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Australian Law Reform Commission  
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**REVIEW OF HUMAN TISSUE LAWS**

I am making this submission as a regular citizen of Australia. As a society we have the obligation to look after those who cannot look after themselves and this also extends to those that do not have their own decision making capacity as adults and children. I hope that words in this submission are helpful in some way forward.

**1. National Legislative Framework**

**Proposal 1** - Regulation should be by uniform Commonwealth legislation.

**Proposal 2** – As much as possible should be in the legislation because the discussion paper allows for regulations to be made to be very flexible which will open the flood gates for decisions that the general population did not intend with legislation.

**2. National Regulator**

**Proposal 3**

A – expending powers and functions of the Organ and Tissue Authority makes sense. Still keeps within the area of focus without wasting resources to set up another National Regulator.

**3. Implementing a national legislative framework**

**Proposal 4**

It should be a) referred legislation where States and Territories allow the Commonwealth to implement national uniform legislation.

**4. The Objects of Human Tissue Laws**

**Proposal 5**

a) Modernise? What does that actually mean? Moving legislation and regulations along with community expectations on the day?

- b) No – this should not be the object of legislation. Government and Legislation should not promote benefits or human tissue donation. It should provide a mechanism but not co-erce people to do so, nor inform them of benefits because at the end of the day, donating is a personal thing and public funds should not be used to promote this practice at all.
- c) Yes
- d) No – for same reasons as above in b).
- e) I don't know how you will ensure respect for individual dignity and autonomy and for the human body when the body is still warm and alive and you inject the body with a paralysing agent to ensure that the 'living' person does not move when organs etc are removed. On top of that, the definition of 'dead person' is not consistent in Australia with those of other countries and the method of determining if someone is actually dead is questionable. At the end of the day, if someone's body is still alive, they are alive until the blood stops running through the veins.
- f) This is contrary to b) and there is no way you can stop exploitation of individuals in relation to how tissue is removed. So on one hand, you want to promote human tissue removal and benefits and on the other you want to stop exploitation. Where human body is concerned, there will always be exploitation.
- g) Yes but you need to prove it, not just legislate it. Too many examples of people having organs harvested with families pressured to do so under the guise of 'you will be helping other people'.

### **Question 1**

No, I do not agree with objects in Proposal 5. Please read comments above. The only objects should be:

- C – ensure it meets Australian international human rights obligations
- E – ensure respect for individual dignity and autonomy and for the human body
- F – prevent exploitation.

### **Question 2**

NA

## **5. National Regulation to have regards to the objects**

### **Proposal 6**

Yes, but only if you include c), e) and f), not the others.

## **6. Promoting equity**

### **Question 3**

No, barriers should not be removed and promotion of human tissue donation, transplantaion and use should not be promoted. It will be abused by those who have something to gain from it from a personal or business or industry level.

## 7. Removing barriers

### Question 4

No, do not remove barriers. Human tissues are not products that you should be able to order off the internet and people should not be coerced to be donors and no legislation will safeguard this from happening.

### Question 5

Option a) and b) are both ok. The current Australian definition should not be used.

Option a) tissue means material which consists of, includes, or derives from human cells (a definition based on section 54 of the Human Tissue Act 2004 (UK)).

Option b) tissue means the human body or any constituent material, substance, or part removed from a human body that is, includes, or derives from human cells (a definition based on section 7 of the Human Tissue Act 2008 (NZ)).

### Question 6

Definition needs to encompass everything that is meant by it, if tissue means substance, material, cell, organ tissue – then use tissue. If the word does not include everything, then change it to something that does.

## 8. Adjusting the scope of the definition

### Proposal 8

No, the human regime should NOT have the mechanism to adjust the scope of the definition as it will be open for abuse and a slippery slope will be developed by possibly well-meaning individuals but the result will yield an undesirable result. The national regulator should not be allowed to make delegated legislation. As human tissue and ethics concerning it are of life and death proportions, literally, most issues need to be thrashed out in the legislation, not regulations that a National Regulator will be able to change as it sees fit.

## 9. Guidelines to support the definition

### Proposal 9

The National Regulator should not create guidelines to provide interpretive guidance and clarity about definition and scope of 'tissue'. This is too important to not be addressed in legislation. This should be done in legislation. Definition should be clear enough in primary legislation to ensure that people understand what it means without the over use of guidelines etc.

## 10. Exclusions from the definition

### Question 7

It is hard to ascertain which materials should or should not be included without knowing what effect it will have on its use. Extracting gametes from deceased donors is very different to human milk that is naturally expressed from the body. It is not so much what is included in the definition, but how the legislation will ultimately treat that material. Human milk and faecal tissue should be excluded as it is something

that is expelled from the body naturally and probably does not need to have a high oversight. Foetal tissue, gametes (from deceased donors) and cell lines should be included for protection purposes.

## 11. New Statutory provisions for determining death

### Proposal 10

Statutory provisions for determining death should be completely reviewed. We need a new definition. The current one is outdated, inaccurate and questionable. Just because a formula was used to determine death does not mean it is an accurate method. And just because one or two doctors uses that formula does not make the formula appropriate. The formula itself of what determines 'death' needs further exploration. We all know that the human body is not actually dead at point of time of tissue harvesting because if it was, you would not be able to get the tissue out for purpose of transplantation. If the body was dead, you would also not need to use paralyzing agent to ensure that the body was not moving while the procedure was performed. The paralyzing agent, paralyzes the body so that the person, even if they could, would not be able to signal pain etc.

## 12. New Statutory location for the determination of death provisions

### Proposal 11

You would think that every jurisdiction in Australia would have one legal standard for determining death. However, you need to research what other countries are using in determining whether death has actually occurred, and new research is needed to do the same. One definition should be developed for the whole of the world really. If different countries and states and territories have different definition of death, what does that say? That there is no one standard or measurement of death, which means no body is truly dead until the blood stops pumping through the body, making the body unusable for human tissue purposes in most instances.

## 13. Consequences of a determination of death provision that applies for all purposes

### Question 8

You would think that if there is a determination of death, then the provision should be for all purposes. You should not have one definition for human tissue donors and one for those that are not. Having more than one definition will open up the area to abuse from those that rely on human tissue donation. The person is either dead, or not dead. The fact that there are a variety of definitions and standards to determine death already means that there is no consistency and no real understanding of what constitutes death. Death should be defined as a body that can no longer sustain life when not supported in any way by artificial means. In order to test that theory, a person would have to be dead for some time in order for blood to stop circulating or person stopped breathing for ie 10 – 15 minutes. If a person dies, then their body cannot be used for tissue organ donation, which means that people are still alive when this procedure is undertaken.

## 14. Maintaining national consistency

### **Question 9**

To maintain national consistency, A uniform Death Act should be adopted as national uniform legislation in each state and territory.

## **15. Post Mortem Interventions**

### **Proposal 12**

Yes, regulations can specify professional standards or guidelines to be complied with for the purpose of post-mortem interventions, however, those must meet some high international standards to ensure that human dignity is preserved and post mortem interventions not abused.

## **16. The Dead Donor Rules**

### **Proposal 13**

1. The fact that a statement is made in the discussion paper that it is important to ensure that 'a deceased donation only proceeds after it has been determined that a person has died' already indicates that a) tissue harvesting takes place before a person is deceased dead and b) there are currently no standards to prevent this happening currently.

2 and 3 - No – use a different definition of death than that is section Y(3). Also, just because a medical practitioner confirming death is not going to be responsible for removing the tissue does not mean that they will not benefit in other ways. The principle 'you scratch my back I will scratch yours' springs to mind in this proposal.

## **17. Current and authorisation for removal of tissue from living persons**

### **Proposal 14**

1. Yes, the legislation should provide what valid consent.
2. Yes, a) – e) inclusive should be used to establish consent.

Provide in legislation that valid consent must be in writing and that there needs to be a cooling off period. How will authorities ensure that there is no coercion and that the person willingly wishes to donate tissue at time of giving? How soon to the gifting of human tissue does person need to have capacity and willingness to gift? What happens if a person decided to gift and they lose capacity to make an informed decision at time of donating. Will there be a requirement that decision making capacity and willingness to donate is there at time of, or immediately of the donating? Who will determine decision capacity? How will determine there is or is no coercion?

## **18. Additional safeguards**

### **Question 10**

Yes, see my comments above in Proposal 14.

## 19. Definition of 'adult' and 'child'

### **Proposal 15**

Yes, 'adult' 18 plus and 'child' person under 18.

## 20. Donation of Blood

### **Proposal 16**

No. For the purpose of blood donation, a child should still be 18 years and older to be deemed an adult.

## 21. Donation of tissue by children

### **Proposal 17**

No, an application should not be allowed to allow a parent or guardian of a child to bring an application to a Committee. The Child should be able to make that decision by themselves when they reach 18.

### **Proposal 18**

What experience will the Committee have and qualifications to deem the child having decision-making capacity and whether the tissue is for child's best interest. How will the committee ensure that the child was not coerced.

### **Proposal 19**

No, children should not have their tissues removed full stop. If we have determined that only an adult can make an informed decision, then children do not. Children's bodies should not be used as an organ donation tool. A child should not have to 'consistently' express their unwillingness to have tissue removed for the committee to not authorise the removal. A child is a child for a reason, it is defined as a child because it lacks capacity to think in a mature enough way. A child should never be put in such a position as to donate an organ etc.

### **Question 11**

No, considerations are not appropriate. Nothing and no one should authorise the removal of human tissue from a child – a person under the age of 18. Full stop. See my comments under Proposal 19 above.

### **Question 12**

The only consent should come from a person who is 18 years of age or older. There should be no provisions to allow the Committee or parents to approve removal of tissue from a child. A person under 18 is a vulnerable person, coercion and pressure will be rife if this provision is legislated. We already have children who are born just to support a previously born child in the family where the parents, by having a second child, were hoping that the second child might be able to help the first one to live etc.

## 22. Definition of tissue by adults who do not have decision-making capacity

### Proposal 20

No, absolutely not. If a person does not have decision-making capacity, that person should not have any tissue removed for the purpose of transplantation or other medical, educational or scientific purposes. This opens up another whole can of worms. So a guardian ie the State of Western Australia would be able to consent to have a 45 year old woman have tissue removed from her body – just because they can. This is morally wrong. People with mental disorders or persons who have not or do not have decision making capacity may potentially be abused by the system that tries to protect them. Ie. The state, to hide the fact that a mentally ill person has gotten pregnant in a government institution may now seek to have the foetus aborted raising various reasons, but ultimately to protect itself, not the person in question. This proposal will open up unintended consequences.

### Proposal 21

No. A committee should never have that power as it is only assuming what will be in the persons best interest.

### Proposal 22

No. A committee should never have that power. What if a person never had the decision-making capacity? Is it then just a human body for the taking?

### Question 13

No, the considerations listed are not appropriate. See my comments above. We should not play God. If the person does not have decision making capacity, then they should not be used as a guinea pig.

### Question 14

No, not at all. First of all, a person who has no mental capacity should not be forced to donate human tissue, full stop. No, there should not be instances where the decision to donate should be made by a substitute decision maker. This will create conflicts of interests and predators over those who cannot protect themselves.

## 23. Composition of committee

### Question 15

There should only be a national Committee for the purpose of consistency. Persons on Committee qualifications/experience – ethics, medical, legal.

## 24. Consent and authorisation for removal of tissue after death

### Proposal 23

No, absolutely not. A person must have decision-making capacity in order to donate their body, this should not be made by an alternative decision maker at all. This is no different to the voluntary assisted dying legislation in Western Australia. A person must have decision-making capacity to be given the potion to die. This is no different. A persons family should not have that decision power, nor should anyone else. It should only be the person themselves.

if you allow other people to make a decision to donate organs etc of another, you are effectively taking away that persons choice. We cant have one set of rules for those that are dying by Voluntary assisted dying and another set for those who are dying of natural causes. If you allow for this proposal 23, then you will allow for abuse of the system.

There will never be another human being who knows intimately what goes through another persons mind. Just because a person states they want their body to go to research after death, does not mean that they actually want that to take place. They might be a donor on their drivers licence but at time of death, they may not wish to have organs harvested. You cannot have another person make decisions in regards to tissue donation. Person donating must have full decision capacity at time of gifting.

The same comments apply to the proposal that children's authorised decision maker can make decision to harvest organs.

**Question 16**

No, keep it as it is. We need a third party oversight.

**Question 17**

No. It is too loose ended. The process can be taken advantage of. There will never be a person who will know full well what another person intended to happen to their body. As soon as you start allowing other individuals, other than the potential donor make decisions there is opportunity for coercion. Also, children who are under the age of 18 should not be used as donors.

**Question 18**

It should be in writing and in person orally. The persons needs to have decision making capacity. If they do not, then their tissue should not be up for donation.

**Proposal 24**

No. Because some persons may feel compelled to donate their tissue and others may feel pressured to do so.

**25. Authorised Decision Maker**

**Proposal 25**

No. Senior next of kin should be the one making decisions. It is only if they are not there, should another person, such as an authorised decision maker make decisions. A decision maker might not be a family member. It removes the family from the loved one to make such important decisions. For example, if a person was under a Guardianship order and the Guardian was the State of Western Australia, the State court ultimately donate the body to science, transplant etc. This should not be allowed. A decision maker sounds good in practice but is taking the matter further away from ethical responsibilities to the donor.

**Question 19**

You don't need to have a hierarchy if you use the senior next of kin as the person making the decisions. Anything else is substandard and wrong.

You need next of kin persons to make those decisions unless there are none, in which case someone close to the person should make a decision, not a 'decision maker' as such.

**Question 20**

If you keep the senior next of kin then there will be no disagreements about the matter. Should decision makers be allowed under legislation, which I oppose, then if there is a dispute, then there should not be human tissue donation taking place.

**26. Pre-mortem interventions****Proposal 26**

Is this 'pre-mortem intervention' going to take place before or after consent has been given? It should definitely be after the donor has been declared dead and after consent for donation has been received. It is crucially important that no pre-mortem interventions take place before a decision is made to provide donor tissue. Otherwise, there may be conflict of interest between what the person should or could have received in terms of care and what is now being prescribed in the hope that they will be a donor.

**Question 21**

No idea. A question for medical personnel.

**Proposal 27**

Unless consent has been given by the donor with decision making capacity, valid consent SHOULD NOT BE sought from a persons authorised decision-maker. NO one can make the decision apart from the person themselves.

**Question 22**

No. A person's blood should not be taken for the purpose of ascertaining whether they would be a good donor without prior consent by the person. It's like birds of prey waiting for the weak gazelle to die so that they can pounce on it. There should be no exceptions to the need for consent. Absolutely not.

**Question 23**

NA

**27. Respectful and dignified treatment of deceased body****Proposal 28**

Yes agree.

**Proposal 29**

Yes, agree.

## 28. Coronial consent to donation

### Question 24

Like I said, apart from the person themselves, no one should have the authority to decide that a part of another human body should be removed for whatever purpose. It is opening up the idea that others, apart from the person themselves will have power to do as they please with the body.

## 29. Authorizations for non-coronial post mortem examination

### Proposal 30

Yes, agree.

### Question 25

Yes, if they have decision making capacity and are not influenced or co-erced by anyone else.

### Question 26

This should only be used in rare cases. All effort should be make to find the next of kin, not a decision maker.

## 30. Use of Tissue removed during a post-mortem examination

### Proposal 31

Tissue removed during post-mortem examination should not be used for any other purpose, regardless of what another person may feel should happen. This will reduce the potential of third parties performing post mortem examination or allow for this to take place for other purposes than the examination itself.

### Question 27

Consent can only be gained from the donor themselves, no one else.

## 31. Consent and authorisation for tissue removal for research - living persons

### Proposal 32

It needs to be in writing and then orally witnessed by two independent doctors in person. Similar to Voluntary Assisted dying. It would also be best if the next of kin could be present to this but ensure that there is no coercion.

### Proposal 33

Yes, agree.

### Proposal 34

Yes, agree.

### Proposal 35

No, absolutely not. Children should not be forced to be donors. They need to be 18 and then given their own consent. They should not be treated like lab rats.

**Question 28**

No, absolutely not. Persons who do not have decision capacity should not have their tissue removed for research. No safeguards can be put in place to prevent harm or exploitation. It is a abuse of the highest form. It is no different to orphaned children being used by medical institutions or adult asylum patients or in some cases prisoners in some countries. Again, unless a person has provided their consent, no one should be allowed to make that decision for them.

**32. Consent and authorisation to remove tissue for research after death****Proposal 36**

No, no, no, unless the donor themselves gives consent, no other third party should be allowed to do so on their behalf otherwise it opens up the whole space to abuse and unethical decision making.

**Proposal 37**

Decision maker could have conflicts of interest in the donor being a donor, so for that purpose this proposal should not be allowed to take place in the first instance. Should decision makers have the ability to make decisions, then yes, they should have access the same as the donor would. But again, this opens up things to abuse even if procedures are put in place to prevent it. That is why it is best if only the donor should be able to make a decision.

**33. Consent and authorisation for body donation after death****Proposal 38**

Only the donor can give this consent, not a third party.

**34. Consent and authorisation for research on the recently deceased****Proposal 39**

Only the donor can give this consent, not a third party.

**35. Consent and authorisation for use of tissue samples****Question 29**

Absolutely, one would think this is happening now.

**Question 30**

There should be no exceptions.

**36. Regulating stored tissue collections****Question 31**

Absolutely, I would have thought this is in place already.

**Question 32**

Absolutely, I would have thought this is in place already.

**Question 33**

All aspects of tissue collection, storage, use transfer and disposal need to be regulated. All types of collections should be regulated and the only exception should be human milk and faeces.

**37. Accession stored tissue****Question 34**

Of course donors should have access to their own tissue by way of asking. The right should be granted to the donor or next of kin.

**38. Prohibiting the exchange of human tissue for reward within Australia****Question 35**

It is interesting that this legislation wants to stop any reward within Australia for tissue donation under this discussion paper but was quite happy to have surrogates compensated/reimbursed for the fact that they were carrying a baby for intending parents. This needs to be explored further. You will have inconsistent legislation about something quite similar.

**39. Giving extra-territorial effect to the prohibition****Question 35**

Yes it should and it should be covered by the human tissue legislation and the *Criminal Code Act 1995 (Cth)*.

**40. Agreement to be void (have no force)****Proposal 41**

Yes, agree.

**41. Exceptions to the prohibition on the exchange of human tissue for reward****Proposal 42**

WOW! Really? So you will be promoting the purchase and sale of tissue removal for the purpose of medical, educational and scientific purposes. This should not be allowed at all.

**Question 36**

There should be no reward, no exceptions. No to paying for plasma.

**Proposal 43**

No, there should be no exemptions. Have one law for everyone and stick to it with no exemptions. Public interested should not come into it. This proposal basically means, there is going to be a law for the ordinary Australians and then there will be another law for researchers, medical practitioners etc. This is wrong.

**Question 37**

Only the donor can make this decision not decision maker.

**42. Guidance on cost recovery****Proposal 44**

If there is cost recovery for those who are involved in the tissue removal, storage etc, why is there no cost recovery for those that are donating.

**43. Prohibiting advertising****Proposal 45**

I agree with this proposal, however it is at odds with the objects of the proposal legislation in that it tries to promote tissue donation yet at Proposal 45 it prohibits the same. That is why it should be taken out of the objects of the legislation.

**Question 38**

Yes, delete the promotion of tissue donation from objects of legislation.

**Question 39**

Yes, it should have extra territorial effect.

**Question 40**

I don't know how you will ensure that the tissue was donated with consent or not paid for, or person not killed to get the tissue from them.

**Question 41**

No, there should not be any exemptions for reporting.

**44. Improving Access to Data****Question 42**

I am assuming data that is needed is what kinds of tissues are needed by the market? It's supply and demand. This should not be taking place. It would be best not to have tissue donation at all because this is where this is leading to, organisations wanting data, what is needed, what is available.

**Question 43**

Voluntary vs mandatory reporting will depend on what kind of data is being captured. Voluntary data will not be very reliable.

**Question 44**

Yes, the authority should conduct inspection of records, absolutely. This should happen on a regular basis with all agencies involved.

**45. Prohibiting non-consensual public disclosure of tissue donors or tissue recipients personal information**

**Proposal 46**

Legislation should prohibit public disclosure of human tissue donors or recipients personal information. There should be no exceptions. The only person giving any information is the donor themselves. Not their next of kin and not their decision making authorised person.

**46. Permission for health practitioners to disclose a tissue donors personal information in limited circumstances****Proposal 47**

Yes, agree.

**47. Who can consent to the disclosure of tissue donors or tissue recipients personal information****Proposal 48**

Consent to the disclosure should only take place by the donor themselves, not any other third party.

**48. Allowing certain people to access and share information for identification and screening purposes****Proposal 49**

It makes it sound like the bodies will collaborate out of which there is potentially a demand supply market developing underground within the medical industry. The thing we are trying to avoid at all costs.

**49. Compliance Mechanisms****Question 45**

The best way to ensure that compliance is enforced is to have it linked to the licence/accreditation to be able to be involved in this practice of human tissue harvesting or using etc. It needs to be audited.

**50. The timeframe for implementing our reform proposals****Question 46**

No.

**51. Are other reforms urgent?**

I do not know.

Thank you for the opportunity to make this submission. I look forward to the next stage.