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REVIEW OF HUMAN TISSUE LAWS

1. What is your personal experience of how human tissue is obtained or used in Australia?

Nil comments.

2. What is your personal experience of how human tissue laws work in Australia? -

Nil comments.

3. When we think about the laws governing how human tissue is obtained and used, what are good aims or objectives for these laws?

You might think about aims such as:

- i. increasing the amount of tissue available for transplantation and/or other uses*
- ii. creating a transparent and easy to navigate tissue donation system*
- iii. making sure tissue donation happens safely*
- iv. making sure people have a good understanding of what is involved in donating tissue*
- v. making sure people understand how their tissue will be used*
- vi. equity, and removing barriers faced by some individuals or groups to human tissue donation or transplantation*
- vii. making sure how human tissue is obtained and used is consistent with respect for persons and the human body.*

Law reform should be centred around all the aims listed (i-vii) and reflect an evolving society technologically and ethically. Here at Macquarie University our work is largely focused on body donations. Organ donations are less relevant and therefore these points do not address organ donation explicitly.

(i); increasing the amount of tissue available through body donations is imperative for student learning, research and clinical skills training. Here at Macquarie University, we view the eight-year period of body retention as a limitation in this aim's success. It is recommended that upon the senior (NOK) informed acceptance, a body can be retained for an additional 4 years, with the option to be renewed indefinitely, (provided a senior NOK has provided approval in the each 4-year anniversary). Here at Macquarie University, it has been difficult to source enough donors for the teaching of anatomy, and by having the ability to hold a donor in our care (with senior NOK permission) for an additional 4yrs periods will provide more thorough teaching material to benefit our students within their medical training. With indefinite renewal potential (with consent) teaching would benefit immensely.

(ii); transparency is one of the most prominent aims which this law reform should seek to create. Transparency not only fosters greater public trust and interest but also supports the technical teams and all parties involved with body donations. An example of lack of transparency in the current Anatomy Act 1977 (NSW) is the lack of information and explicit examples of what 'research, development, testing and evaluation (RDT&E)' means. RDT&E is a crucial sector which uses donated bodies for the advancement of scientific and medical technologies. Here at Macquarie University, RDT&E includes areas such as joint replacement RDT&E, which can use donated bodies upper limbs in testing new joint replacements. RDT&E can include a wide array of activities which here at Macquarie University, we view as information pertinent to this reform.

(iii); whilst it is an important consideration for concern, we have limited comments on safety. Please find our responses and recommendations to aspects of safety in subsequent questions

(iv); making sure people understand what the specifics of donating tissue involves is crucial to law reform. Currently, the Anatomy Act 1977 (NSW) does not go into detail about the logistics of body donation, however, these details should be covered in universities and other institutions internal body donation forms. For this aim to be realised, a universal, comprehensive and up-to-date body donation form is recommended. In addition, it is recommended that body donation is a topic raised and addressed to a broader population,

(such as high school students) in an open and scientific manner to reduce the taboo and lack of knowledge the general population has on this very important topic.

(v); largely reflective of responses to (iv).

(vi); equity had little comments.

(vii); making sure how human tissue is obtained and used is consistent with respect for persons and the human body is, of course, a fundamental aim this law reform commission should aim to achieve. Issues that current Anatomy Act 1977 (NSW) has to this aim is the lack of information regarding informed consent and cognitive capacity. Potential body donors which have medically impaired rational and cognisant thinking, through diseases such as Dementia, Alzheimer's disease or Parkinson's disease should not be eligible to donate their body as consent has not ethically been obtained. However, if the donor did consent during a period in which they were not mentally impaired then this should be allowed. Of course, other documents, like a will or an end-of-life directive can support a donor's wish for body donation.

4. When we think about reforming human tissue laws, what principles should guide reform?

- *You might consider principles such as:*
 - i. *respect for persons and for the human body*
 - ii. *Equity*
 - iii. *the importance of public trust in the framework that governs how human tissue is obtained and used in Australia*
 - iv. *the importance of laws that are well designed and effective.*

Naturally, law reform should include all principles listed out in question 4 (i-iv). Here at Macquarie University our work is largely focused on body donations. Organ donations is less relevant and therefore these points do not address organ donation explicitly.

(i); respect is, of course, fundamental in all areas of this law reform. An example of this respect is ensuring that if a senior NOK changes address, location or passes away, this information should have a standardised procedure to be relayed back to the relevant institution (including a standardised method of information recovery, such as how many times to call the donors senior NOK.). This information should also be included in all donor registration internal forms. In addition, it would be reasonable to decide on a period during which contact (by phone, email or post) is required, but after which the lack of contact should be interpreted as reason to dispose of the ashes.

(ii); equity had little comments.

(iii); As previously stated, public trust needs to be strengthened regarding usage of human bodies for research and education. Exposure and education should be utilised here.

(iv); ensuring that the law reforms are well designed and effective is imperative, as without this, there is no point in changing anything. It is therefore recommended that all major HTA's are reviewed and all inconsistencies and gaps in information are addressed. For instance, the Anatomy Act 1977 (NSW) should have the exact same depth of information regarding research as the Anatomy Act 1930 (WA) or the The Transplantation and Anatomy Act 1983 (SA). Future-proofing legislation is incredibly relevant to this principle, as tissue and bodies may have different definitions in the future with advances in robotics and technology.

5. Do you agree that the issues set out in the section 'Priority reform areas' should be a focus for our Inquiry? Please tell us about why you think these issues should or should not be a focus.

All issues discussed in the 'priority reform areas' are pertinent to this inquiry and should remain as key focuses of this inquiry. However, we recommended additional areas of reform not listed in this priority section need to be considered. For instance, the indefinite retention of tissue, whilst different between all institutions and universities, should have a nation-wide definition. Conditions for consent should be addressed and standardised. With developing

technologies and a higher demand for anatomical models, utilization of photography and even 3D printing is now a reality. To align with reform aims such as transparency and public trust, a section detailing the parameters of digital technology and permanent retention should be discussed, for ethical and practical reasons.

6. What, if any, other issues should we be focusing on in this Inquiry?

- *You might think about areas where improvements in the law would be easy; or areas where law reform might be difficult but still important, because the current law is not working well. You might also think about*
- *if there are issues caused, or likely to be caused, by current or emerging technology that we haven't identified in this Issues Paper; and*
- *if there is a need to update the HTAs to account for contemporary community values, in ways that we haven't identified elsewhere in this Issues Paper.*

The additional issues that we propose should be addressed are as follows (the number at the end of the point references the clause which it pertains to in the 'Review of Human Tissue Laws Issues Paper 51'):

- To the exact degree we cannot say, however there ought to be greater transparency regarding practices and procedures that occur posthumously. It could be beneficial for the senior next-of-kin to be explicitly informed of these practices to better inform their decision to consent on a donor's behalf. This is consistent with clauses 44 - 47 on 'Reform should promote and uphold public trust'.
- Macquarie University proposes that a unanimous decision must be reached by the hierarchy of NOK for the institute to accept consent on behalf of the donor, should it not be explicitly given directly by the donor. Additionally, lower ranking NOK may object to the body donation. The senior NOK is responsible for contacting the rest of the hierarchy NOK, obtaining consent from them and communicating that to the body donation programs.
- Research must be more explicitly defined, and persons should consent to research specifically. If there is the potential for use of tissue for research purposes after its initial use for other purposes (such as anatomical teaching or surgical skills training),

consent must be obtained either by the donor forms prior to donation or by some other mechanism (senior NOK). (57).

- Reduce inconsistencies on donation of tissue obtained from children with protective laws in place to ensure that the wellbeing and interest of the child is sufficiently protected. (58)
- Cognitive capacity and capacity to make decisions should be assessed or at least considered when accepting bodies into donor programs. We suggest it is acceptable for the senior NOK to be responsible for providing evidence of the donor's expression of interest or consent to donate their body when they were of sane mind. (59 - 60).
- Legacy tissue retention - Macquarie University would like to request that additional, tissue extensions in 4 year blocks may be requested after the first 4 years. This would greatly benefit students as there are many unique anatomical variations that may be taught from. Please see response for Question 3 (i) regarding further clarification for continuous tissue extension requests.
- Additionally, if permission is granted for permanent or indefinite tissue retention, it must be explicitly communicated to the donor or the NOK even if that permanent retention is only for small amounts of human tissue. Consent for photography should also be obtained in a similar manner, and it must be explicit that photographs (deidentified) may be retained indefinitely. (82).
- Improving documentation and record keeping - If tissue extension time periods may be extended, so too should the retention of hard-copy documentation and records of the donor's consent forms and preferences. Tangible records of indefinitely retained tissue should be always kept on site whilst the institute holds the tissue.
- If a donor's NOK cannot be contacted to return the remains, there should be a standard procedure in place. What is a reasonable amount of contact or attempted contact to the donor's NOK? Additionally, what would be a reasonable amount of time to store remains before disposing of them respectfully if any NOK is unresponsive or uncontactable. What are standard and acceptable recommended methods of contact that should be incorporated into university procedure to contact families.
- A potential issue identified was 'reimbursement of necessary costs for donors' - This could be a potential conflict of interest encouraging financial incentive for families to

donate on the donor's behalf. The specific reimbursement of necessary costs for donors should be explicitly defined as to avoid confusion around body donation program costs, which are entirely practical based (institutions pay for transport, cremation, death certificate costs), as opposed to reimbursement for time which is provided in organ donations. (86).

Additionally, Macquarie University would like to pose several questions to be considered in this reform:

If an under-18-year-old provides written consent on his/hers wishes regarding body donation (in the presence of a witness), should their wishes be legally binding? This ethical question can be further broadened to include foetuses.

We would like some guidance, should our body donation programs encounter donors with unknown pregnancy. At which point is, or should, the foetus be considered as human tissue belonging to the initial donor? Is it ethically acceptable for the university institution to hold onto the foetal tissue as a separate entity? We would like some guidance upon how to ethically and respectfully undertake disposition of foetal tissue or how best to return this tissue to the family without potentially breaching donor confidentiality by exposing previously unknown medical information to NOK.

7. Are there inconsistencies between the HTAs that we have not identified in this Issues Paper that are causing problems and should be a reform focus for us?

The inconsistencies between public health jurisdictions and how they regulate anatomical examination, accept body donors and identify human tissue are salient issues that must be addressed. There should be a consistent set of criteria or regulation that governs anatomy licenced facilities regarding who can consent to body donation (as it currently stands, different educational institutes prioritise different models of autonomy for the acceptance of bodies). Whether we accept consent from the senior next-of-kin on behalf of the donor or only from the donor themselves explicitly should be consistent between anatomical institutes. Additionally, there are inconsistent regulations between educational institutes regarding the

acceptance of older osteological remains (with a known or unknown source). This too should be consistent in all public health jurisdictions.

An additional consideration of note is producing a more specific definition of de-identifiable human tissue. During dissection and various other anatomical examination processes, there are small amounts of human tissue that are removed that are not used for teaching or any other purpose. Whilst this is currently acceptable to be disposed of as per clinical and biological waste guidelines, there are different definitions between public health jurisdictions about what constitutes as 'de-identifiable' human tissue, and the amount of which may be disposed of through clinical waste. Macquarie University would like to see a uniform definition consistent in all public health jurisdictions which can be regulated more easily.

8. Do you think it is important that we consider any of the issues in the section 'Issues we are unlikely to focus on in this Inquiry'? If so, why?

Yes, particularly the 'First Nations ancestral remains, to the extent they are dealt with under cultural heritage laws'. This should be addressed, as the regulation of anatomical institutes osteological collections is impacted by cultural heritage laws as bones of unknown origin donated to university establishments may belong to deceased First Nations individuals. Thus, cultural heritage laws would intersect with the HTAs. All anatomical institutes should be able to accept osteological remains for (or from) teaching purposes. Legislation reforms to consider donations from members to universities and guidance to universities on protocol should these remains be identified as First Nations.