Lions Eye Donation Service
MELBOURNE

6th February 2026

Australian Law Reform Commission: Review of the Human Tissue Laws Discussion Paper 90

Dear Dr Teows,

On behalf of the Lions Eye Donation Service (LEDS), I wish to thank you for the opportunity to provide comment on the second round Discussion Paper (# 90) provided by the Commission's Working Group.

LEDS at the Centre for Eye Research Australia (located within the Royal Victorian Eye and Ear Hospital) Melbourne, is the primary agency involved in the recovery of consented eye donations from Victorian and Tasmanian donors, and the allocation of their donations towards transplant, training, service validation and research use around Australia and New Zealand. LEDS is licensed to provide ocular human biologicals for therapeutic purposes through the Therapeutic Goods Administration (TGA) and prepares those donations in accordance with the relevant therapeutic goods orders and good manufacturing practice standards. LEDS also manages the ethics approved CERA Biobank which supports the advancement of medical research across Australia and beyond.

As co-Chair of the Eye Bank Association of Australia and New Zealand (EBAANZ) and co-author of the submission provided by EBAANZ – written in collaboration with BAA, and endorsed by Vision 2020 Australia, I feel we have addressed many of our responses to Discussion Paper #90 in that submission. Therefore, please refer to that submission for our general response.

The below outlines additional comments not included in the BAA-EBAANZ submission which LEDS feels would benefit from further consideration:

1. **Artificial Reproductive Technologies (ART)**

   Artificial Reproductive Technologies (ART) should retain its own legislation, as donation, use, and long-term implications of ARTs are different from those experienced in other areas of the donation field. Their legislation does, however, require updating to meet contemporary needs and should include the development of ART regulations. As required, their legislation could make reference to the wider tissue/substances of human origin legislation under review by the Commission.

2. **Legacy Collections**

   We support the consideration of a national regulator for legacy collections; however, we are undecided as to where and how they would practically be placed and supported when considered in the same context of contemporary donation and use, under review by the Commission.

   For example, should they be in the same legislation as other 'donations' or separated. Indeed, the word 'donation' used in the legislation and regulations under review by the Commission does not universally fit in this instance. For example, legacy 'human materials' may have been taken without consent or knowledge and/or were stolen – and are therefore not always a donation. They may also be in the custody of organisations in foreign countries with their import back to Australia (repatriation) a different form of importation to other donations under review.

While there are some overlaps in other aspects, such as improving transparency and record keeping, the discussions today around legacy collections tend to refer to their return rather than, as we see in other human materials collected today - their use. For example, legislation regarding legacy collections may focus on their repatriation and return to ancestral descendants and/or may involve non-clinical/scientific organisations and uses (e.g. museums), whereas the majority of legislation under review by the Commission, and as outlined by current practice, flows in the reverse direction, i.e., from the donor to the donation's end-use, such as a transplant recipient.

Additionally, discussion about legacy collections often centre around the materials transfer to custodian descendants rather than, as would happen today, transferred back to the donor or a person identified as, and signed on a consent form, as the next-of-kin at the time of donation. Similarly, their regulations, while essential may not require the same type of regulation as routine clinical and research services do.

To reaffirm, we support legacy collection inclusion in both national legislation and regulation, but due to the practical differences and complexities, we are unclear as to how they could be supported effectively in the same legislation or regulation as donations used in clinical application and/or for research use today. If legacy and contemporary 'human materials' were integrated into the same legislation and regulator, then there would need to be modifications/exemptions to ensure legacy collections were supported appropriately and not hindered in the process by current day clinical/research purposes and system requirements. If they were to be provided with their own legislation, then that legislation could reference the tissue/substances of human origin legislation under review by the Commission, as required.

3. End-user facilities

We recommend that the important role and responsibilities of end-user transplant facilities, that receive donations from banks, be included in the legislative update. Facilities (e.g. hospitals and day surgeries) that receive donations from the bank, are essentially the custodians up to the point of transplantation. We recommend their inclusion in the legislation because donations provided fresh and/or stored on consignment are sometimes seen as a routine prosthesis and/or a regular consumable. While a majority of facilities treat donations with care and consideration, at times, facilities may:

- open the donation without use – therefore the donation is not able to be re-allocated to another patient;
- lose the donation – due to facility operational issues, e.g. thrown away rather than returned to the bank for re-allocation if not needed;
- store the donation incorrectly – e.g. a fridge preserved tissue accidently put in the freezer, rendering it non-viable for transplant; and
- cancel patients at short notice (which cannot always be avoided). This impacts corneal tissue which is essentially living time-sensitive tissue and puts increased pressure on the eye bank to re-allocate to another recipient, before the donation expires. There are many times when eye banks are unable to re-allocate, resulting in tissue waste.

These examples place burden on the system in terms of lost donations and resources but moreover provide a disappointing outcome to donors and donor families who would prefer their donation to be maximized and used. Additionally, donor coordinators who spend countless days facilitating the donation are also impacted by tissue waste and are often deflated and saddened to hear that a donation, from a donor they cared for has been wasted unnecessarily.

While this can all be managed by a bank-to-facility agreement (e.g. asking facilities to cover the cost regardless of it being transplanted), without facility responsibility outlined in the legislation there is no incentive to address issues as a collective. In turn, the system loses donations that could be used to help other people waiting for a transplant. This also results in financial loss for some banks. This can be critical for the banks as they operate on a cost-recovery model with limited margins to buffer continual losses long-term. Therefore, placing some level of responsibility on the transplant facilities in the legislation will support banks to retain a sustainable service, ensure donors' wishes are honoured, prevent donation waste and improve greater access to those waiting for a transplant.

Thank you for this opportunity to participate in the review. LEDS welcomes the opportunity for further engagement.

Regards

Dr Heather Machin

Head of the Lions Eye Donation Service.