Purpose:
To describe the requirements for ethical approval of research studies involving the use of human tissue, including the requirement for donor consent for the use of that tissue.

Scope:
Human Research & Ethics Committee (HREC) approval of the use of human tissue may relate to:

- tissue discarded after surgery;
- tissue removed at autopsy;
- tissue collected for 'one-off' research projects;
- tissue stored in ‘tissue banks’; or
- tissue donated or received.

This procedure is based on the principles described more fully in the following documents:

- Human Tissue Act 1982
- National Statement on Ethical Conduct in Human Research 2007 (NS)
- National Code of Ethical Autopsy Practice
- Victorian Government Policies and Practices in Relation to Post-Mortem Examinations

Use of human tissue in research must be in accordance with the NS. Specifically, research involving human tissue must observe the fundamental ethical principle of respect for the tissue donor, including the provision of full information, consent, professional removal of samples and secure storage of the tissue to maintain confidentiality and privacy. The cultural or religious sensitivities of the donor should be considered when soliciting or accepting human tissue samples.

The use of human tissue in research at the Royal Victorian Eye & Ear Hospital (RVEEH) must be carried out in accordance with the RVEEH HREC requirements outlined in this document.

Donor consent for the use of tissue is generally required, but the requirement may be waived by the RVEEH HREC in appropriate circumstances. In general, consent should be given voluntarily, by an appropriately informed person who has the capacity to agree to the activity in question. The intended use of the tissue so donated should be disclosed. The consent itself should specify whether it is enduring or time-limited and consideration should be given to circumstances in which the person who has given consent wishes to revoke such consent. Withdrawal of consent cannot be effective, however, where tissue has already been used.

Disposal of tissue must be compliant with local regulations and should be performed in a sensitive and respectful manner. In general it will be infeasible to return any tissue to the donor or donor’s relatives.

Acquisition of tissue from an external source for research at the Royal Victorian Eye & Ear Hospital and/or supply of tissue to an external source requires review by the HREC through a formal application.

Transfer of tissue either into or from the hospital in relation to HREC approved research projects should be the subject of a Materials Transfer Agreement (MTA).

Procedure
1. Application to use human tissue in research (general)

   It is a requirement of the National Health & Medical Research Council (NHMRC) that all medical or scientific research done on humans or animals must be approved by a properly constituted HREC. Applicants seeking HREC approval to use human tissue in research must complete and forward to the HREC the application forms relevant to their particular research.
1.1 Consent

Documentation of consent by the donor for the use of tissue in research is also required, unless one of the exceptions below applies.

a. Applications for approval of research projects in which unconsented tissue held at the RVEEH will be used must include a request for waiver of the consent requirement addressing the factors identified in sections 2.3.5 to 2.3.8 of the NS. The Committee will then assess the merits of each request.

b. Applications for approval of research projects in which unconsented tissue will be used where the tissue is held external to the RVEEH must include a request for waiver of the consent requirement addressing the factors identified in sections 2.3.5 to 2.3.8 of the National Statement.

Such applications must also include:
- as much information as possible regarding the source of the tissue, the consent policies of the facility where the tissue is stored/archived, the nature of the consent obtained at collection, and if applicable, evidence of approval of the consent process provided by another HREC or,
- a statement as to why this information cannot be provided.

c. The HREC may also request further information from researchers proposing to use unconsented tissue in order to comply with RVEEH or national standards. The Committee will then assess the merits of each application on a case-by-case basis.

1.2 Transfer of tissue

Where tissue is to be obtained from an external source by a RVEEH researcher for use in research at the RVEEH, whether or not as part of collaborative research, approval by the Ethics Committee is required. Evidence of application for approval of the proposed research project by the HREC at any other site(s) must be submitted to the RVEEH HREC before the research can proceed.

Where tissue is to be used in a RVEEH research project and which has been obtained from an external tissue bank and is to be transferred to the research team, the transfer of tissue shall be subject to a MTA. The MTA must document the formal transfer of authority from the external institution to the research team with respect to management of the tissue.

Where tissue is to be provided by RVEEH tissue bank(s) for use in research at another site(s), whether or not as part of collaborative research, approval by the RVEEH HREC is required. Evidence of application for approval of the proposed research project by the HREC at the other site(s) must be included in the application to the HREC for approval of the arrangement.

Any transfer of tissue from RVEEH tissue bank(s) to the control of another site(s) shall be subject to a MTA which documents the formal transfer of authority from the RVEEH to the external institution with respect to management of the tissue.

2. Application to use discarded tissue in research

Applicants applying for clearance to use discarded tissue must apply to the RVEEH HREC.

3. Applications to use tissue stored in tissue banks

Applicants should follow the procedures outlined in the section 'Application to use human tissue in research (general)' above.
Specific issues to consider when applying for HREC approval include:

- the original reason for which the tissue is collected, that is, whether it is donated for the purpose of research or removed as part of a medical procedure performed for a therapeutic purpose;
- whether the proposed use of the samples is different from the original purpose of collection of the stored human tissue samples;
- whether consent was obtained at the time of collection and whether the current proposed use differs from the consented use;
- the research use to which the tissue will be put, that is, whether this will be epidemiological, non-identifying or identifying use, given that the results of such research may have consequences for the donor or the donor’s family;
- whether information of clinical importance to the health of the donor may be discovered;
- whether there may be potential commercial applications for research outcomes and whether the donor, or an authorised third party, understands and approves the research and its objectives.

Issues of religious and cultural sensitivity to the collection, storage and use of particular human tissue samples should also be considered.

5. Applications to conduct genetic research

Applicants should read ‘Chapter 3.5: Human genetics’ of the NS.

Applicants should follow the procedures outlined in the section 'Application to use human tissue in research (general)’ above.

6. Museum Specimens

It is becoming increasingly rare to preserve and store human tissue or organs for teaching, training or as part of a museum or reference collection. Researchers who wish to use human tissue in this way must apply to the HREC directly. Applications will be considered on a case-by-case basis.

References

Human Tissue Act 1982
National Statement on Ethical Conduct in Human Research 2007
National Code of Ethical Autopsy Practice
Policies and Practices for Post-Mortem Examinations

Standard:

NSQHS National Standard 1.1 Implementing a governance system that sets out the policies and procedures and/or protocols

Linked Policy & Procedure:

Research Policy

Approval / Committees:

Human Research & Ethics Committee
Executive Director Medical Services

Evaluation:

This procedure will be reviewed to comply with current legislation, regulations, industry standards, guidelines, codes of conduct and codes of ethics.
### Author / Contributors:

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<tr>
<th>Name</th>
<th>Position</th>
<th>Service / Program</th>
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<tbody>
<tr>
<td>Dr Caroline Clarke</td>
<td>Executive Director</td>
<td>Medical Services</td>
</tr>
<tr>
<td>Dr Marc Sarossy</td>
<td>Chair, Human Research &amp; Ethics Committee</td>
<td>Medical Services</td>
</tr>
<tr>
<td>Kerryn Baker</td>
<td>Administrative Officer</td>
<td>Medical Services</td>
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