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Professor Arun Sharma
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4 January 2019

The Hon. Mr Aaron Harper, MP
Chair, HCDSDFVPC
Parliament House
George Street
Brisbane QLD 4000
Email: health@parliament.qld.gov.au

Dear Mr Harper

I write regarding the proposed amendment to the current *Transplantation and Anatomy Act 1979* (Qld) (the Act) under the Health and Other Legislation Amendment Bill 2018 (the Bill).

The proposed amendment to the Act, as detailed under the Bill is welcomed by the research community and does in part remove some degree of ambiguity, particularly for research involving children. However, the University recognises that this amendment presents a valuable opportunity to address other relevant legislative issues in light of the advances made in the use of human tissue for purposes relating to approved research more broadly. These other legislative issues are detailed in the attached submission.

I trust this submission will assist the Committee's inquiry and subsequent recommendations made to Queensland Parliament.

If you have any queries relating to this submission, please contact Ms Anne Walsh, Acting Director, Office of Research Ethics and Integrity on [redacted] or [redacted]

Yours sincerely

Mr Michael McArdle
A/Deputy Vice Chancellor and Vice President (Research and Innovation)

Queensland University of Technology

Submission to the Queensland Parliament Health, Disability Services and Domestic and Family Violence Prevention Committee

Health and Other Legislation Amendment Bill 2018

This submission seeks further consideration and changes to the *Amendment of Transplantation and Anatomy Act 1979 (Qld).*

The proposed amendment to the current *Transplantation and Anatomy Act 1979* (Qld) (the Act) is welcomed by the research community and does in part remove some degree of ambiguity particularly for research involving children. However, we recognise that this amendment presents a valuable opportunity to address other legislative issues that require further consideration, particularly in light of the advances made in the use of human tissue and cell lines for purposes relating to research. Specifically, these considerations are related to Part 7 of the Act that details the Prohibition of trading in tissue. We request that the legislative committee considers further legislative amendments to ensure the Act achieves relevancy within a contemporary research environment whilst maintaining its regulatory intent.

Clarification of 'human tissue' and what constitutes a 'substance extracted' as defined under the Act

The definition of 'human tissue' as used in the current legislation should be reviewed to reflect the contemporary language of 'bio-specimens' as defined in the National Health and Medical Research Council (NHMRC) National Statement on the Ethical Conduct in Human Research 2007, (Updated 2018) (the National Statement). Chapter 3.2 of the National Statement states that 'Human biospecimens….refers to any biological material obtained from a person including tissue, blood, urine and sputum; it also includes any derivative of these, such as cell lines' (p 42). Harmonising the Act's definition of 'human tissue' will assist with clarifying the scope of what human tissue is included within the meaning of the Act and authorised tissue donations for approved research under Division 6 of the Act.

The Act's definition of 'tissue' includes in its meaning 'a substance extracted from an organ, blood or part of – a human body; or a human foetus'. It is ambiguous as to whether derivatives of human tissue, such as, cell lines are considered a 'substance extracted' and would therefore be included in the scope of the Act's definition of a 'tissue'. This ambiguity presents confusion for what types of derivatives of human tissue should fall within the regulatory framework of the Act and be subject to its provisions addressing Donations for approved research (Division 6), Prohibition of trading in tissue (Part 7) and for compliance reporting under the Act and its regulations.

With respect to cell lines, these are critical research tools used extensively in biomedical research and they have led to a number of significant research outcomes including the development of the vaccine Gardasil. This innovation arose from the international collaboration with Professor Ian Frazer from the University of Queensland and the late Dr Jian Zhou from China. Cell lines as defined by the National Statement *are, 'cells grown in the laboratory over an extended period. Cell lines can be created from many different types of tissues and include those that will only grow for a limited period of time as well as those that may become 'immortal' through alteration of their genomes either through mutations arising naturally or induced artificially. Cell lines usually comprise a stable population of cells, although some heterogeneity is generally present and changes in the characteristics of the cells may occur over time.* (p 99)

Prohibition of trading in tissue

With reference to Part 7 of the Act 'Prohibition of trading in tissue,' we wish to seek legislative amendments that change the Act's provisions for sections 42A 'Person who owns a prescribed tissue bank may charge amount to recover certain costs etc.' and/or section 42AA 'Trading of tissue for particular purposes' as described below:

42A Person who owns a prescribed tissue bank may charge amount to recover certain costs etc.

The Act's regulations (section 12) list a small number of 'tissue banks' prescribed for the purposes of the Part 7 provisions. Under section 42A, these 'prescribed tissue banks' are exempt from the Act's general prohibition on trading in tissue and are permitted to recover reasonable costs associated with tissue removal and handling activities, including processing and storing donated tissue (the Act, section 42A(1)).

Currently, there are a number of tissue banks within QUT as well as in research and healthcare organisations across Queensland and Australia, including other universities, hospitals and research institutes. Many of these tissue banks provide tissue, on a cost recovery basis, for the purposes of research. The ability for these tissue banks to trade on a cost recovery basis is important for their ongoing sustainability to ensure valuable and rare tissue or bisopecimens are maintained and curated for the benefit of further research.

Under the Act's current provisions, tissue banks not 'prescribed' under the Act must seek a Ministerial permit (section 40(2)) to 'buy tissue' for the purposes of research. This creates a number of challenges for custodians of tissue banks in terms of the operational and resourcing demands this will potentially require and also the impediment (time and administration) this will create for researcher applicants requesting access to tissue for the purposes of research. At present, the only alternative option for researchers and tissue bank custodians is to share human tissue at no cost which will have negative implications for the ongoing sustainability of tissue banks.

The number of non-prescribed 'tissue banks' implicated by the Act's current provisions relating to the broad prohibition on trade is significant. Under the National Health and Medical Research Council (NHMRC) National Statement, human tissues collected for the purposes of research and stored in 'tissue banks' are subject to the review and approval of a human research ethics committee. The National Statement defines a 'databank' as a 'systematic collection of data' where data includes 'information derived from human biospecimens such as blood, bone, muscle and urine'. The Act's requirement for Ministerial permission to charge a cost-recovery amount for the trading of human tissue systematically collected as part of approved research will potentially pose significant administrative burdens on both the research applicants and the regulator. The current ethical review mechanism for the collection of tissue for the purposes of research is well articulated in the National Statement and should be recognised and used as the legitimate mechanism to enable researchers to access tissue from well curated tissue banks and collections for the purposes of research without a secondary administrative hurdle of the current Act.

Access to 'human tissue' sourced from International tissue banks or commercial companies

An additional issue related to the broad Prohibition on trading in tissue (Part 7) is where human tissue, as defined by the National Statement, is accessed through commercial providers for the purposes of research. In some instances, these commercial providers are located outside the State of Queensland, including international companies and tissue banks situated in other

international research organisations. The Act's current requirement for researchers and tissue bank custodians to seek a Ministerial permit to trade human tissue on a cost recovery basis or import tissue for the purposes of approved research poses significant administrative burdens for the research community and will significantly impact the ability of Queensland researchers to competitively undertake world class biomedical research.

42AA 'Trading of tissue for particular purposes'

Suggested legislative amendments that may resolve the above issues include broadening the legislative scope of what is considered a 'prescribed' tissue bank, or amending section 42AA 'Trading of tissue for particular purposes' to include human tissue collected for the purposes of approved research where trade is limited to charging a cost-recovery amount to recover the reasonable costs associated with removing, evaluating, processing, storing or distributing donated tissue. The most desirous amendment would be to remove the need for any permit for the exchange either as traded or imported human tissue where there is an ethical approval in place or the research is deemed as being negligible risk as defined under the National Statement or an international equivalent standard.