HREC Standard Operating Procedure

3.4 Human Tissue Samples

Statement of Intent and Outcomes

The St Vincent's Hospital Melbourne (SVHM) Human Research Ethics Committee (HREC) is committed to fulfilling Section 3.4 of the National Statement on Ethical Conduct in Human Research (2023) by ensuring the appropriate collection, use and storage of human tissue samples for the purposes of research.

Definitions

Human Tissue is defined as any sample of tissue collected from a human, including blood and body fluids.

Procedures

To ensure the appropriate assessment of research protocols involving the collection, use and storage of human tissue samples for research purposes, all members of the SVHM HREC must be familiar with, and apply the principles of the National Statement on Ethical Conduct in Human Research (2023), and in particular, Section 3.2, to the ethical review of research.

The collection, use and/or storage of tissues may be prospective or retrospective. Prospective tissue collection requires that appropriate patient consent is obtained prior to collection, or that the HREC grants a waiver of consent (most often when the tissue collected would be routinely disposed). Retrospective tissue collection may include the use of tissues that have already been stored in either a tissue bank, or pathology.

Retrospective tissue collection from existing sources must be justified in writing at the time of application, and must address whether consent was obtained at the time of collection, and if so, whether it was specified or unspecified.

The HREC may reserve the right to use discretion when considering the collection and/or use of tissues from existing sources, particularly those collected from deceased patients.

All research which incorporates a sub-study involving additional tissue collection for either analysis and / or banking (that is additional to the main study protocol) must provide a separate Participant Information and Consent Form (PICF) for ethical review and approval. This ensures that participants are aware that the tissue collection is additional, and does not preclude participation in the main study.

In most cases, the collection of tissue will be prospective and requires consent. Informed consent must be voluntary and encompass the key principals in the National Statement, as per procedures 1.1, 2.1 and 2.2.

Specifically, researchers should provide clear and comprehensive information about how the tissues will be collected, where they will be stored, the purpose/s for which the tissue will be used and/or disclosed, whether there is potential for the tissue to be used commercially and/or for commercial gain, and whether specific, extended or unspecified consent for future research is being sought.

Consent may be classified as:

1. Specific and limited to the project under consideration
2. Extended and given for the use of data and tissue for use in future related research. This must be closely related to the original project and/or the general area of the initial research.
3. Unspecified for the use of information for unrestricted future research.

Where unspecified consent is sought, the PICF must detail the terms and wide-ranging implications associated with participation, as comprehensively as possible (including examples where possible). This must also be accompanied by a statement which informs participants that the complete scope of potential use is unknown, but that all subsequent, unrelated work involving such information will be reviewed and approved by an appropriate constituted HREC prior to use.

A full copy of the signed PICF for the research project must be stored in the patient's hospital medical records. In the case of Tissue Banks, a copy of the PICF must also be stored within the study file held by the custodian of the tissue bank i.e. the Tissue Bank Trustee and Tissue Bank Coordinator.

The PICF should be supplemented by a manual entry into the participant's hospital medical record that includes the name of the study, who obtained informed consent and what samples the participant has consented to being taken. A further entry should be made when the samples are taken, with specific reference that the samples were collected for research purposes.

It is the responsibility of the Tissue Bank Trustee to ensure that all required documentation is kept in relation to tissue stored in tissue banks. This includes:

- PICFs
- The scope for which the tissue may be used
- Any restrictions on the use of the tissue
- Records detailing the access, use and/or disposal of any samples within the tissue bank, including the names and designations of responsible persons
- HREC approval
- Documentation relating to the effective storage of the samples, e.g. temperature control procedures and the calibration of equipment
- The coding key in the case of samples that are labelled in a re-identifiable format

Documentation must be stored securely in the vicinity of the tissue bank, in lockable filing cabinets and password protected computer systems, in an access controlled area.

If consent cannot be obtained for the prospective collection of tissue, a comprehensive justification is required to demonstrate why it is not possible or practicable. The project should also incorporate measures to ensure an appropriate level of participant protection is assured in regard to the privacy and confidentiality of identifying health or personal information. It must also be demonstrated that the potential benefits associated with the

research outweigh the risks. If this is successfully demonstrated the HREC may waive the requirement for consent.

Access to samples that were stored as part of diagnostic requirements

Hospitals have collections of stored archival samples as required by law for diagnostic and forensic requirements. Use of these samples in research that may advance medical knowledge and/or treatment of a disease may be of benefit to the community and is therefore encouraged.

To access these tissues for research purposes without obtaining further informed consent, an application for a waiver of consent should be made to the HREC. The HREC can only approve such access if the research project has scientific merit, protects the identity of the participant, and has a potential benefit to the community.

Collection of Samples

Samples must be collected in accordance with the declared process as stated in the PICF including the stated amount, frequency and type of tissue collection that has been approved by the HREC.

The PICF must contain full disclosure relating to how the samples will be collected, who will collect the samples and any risks involved in the collection of the samples.

Confidentiality and privacy

Confidentiality must be maintained in all aspects of research. Researchers are responsible for ensuring that confidential information is maintained whilst samples are in their care.

In most cases, samples can be used satisfactorily in research in a re-identifiable or non-identifiable state. This is the preferred method of storage and should be used in all research whenever possible. Researchers should endeavour to develop coding methods that do not use identifying information such as the initials or date of birth of the participant.

Access and use of samples

Samples may only be used in accordance with the statement of use as specified in the PICF and as declared in the submission to the HREC. All types of testing must be clearly declared in the PICF.

Samples can only be sent interstate and/or overseas if the researcher is aware that the jurisdiction to which the samples are being sent is covered by similar laws and codes of conduct as apply in Victoria in relation to the use of human tissue in research. Participants must be made aware of where their sample will be sent, via the PICF.

In accordance with privacy laws, identifiable tissue samples should not be sent outside of the institution at which they were collected. All such samples must be rendered potentially re-identifiable prior to distribution. If it is necessary to be able to identify the participant, the sample and accompanying documentation must be made re-identifiable prior to being shipped. The key to the code must remain within the institution at which they were collected and cannot be distributed to a third party.

Disposal of Tissues

All tissue samples should be disposed of according to the time frame stated in the PICF Form or according to law in regard to samples kept for hospital diagnostic and forensic purposes. Samples must be disposed of in a manner that does not risk the confidentiality of the participant and according to standard laboratory practices.

Documentation relating to the disposal must be kept.

Imported Tissues

Where tissue is imported from another country for use in Australia, researchers should to confirm whether there are ethical and professional policies in that country, or relevant institution, governing the collection of tissue for use in research. This information must be communicated to the HREC with the application form and include any certificate or comments from a local HREC from the institution where the tissue was collected.

If the collection of tissue cannot be confirmed as being collected in line with ethical and professional policies in that country, tissue should not be used in research at SVHM.

Cadaveric Tissue

Any wish expressed by a person about the use of his/her post-mortem tissue for research should be respected. If no such wish can be established, consent for the use of the tissue must be sought from the next of kin.

At the time of seeking this consent, the next of kin must be provided with information regarding what tissues will be collected, what the tissue is being collected for, how the tissue is to be disposed of.

Commercialisation

SVHM prohibits the collection of tissue for research purposes which are intended for commercial sale.

Embryonic Tissue

As part of the Code of Ethical Standards for Catholic Health and Aged Care Services in Australia (2001), embryonic tissue may be used for the purposes of research with consent of the parent. However, embryonic and foetal tissue derived from sources of deliberate abortion may not be used under any circumstance.

Associated Procedures/Instructions

Procedure 2.2 – Obtaining and Honouring Consent
Procedure 2.3 – Qualifying or waiving conditions for consent
Procedure 3.2 – Databanks

Reference Documents

- The National Statement on Ethical Conduct in Human Research (2023)

- Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities: Guidelines for researchers and stakeholders (2018)
- Australian Code for the Responsible Conduct of Research (2018)

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3.4 Human Tissue Samples

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