Guidelines for establishing a Tissue Bank

What is a tissue bank?

A tissue bank (also known as a biobank) is a repository of human tissue which is stored (or ‘banked’) for possible future use in research (or education). This tissue is usually made available for use by other researchers.

The person(s) responsible for managing the tissue bank become known as the ‘custodian’ and are responsible for governing the storage, release and destruction of the tissue held in the repository.

Custodians are responsible for ensuring any release of tissue from the bank for research purposes is done so only under appropriate ethics approval for the use of that tissue and in accordance with the relevant legislation.

There are specific legislative and ethical requirements when proposing to collect human biospecimens for research. If you are intending to hold or manage a tissue bank at this institution the University is also responsible for ensuring the governance of the bank meets the expected standards and complies with the relevant legislation.

What does the HREC consider when reviewing a tissue bank?

Like all ethics applications, the HREC will review your tissue bank proposal in line with the key values of the National Health and Medical Research Council (NHMRC)’s National Statement on Ethical Conduct in Human Research, 2007 (The National Statement).

In addition, the following chapters in the National Statement are specifically relevant to the review of a tissue bank:
- Chapter 3.2: Databanks
- Chapter 3.4: Human biospecimens in laboratory based research
- Chapter 3.5: Human Genetics

The HREC will also be reviewing your application to ensure that the tissue is collected, stored and used in accordance with the relevant legislation and standards.

The HREC will consider things such as:
- The training and expertise of research personnel
  including those involved in the collection of biospecimens and the custodian(s) governing the bank i.e. staff training and standard operating procedures
- The mechanism for collecting the tissue
  including the processes for consent, collection from donors and transfer of tissue to the bank
- What personal data you propose to store with the tissue
  including how you will protect donor privacy
- Whether an ethically defensible plan may be required
  An ethically defensible plan is a plan for returning (or withholding) research results to individuals where information might be generated which has potential importance to donors or their blood relatives (see Chapter 3.5 of the National Statement).
- The proposed arrangements for the storage and retention of the tissue
including the relevant biosafety and infection control protocols and how biospecimens are protected against loss (e.g. loss due to storage failure, misplacement or inappropriate removal)

- The protocols for release of the tissue
  including ensuring ethical approval from an appropriate review body is in place for the release of the tissue, the release is consistent with the original consent of the donor and the ethical approval for the tissue bank and that there are processes in place for the transfer of tissue (which may require material transfer agreements)

- The governance of the bank
  including the processes to ensure compliance with relevant laws and guidelines and the financial and other resources required to support the intended processing, storage, distribution and/or use and disposal of biospecimens and the long term financial governance strategy (e.g. process for cessation of the bank should financial support expire)

What do I need to include with my application?

You will need to complete your application in IRMA (the University’s online ethics application system) and ensure the following is attached:

- All documentation relevant to your recruitment and consent process for collecting the tissue, including recruitment notices or invitations, participant information statements and consent forms
- A CV or information on the custodian(s) and any other relevant personnel involved
  A Tissue Banking Protocol which will need to include details on all of the above points that will be considered by the HREC in relation to the management and governance of the proposed tissue bank.

What other requirements do I need to meet?

Financial and governance arrangements should be developed in consultation and with the approval of the Head of School or Unit to ensure the tissue bank can be adequately resourced at the University. You should ensure that consultation regarding governance and resources with the relevant Department or Unit within the University is ongoing throughout the lifespan of the tissue bank.

As with all projects that seek ethical approval, you have responsibilities to report your continued ethical compliance, which includes:

- managing your records and data
- reporting any breaches or adverse events
- seeking approval for any changes to the approved tissue bank protocol
- reporting annually on the governance and compliance of the bank

Legislation and standards governing the collection and use of human tissue

- Human Tissue
  State and Territory Human Tissue Acts govern the consent for donation of tissue
  If collecting samples in NSW: The Human Tissue Act, 1983 (NSW)
- Privacy
  The Privacy Act, 1988 and relevant state and territory legislation
- Standards for storage and retention
  Standards and guidelines which apply to pathology laboratories accredited in Australia are a useful resource when retaining tissue in different forms and determining the appropriate retention periods.
- Ethical standards
  The NHMRC’s National Statement and other policy documents.