSW HTA) enables small samples of tissue held in the form of blocks and slides to be used for research, without consent. It seems other Australian jurisdictions may not necessarily distinguish the tissue types permitted to be used for research under a consent waiver. It would be helpful for human tissue laws to more closely align in this regard.

Slides and blocks represent some of the most valuable forms of tissue available for therapeutic, medical or scientific purposes having been intentionally preserved for diagnosis and analysis; and they are vital resources for research. It seems incongruous that the NSW HTA requires patient consent for research use of other forms of residual or surplus diagnostic tissue which may have no future diagnostic value and are often regarded as clinical waste, such as residual saliva, urine or stool samples.

Due to risk of potential non-compliance with the NSW HTA, NSWHP is occasionally placed in the difficult position of not being able to accept a research request for tissue that is not in the form of a block or slide where such use has been approved by a human research ethics committee under a consent waiver model, It would therefore be preferable for there to be a consistent approach to consent waivers, i.e if s 34(1)(b1) could be amended to include other types of small tissue samples, such as blood and blood products, saliva, urine, and stool.

[1] discussed in paragraph 49 of the Issue Paper

3. Exemption for consent under s34(1)(b3) HTA for Quality Assurance (QA), Quality Improvement (QI) or Quality Control (QC)

S34(1)(b3) of the NSW HTA permits use of small samples of tissue without consent for the purposes of analyses or tests that are part of a program to ensure or improve the quality of services carried out by a hospital, forensic institution, or laboratory including a quality assurance program, quality control program, audit or evaluation or as necessary for delivery of services or accreditation for named entities. Unlike the research exemption under 34(1)(b), this is not limited to tissue in the form of blocks and slides.

There are significant benefits in this exemption, and it is critical to the clinically-safe functioning of pathology laboratories to use tissue for legitimate QA, QI and/or QC purposes.

However, given the exemption from consent requirements for research use being limited to blocks and slides, this could risk misapplication of the QA/QC/QI exemption, noting NSWHP has seen projects where there is a blurred line between research and QA/QC/QI. Broadening s34(1)((b1) beyond blocks and slides, would enable a more consistent approach to use of residual tissue under ethically approved consent waivers, whether for research or QA/QC/QI.

Technological advances in genomics in the QA context.

The advances in genomic testing mean that data generated from extracted DNA in a de-identifed sample is potentially re-identifiable, particularly for rare DNA changes. It may be helpful for consideration to be given to the intersection between human tissue and privacy laws, noting that biological specimens are currently captured within the definition of tissue in the NSW HTA as well as the definition of personal information in the NSW privacy legislation. This overlap creates the potential for inconsistent or conflicting regulatory requirements.

4. Distinction between legal and ethical approvals.

It would be helpful for the Inquiry to look at how the various HTAs align with not only each other but also the interaction with the *National Statement on Ethical Conduct in Human Research (2023)*.