PROCEDURE

HREC Procedure: Use of Human Biospecimens in Research

Purpose:

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

Scope:

Human Research Ethics Committee (HREC) approval of the use of biospecimens may relate to biospecimens:

- excess to diagnostic needs and discarded after surgery;
- removed at autopsy;
- collected for 'one-off' research projects;
- stored in biospecimen banks/biobanks/biospecimen banks; or
- donated or received.

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

- Human Tissue Act 1982 (Vic)
- NHMRC National Statement on Ethical Conduct in Human Research (2023 and as amended)
- National Code of Ethical Autopsy Practice (Australian Health Ministers Advisory Committee 2002)
- Victorian Government Policies and Practices in Relation to Post-Mortem Examinations

Use of human biospecimens in research must be in accordance with Chapter 3.2 Human Biospecimens in Laboratory Based Research in the National Statement. Specifically, research involving human biospecimens must observe the fundamental ethical principle of respect for the biospecimen donor, including the provision of full information, consent, professional removal of samples and secure storage of the biospecimen to maintain confidentiality and privacy. The cultural or religious sensitivities of the donor should be considered when soliciting or accepting human biospecimen samples.

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

Donor consent for the use of biospecimens is generally required, but the requirement may be waived by the 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 biospecimen so donated must 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 biospecimen has already been used.

Disposal of biospecimens must be compliant with local regulations and should be performed in a sensitive and respectful manner. In general it will not be feasible to return any biospecimen to the donor or donor's relatives

Acquisition of biospecimens from an external source for research at the Eye and Ear and/or supply of biospecimens to an external source require review by the HREC through a formal application.

Transfer of biospecimens either into or from the hospital in relation to HREC approved research projects must be the subject of a Material Transfer Agreement (MTA).

Risks/Precautions:

None have been identified at the time of last review.

Procedure/Method:

1. Application to use human biospecimens in research (general) must be submitted to the Eye and Ear HREC.

   Applicants seeking HREC approval to use human biospecimens in research must complete and forward the application forms relevant to their particular research to the HREC.

   1.1. Consent

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

   a. Applications for approval of research projects in which unconsented biospecimen held at the Eye and Ear will be used must include a request for waiver of the consent requirement addressing the factors identified in element 3 (sections 3.2.11 and 3.2.12) of the National Statement. The Committee will then assess the merits of each request.

   b. Applications for approval of research projects in which unconsented biospecimen will be used where the biospecimen is held external to the Eye and Ear must include a request for waiver of the consent requirement

addressing the factors identified in sections 3.2.14 of the National Statement.

Such applications must also include:

- as much information as possible regarding the source of the biospecimen, the consent policies of the facility where the biospecimen 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 biospecimen in order to comply with Eye and Ear or national standards. The Committee will then assess the merits of each application on a case-by-case basis.

1.2. Transfer of biospecimens

Where biospecimens are to be obtained from an external source by an Eye and Ear researcher for use in research at the Eye and Ear, whether or not as part of collaborative research, approval by the HREC 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 Eye and Ear HREC before the research can proceed.

Where biospecimen is to be used in an Eye and Ear research project and which has been obtained from an external biospecimen bank and is to be transferred to the research team, the transfer of biospecimen 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 biospecimen.

Where biospecimen is to be provided by Eye and Ear biospecimen bank(s) for use in research at another site(s), whether or not as part of collaborative research, approval by the Eye and Ear 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 biospecimen from an Eye and Ear biospecimen bank(s) to the control of another site(s) shall be subject to a MTA which documents the formal transfer of authority from the Eye and Ear to the external institution with respect to management of the biospecimen.

2. Application to use discarded biospecimen in research

Applicants applying for clearance to use discarded biospecimen must apply to the Eye and Ear HREC.

3. Applications to use biospecimen stored in biospecimen banks

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

- the original reason for which the biospecimen was 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 biospecimen 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 biospecimen 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.

4. Issues of religious and cultural sensitivity to the collection, storage and use of particular human biospecimen samples should also be considered.
5. Applications to conduct genetic research

   Applicants should read Chapter 3.3 Genomic Research of the National Statement.

   Applicants should follow the procedures outlined in the section 'Application to use human biospecimen in research (general)' above.
6. Museum Specimens

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

Outcome:

Staff act in accordance with this document and best practice evidence at the time of review.

Standard:

NSQHS Standard 1: Clinical Governance

Legislation:

Current Legislation may be sourced at: http://www.austlii.edu.au/ or Victorian legislation at: https://www.legislation.vic.gov.au/

- *Human Tissue Act 1982 (Vic)*

References:

- Procedure adapted from the Alfred Hospital Ethics Committee Guidelines – Use of Human Biospecimens in Research (May 2014)
- NHMRC National Statement on Ethical Conduct in Human Research (2023 and as amended)
- National Code of Ethical Autopsy Practice (Australian Health Ministers Advisory Committee (2002)
- Victorian Government Policies and Practices for Post-Mortem Examinations

Linked Policy & Procedure:

Research Policy

Approval/Committees:

Human Research Ethics Committee

Responsible Executive:

Executive Director Medical Services

Document Author:

Manager Research

Procedure Review:

This procedure will be reviewed at least every 3 years.

Evaluation:

This procedure will be reviewed regularly to ensure it complies with current legislation, regulations, industry standards, guidelines, codes of conduct and codes of ethics.

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Details	
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