PROCEDURE

The Use of Human Biospecimens in Research

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TARGET AUDIENCE and SETTING

Principal Investigator and all staff conducting research at, or under the auspices of, Monash Health or which involves Monash Health staff, resources, patients, their tissue samples, test results or medical records.

Monash Health will conduct all research in accordance with legislative requirements and national guidelines.

PURPOSE

Research involving human biospecimens 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.

DEFINITIONS

Human biospecimens: refers to any biological material obtained from a person including tissue, blood, urine, sputum, cells, DNA, RNA and other genetic or genomic material. It also includes derivatives of these materials, such as cell lines and extracted biological products used for research.

Child: means a person who has not attained the age of 16 years.

HREC: means a Human Research Ethics Committee established in accordance with the National Statement on Ethical Conduct in Human Research –(NHMRC 2025).

National Statement: means the National Statement on Ethical Conduct in Human Research (NHMRC 2025).

NHMRC: means the National Health and Medical Research Council.

Tissue: includes tumour biopsies (fresh or paraffin-embedded blocks), samples of normal tissues, blood and serum samples, urine and other body fluids, and tissue derivatives including DNA, RNA, and proteins obtained from human beings.

Unconsented tissue: is tissue for which consent to its use in research was not obtained at the time of collection.

PRECAUTIONS/CONTRAINDICATIONS

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

- Human Tissue Act 1982 (Vic)
- National Statement on Ethical Conduct in Human Research (NHMRC 2025)
- National Code of Ethical Autopsy Practice

PROCEDURE

It is a requirement of the NHMRC that all medical or scientific research done on humans or animals must be approved by a properly constituted HREC or an Animal Ethics Committee (AEC). Applicants seeking HREC approval for the collection and/or use of human biospecimens in research must address the following considerations within the ethics application.

Key ethical considerations when conducting research using human biospecimens:

1. Recruitment/Collection method.
2. Obtaining Informed Consent.
3. Communication plan of research findings or results to donors/participants.
4. Future use of biospecimens and associated data, including any consent for future related or unspecified research.
5. Proposed future genetic, genomic, artificial intelligence (AI) or machine learning uses of biospecimens or associated data, where applicable.

Provision of information to research participants

Where proposed research involving the use of human biospecimens may reveal information that may be important for the health of the donor(s), their blood relatives or their community, whether anticipated or incidental to the scope of the research, researchers should prepare an ethically defensible plan to describe the management of any proposed disclosure or non-disclosure of that information. This plan must be approved by a HREC and should include consideration of the following:

- the circumstances in which the human biospecimens were obtained, including the type of consent provided (see paragraph 2.2.14 of the National Statement) and the manner in which the consent was obtained;
- the likelihood of the research generating information that may be important for the health of the donor(s), their blood relatives or their community;
- whether a recognised intervention exists that can benefit or reduce the risk of harm to the donor(s), their blood relatives or their community from any health impact revealed by this information;
- the resource requirements and infrastructure in place to support the return of information of the kind referred to in (b) and (c) in an ethically appropriate manner;
- whether participants will be given a choice to receive such information;

- whether there is a pathway to identify and recontact the donor(s), their blood relatives or their community, taking into account the relationship between the researchers and the donor(s), if any;
- the potential for sampling or coding errors that may compromise the certainty that the human biospecimens came from a particular donor;
- whether the findings of specific tests being undertaken as part of the research have been produced or validated in an accredited laboratory;
- where clinically significant findings may be generated, researchers should describe the process for validation, return of results, participant choice and any re-contact arrangements.
- who will take responsibility for any subsequent care requirements.
- researchers should clearly describe the options available to participants should they decide to withdraw consent, including whether stored biospecimens and associated data may continue to be used, whether future use can be withdrawn, and any limitations where biospecimens or data have already been distributed, analysed or incorporated into research findings.

Guidance for Research Involving Biospecimens

A Human Research Ethics Application and an application for Site Specific Authorisation is required, prior to commencement of the research. The below guidelines specify, along with the HREC Application Form, what supporting documents must be provided. Please note that following HREC approval, Site Specific Authorisation must be obtained.

1. **Prospective collection of human biospecimens for research with informed consent**
   a) Protocol, that specifies collection method, processing method, storage and distribution or disposal protocol;
   b) Participant Information and Consent Form.
2. **Use of stored human biospecimens for research where informed consent has been obtained in another study or biobank:**
   a) Protocol, detailing the use of the tissue in the specific research study;
   b) Supporting documentation showing the HREC Approval letter/Certificate which provides approval for the collection, storage and use of the tissue in future research;
   c) A copy of the HREC approved Participant Information and Consent Form that demonstrates that participants have provided informed consent for the future use of tissue in research of this nature or unspecified research;
   d) Supporting document from the custodian of the samples that are being retained for future use that the researcher/s have satisfied the requirements of the custodian for the samples to be transferred to the researcher/s.
   e) The application should include whether the research may give rise to information that may be important for the health of the donors, their blood relatives or their community where the identity of the donors will be known to, or can reasonably be ascertained by, those conducting the research or with access to health or research data related to donors.
3. **Use of stored human biospecimens for research where informed consent has not been obtained**
   a) Protocol, detailing the use of the tissue in the specific research study;
   b) An application for a waiver of consent addressing the National Statement on Ethical Conduct in Human Research (NHMRC 2025) Waiver of Consent Criteria.
4. **Human biospecimens obtained after death for research**
   a) Protocol, detailing the use of the tissue in the specific research study;

b) obtain permission from the next of kin or an application for a waiver of consent addressing the National Statement on Ethical Conduct in Human Research (NHMRC 2025) Waiver of Consent Criteria.

5. **Application for the removal and use of tissue from a child**
   a) Protocol, detailing the use of the tissue in the specific research study;
   b) Written informed consent from the parent/guardian must be recorded by the Principal Investigator or delegate;
   c) It must be ensured that both, the parent/guardian and the child are capable of understanding and consenting to providing the providing the biospecimens for use in research;
   d) Under the Victorian Tissue Act it is an offence for a person under 16 years to undergo a procedure for providing regenerative tissue for research purposes. In the event a young person is undergoing a procedure for clinical purposes and there is tissue remaining this is permissible;
   e) The application should include whether the research may give rise to information that may be important for the health of the donors, their blood relatives or their community where the identity of the donors will be known to, or can reasonably be ascertained by, those conducting the research or with access to health or research data related to donors.
6. **Documentation describing storage location, retention period, access controls, security measures and planned destruction or disposal arrangements for biospecimens and associated data.**
7. **Where applicable, documentation describing electronic systems, databases or biobank management systems used to manage biospecimen inventories and associated research data.**
8. **Where biospecimens are stored, processed or analysed by an external biobank, laboratory or service provider, appropriate oversight arrangements must be documented and maintained.**

Governance

Site Specific Authorisation (SSA) application must be submitted by the principal Investigator or delegate, and SSA authorisation must be provided by the Research Support Services team prior to any research commencing at Monash Health.

The SSA application should include a copy of the HREC approval for the use of the human tissue or biospecimens required for the research, along with a copy of all other HREC approved documents.

Material Transfer Agreement

Transfer of tissue between Monash Health tissue bank and an external tissue repository is subject to a Materials Transfer Agreement (MTA) that complies with Monash Health specifications.

BACKGROUND

Use of human biospecimens in research must be in accordance with the National Statement (NHMRC 2025) and the Victorian Human Tissue Act (1982). Specifically, research involving human biospecimens 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 must be considered when soliciting or accepting human biospecimens.

The use of human biospecimens in research at Monash Health must be carried out in accordance this procedure.

Donor consent for the use of tissue is generally required, but the requirement may be waived by the HREC in appropriate circumstances.

KEY STANDARDS, GUIDELINES OR LEGISLATION

1. National Statement on Ethical Conduct in Human Research(2025)
2. ICH GCP E6(R3) Guideline for Good Clinical Practice
3. Human biospecimen Act 1982 (Vic)
4. National Code of Ethical Autopsy Practice
5. Australian Code for the Responsible Conduct of Research(2018)
6. Health Records Act 2001 (Vic)
7. Australian Privacy principles
8. Privacy and Data Protection Act 2014 (Vic)

Document governance	
Policy or Framework supported by this Procedure	Human Research Policy
Executive Sponsor	Chief Medical Officer
Responsible Program, Service, Unit, Department or Committee	Research Support Services
Primary Contact	Research Quality Improvement Manager