Submission on sections of Discussion Paper 90: Review of Human Tissue Laws

Definition of human 'tissue'

I agree with Proposals 7, 8 and 9 in relation to the definition of human 'tissue'.

Question 5

How do you think 'tissue' (or an alternative label) should be defined in order to be suitably broad?

The example of section 54 of the Human Tissue Act 2004 (UK) is useful starting point for the 'it's in unless it's out' operational model.

Question 6

In new human tissue legislation, should the word 'tissue' be replaced with another label?

The suggestion of replacing 'tissue' with 'cell, organ, and tissue' would improve clarity for readers bringing a specific frame of reference to the Human Tissue Act (HTA).

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?

Human milk should be excluded from human tissue laws because issues related to uses of human milk are different from other materials covered by the HTA. Individuals considering uses of human milk may not understand that the HTA applies, putting them at risk of non-compliance.

Foetal tissue should be included in human tissue laws, with consent provisions consistent with other authorised decision-maker specifications.

Faecal material should be included because it may contain human cells and DNA could be extracted from it even though faecal material itself may not be considered as derived from the human body. Exclusion of faecal material in consideration of donation of tissue for transplantation may be appropriate since the issues relating to faecal transplantation are clearly different from organ transplantation.

Gametes from deceased donors would be more appropriately dealt with in alternative legislation.

Human cell lines should be included because they are derived from human tissues. However, the NZ Human Tissue Act 2008 example of applying only certain parts of the legislation to cell lines should be applied to avoid unworkable restrictions on the use of human cell lines for research and therapy. The proposed National Regulator would be an appropriate mechanism to manage these technically specific and evolving issues.

Use of tissue removed during a post-mortem examination & Consent and authorisation for use of tissue samples

Question 27 and 29

Should new human tissue legislation contain an exception to the need for consent so that 'small samples' can be used for scientific, medical, or educational purposes? If so, what samples should fall within the exception?

Should there be a legal requirement to obtain consent from people who provide tissue samples before using their tissue for research or other purposes that they did not consent to?

Provision in the NSW Human Tissue Act 1983 allowing use of small tissue samples that have been lawfully removed, for therapeutic, scientific, or medical purposes works well and has been very important for medical research. The safeguard of Human Research Ethics Committee approval for research use of tissue samples in accordance with specifications of the National Statement on the Ethical Conduct in Human Research, ensures that proposed use of this material and a waiver of the requirement for specific consent is consistent with community expectations and gives appropriate priority to the interests of tissue donors.

Consent and authorisation for tissue removal for research – living persons & Consent and authorisation to remove tissue for research after death

In relation to **Proposals 33** and **37**,

Tissue may be held in research biobanks for years or even decades after it is donated. It may not be practicable for biobanks to make an undertaking to tissue donors (or their authorised decision-maker), that questions about samples or their research uses can be answered in perpetuity. For example, a biobank may be archived if resources or key personnel are no longer available. Realistically, a timeline needs to be set for this undertaking. If a biobank is no longer resourced to respond to donor enquiries questions, all samples may need to be disposed of or de-identified under these proposals.

Consent and authorisation for use of tissue samples

Question 30 If a legal requirement for consent is imposed (Question 29), should there be exceptions to it? If so, what exceptions should exist?

In relation to research use of tissues, an exception should be if a Human Research Ethics Committee approves a waiver of the requirement for consent.

Regulating stored tissue collections

Question 31 - 33 Are legal rules needed to regulate the storage, access, transfer, and disposal of human tissue used in research biobanks?

Resource implications are a concern in relation to increased regulation requirements for research biobanks. Research biobanks generally operate in academic or healthcare

settings. Notwithstanding their proven value to health research, they are expensive to set-up and maintain. There are few long-term sources of funding for biobanks and cost-recovery mechanisms do not come close to meeting running costs. Additional compliance and licensing costs would be difficult for research biobanks to meet with current funding arrangements.

Accessing stored tissue

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?

Individuals should have the right to access their stored tissue. In this context, the concept of 'ownership' of tissue often arises. It may be appropriate for this to be explicitly considered by this review.