Thank you for the opportunity to provide comment regarding the proposed, and very much welcome, review of the Human Tissue Act 1982. I am a fertility specialist and head of the Reproductive Services Unit at the Royal Women's Hospital in Melbourne and head of clinical research at Melbourne IVF. I am the head of the Fertility Preservation Services (FPS) at both institutions and co-chair the group developing and updating the national guidelines for fertility preservation with the Clinical Oncology Society Australia. Therefore I have a particular focus in fertility preservation for cancer patients both clinically and in a research context.

There are several aspects which I wish to raise for review.

1. Research using donated tissue.

Currently, there is a lack of clarity with respect to NHMRC guideline interpretation regarding paediatric tissue being donated for research. For paediatric tissue, we will require clarity regarding the ability to conduct important research which will improve options both for individual patients and for fertility success for the wider community of young patients with cancer in the future. This is particularly the case for testicular tissue grafting which is anticipated to be an increasingly important part of medical fertility preservation for cancer patients but grafting technology remains experimental due to an inability to improve the process through research.

We have had many patients who have volunteered to donate a small part of their gonadal tissue for research, either from parents on behalf of their children or from Gillick competent children. Additionally, we have had families of children who have died who have specifically requested that their child's tissue is donated for research, always highlighting that this would give some substantial comfort regarding a contribution to research for future fertility preservation options for young cancer patients. Equally, there are also many children who survive their cancer and as adults would like to consent to donate some of their stored tissue, either because they do not need it, or because they want to donate some of the stored tissue for research to improve outcomes. Yet the lack of clarity around the research use of gonadal tissue collected from paedatric patients has thus far prevented such work.

Our strong request, on behalf of these families is that parental consent, or consent from adult survivors of childhood cancer, be deemed sufficient to enable donation of tissue for research. This is of extreme importance given our strong focus on research strategies to increase the safety and efficiency of gonadal tissue grafting for fertility, particularly in the case of haematological or ovarian malignancies.

2. Donation of ovarian/testicular tissue for reproductive use and tissue grafting to another person for patient fertility.

While there are risks of transplanting tissue from a patient with haematological malignancy to a non-autologous recipient, and there are also limitations in the absence of HLA compatability currently, both these barriers are likely to be overcome in the very near future with the emergence of new technologies. In particular, in vitro maturation of gametes extracted from these tissues is extremely likely to be (and in some cases is already) feasible to provide realistic options for embryo creation, consistent with existing donor gamete programs.

We request consideration of a process allowing patients to have the opportunity, where safe and where feasible, to either donate their tissue (and the gametes extractable from this tissue) or to enter therapeutic relationships to allow others to undergo tissue grafting with a plan for pregnancy for the patient/recipient.

3. Increasing merging of tissue and gamete usage opportunities.

Related to this, as we make progress in success with in vitro maturation of oocytes from ovarian tissue and spermatogonia and immature sperm maturation into spermatozoa, the distinction between tissue and gametes becomes less appropriate and needs to be addressed. The only framework currently available for reference is the *NHMRC Ethical Guidelines for the Use of Assisted Reproductive Technology in Clinical Practice and Research 2017* which recommends that tissue be considered a gamete. Of course (see point 1) we need to be able to do research on these tissues to provide meaningful development of techniques for clinical usage.

We request consideration of the need to review and provide clear yet distinct regulations for tissue and gametes, given the discussion above.

4. Posthumous tissue extraction and use.

While your discussion paper correctly articulates responsibilities for designated hospital officers with respect to approval for posthumous extraction, there is state-to-state inconsistency in the processes, both of extraction and, more importantly, subsequent use eg by a patient's partner. This latter process is loosely covered in state reproductive treatment acts, if they indeed have them (not all states!). However I am not clear that there are documents which describe consistent regulatory requirements for posthumous tissue collection from women, for subsequent use by partners.

National guidance would be enormously helpful regarding extraction (either posthumously or for brain-dead patients) and subsequent use.

I am sure you are already well aware of the need for young cancer survivors to be able to have the best opportunities to conceive as part of living a long and healthy life, using whatever methodologies are required (sometimes requiring a third party). In highlighting above the strong wishes of families of deceased children with cancer to be able to contribute their child's tissue to meaningful research, clear regulations that support their involvement in this decision-making process will help the broader community and support scientific advances that improve clinical management (which requires access to this tissue to move forward).

Thank you for the opportunity to make a submission.

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Catharyn Stern AO

FRANZCOG FRCOG CREI

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