
ALFRED HOSPITAL ETHICS COMMITTEE GUIDELINES: USE OF HUMAN BIOSPECIMENS IN RESEARCH

PURPOSE AND SCOPE

This document describes the Alfred Hospital Ethics Committee's requirements for ethical approval of research studies involving the use of human biospecimens¹.

Ethical review of the use of human biospecimens may relate to biospecimens:

- discarded after surgery
- removed at autopsy
- collected for 'one-off' research projects, and/or for storage and use in future research
- sourced from 'biobanks' or other kinds of biospecimen 'archives' (e.g. pathology labs)
- transferred to and from the Alfred.

These Guidelines are based on the principles described more fully in the following documents.

National Statement on Ethical Conduct in Human Research (2007)²

The National Statement consists of a series of Guidelines made in accordance with the National Health and Medical Research Council Act 1992. It provides guidance on:

- databanks (including biospecimen 'banking') (Chapter 3.2)
- the use of human biospecimens for therapeutic purposes (Chapter 3.3)
- the use of human biospecimens in laboratory-based research (Chapter 3.4)
- human genetics (Chapter 3.5)
- collecting human biospecimens from particular categories of participants (Chapters 4.1 to 4.8)

Values and Ethics – Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research 2003

Human Tissue Act 1982³

National Code of Ethical Autopsy Practice (2002)⁴

The Code includes advice for informing and involving families (including written material provided to families), and guidelines for handling and disposing of organs and body parts. The Code recommends that:

- the use of organs for research should be the subject of a separate and specific consent
- approaches to family for consent should be through a counsellor if possible
- the eventual disposal of biospecimens should conform with the family's requests.

Victorian Government Policies and Practices in Relation to Post-Mortem Examinations⁵

Includes model Victorian Guidelines on requesting consent for non-coronial post-mortem examination; a model request form for non-coronial post-mortem (PM) examination; and information for next-of-kin regarding non-coronial post-mortems.

POLICY

Use of human biospecimens in research must be in accordance with the National Statement on Ethical Conduct in Human Research and any relevant legislative requirements. In particular, research involving human biospecimens must observe the fundamental ethical principle of respect for the donor, including the provision of full information and donor consent (where feasible), professional removal of samples and secure storage of these to maintain confidentiality and privacy. The cultural or religious sensitivities of the donor should be considered when soliciting or accepting human biospecimens.

The use of human biospecimens in research at Alfred Health must be carried out in accordance with the Ethics Committee requirements outlined in this document.

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

Where the research might discover information of importance to the health of the donor and/or the donor's blood relatives or their community, an ethically defensible plan to manage the disclosure or non-disclosure of this information must be provided by the researchers and approved by the Ethics Committee.

Acquisition of biospecimens from an external source for research at Alfred Health and supply of biospecimens from Alfred Health to an external source requires review by the Ethics Committee through a formal application.

Transfer of biospecimens between Alfred Health biospecimen banks and an external biospecimen repository is subject to a Materials Transfer Agreement (MTA)⁶ that complies with Alfred Health specifications.

PROCEDURE

APPLICATION TO USE HUMAN BIOSPECIMENS 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 via the appropriate ethical review process established by the relevant institution.

Applicants seeking ethical approval to use human biospecimens in research must complete and forward to the Office of Ethics & Research Governance an application using one of the following pathways⁷:

Full ethics application (NEAF application pathway only)

- for the prospective collection of biospecimens from participants for research (unless the risks associated with the collection or use of the biospecimens are no more serious than discomfort)
- where the research may give rise to information important to the health of the donors, their blood relatives or their community
- for research involving genetic testing
- for proposals to establish a research biobank

Full applications are reviewed by the Ethics Committee, and also by the Research Review Committee if a detailed scientific review is also required, at their monthly meetings.

Low Risk application (with Low Risk Biospecimen Addendum)

- for the prospective collection of biospecimens from participants for research where the risks associated with the collection or use of the biospecimens are no more serious than discomfort (e.g. small blood sample from healthy participant)
- for the use of stored samples if the research is unlikely to give rise to information important to the health of the donors, their blood relatives or their community; and if none of the other exclusions set out in the Low Risk Guide, Checklists 1 & 2 apply.
- where biospecimens would otherwise be discarded (e.g. after surgical operations, surplus to clinical requirements).

Projects considered via the Low Risk review process are reviewed by delegated members of the Ethics Committee. Approved projects are reported to the Ethics Committee, for endorsement of approval, at the next month's meeting.

CONSENT

Consent for collection of biospecimens

Prospective collection of biospecimens from individual donors for research use requires informed consent from the donor.

Consent for use of already-collected biospecimens

Where prior donor consent for the use of biospecimens in research has been obtained, evidence of such a consent process is required (e.g. a PICF from an earlier study with consent for use of samples in future research).

Where consent for use in research was not obtained from donors at the time the biospecimens were collected, a consent waiver may be considered for low or negligible risk research in accordance with the following process:

1. The applicant requests a waiver of the consent requirement addressing the factors identified in section 2.3.5 & 2.3.6 of the National Statement on Ethical Conduct in Human Research (2007). The Committee will then assess the merits of the request.
2. Where the applicant proposes to use unconsented biospecimens from sources **external to Alfred Health**, a waiver of the consent requirement must be requested as above. Such applications must also include:
 - (a) as much information as possible regarding the source of the biospecimens, the consent policies of the facility where the biospecimens are 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,
 - (b) where it is intended to import biospecimens from another country, information about that country/institution's ethical and professional policies governing biospecimens (refer to 3.4.13 of the National Statement), or,
 - (c) a statement as to why this information cannot be provided.
3. The Ethics Committee may also request further information from researchers proposing to use unconsented biospecimens in order to comply with Alfred Health or national standards.

The Committee will then assess the merits of each application on a case-by-case basis.

Consent for use of biospecimens obtained after death for research

Cadaveric (post-mortem, autopsy) biospecimens may not be used for research purposes unless:

- (a) this is in accordance with any wish expressed by the donor, or,
- (b) (if no such wishes are discovered) consent has been obtained from the senior available next of kin. (NS 3.4.5)

TRANSFER OF BIOSPECIMENS

Where biospecimens are to be obtained from an external source by an Alfred Health researcher for use in research at Alfred Health, whether or not as part of collaborative research, approval by the Alfred Hospital Ethics Committee is required. Evidence of application for approval of the proposed research project by the Human Research Ethics Committee at any other site(s) must be submitted to Alfred Health's ethics committee before the research can proceed.

Where biospecimens to be used in an Alfred Health research project are to be obtained from an external biobank and are to be transferred to the control of Alfred Health biobanks, the transfer of biospecimens shall be subject to a Material Transfer Agreement (MTA). The MTA must be completed in accordance with the policies and procedures of the Alfred Health

biobanks and must document the formal transfer of authority from the external institution to the Alfred Health biobanks with respect to management of the biospecimens. Where biospecimens are to be provided by Alfred Health biobanks for use in research at another site(s), whether or not as part of collaborative research, approval by the Alfred Hospital Ethics Committee is required. Evidence of application for approval of the proposed research project by the Human Ethics Research Committee at the other site(s) must be included in the application to the Ethics Committee for approval of the arrangement.

Any transfer of biospecimens from Alfred Health biobanks to the control of another site shall be subject to a Material Transfer Agreement (MTA) completed in accordance with the policies and procedures of the Alfred biobanks and which documents the formal transfer of authority from the Alfred to the external institution with respect to management of the biospecimens.

SOME ETHICAL ISSUES FOR APPLICANTS TO CONSIDER

Specific issues to consider when applying for ethics approval include:

- the original reason for which the biospecimens are/were 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 biospecimens
- 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 biospecimens will be put; that is, whether this will be epidemiological, non-identifying use, or identifying use, taking into consideration that the results of such research may have consequences for the donor or the donor's blood relatives or their community
- whether information of clinical importance to the health of the donor and/or the donor's blood relatives or their community 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 of the research and its objectives.

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

APPLICATIONS TO CONDUCT GENETIC RESEARCH

Applicants should read 'Chapter 3.5: Human Genetics' of the National Statement on Ethical Conduct in Human Research (2007).

Applicants should submit a full ethics application using the NEAF (National Ethics Application Form) pathway.

STORAGE OF BIOSPECIMENS FOR EDUCATIONAL PURPOSES

It is becoming increasingly rare to preserve and store human biospecimens (e.g. tissue or organs) for teaching, training or as part of a museum or reference collection. Researchers who wish to use human biospecimens in this way must apply to the Ethics Committee directly via an 'Application by Letter'. Applications will be considered on a case-by-case basis.

FURTHER INFORMATION

Any enquiries regarding submission forms and processes, documentation, or variations to the procedures outlined above should be directed to:.

Office of Ethics & Research Governance
The Alfred
Commercial Road
Melbourne VIC 3004
t: +613 9076 3619
f: +613 9076 8841
e: research@alfred.org.au

REFERENCES

Alfred Health Ethics & Research Governance Unit
<http://www.alfredresearch.org>

Human Tissue Act 1982
http://www.austlii.edu.au/au/legis/vic/consol_act/hta1982160/

National Code of Ethical Autopsy Practice
<http://www.health.sa.gov.au/autopsy-organs/documents/National%20Code%20of%20Autopsy%20Practice.pdf>

National Statement on Ethical Conduct in Human Research (2007)
<http://www.nhmrc.gov.au/publications/synopses/e72syn.htm>

Victorian Government Policies and Practices in Relation to Post-Mortem Examinations
<http://www.health.vic.gov.au/humantissue/postmortem>

NOTES

¹ For the purposes of this document, the term 'biospecimens' is used for conciseness and refers to 'human biospecimens'.

- The term 'Human biospecimens' is defined in the National Statement as: "any biological material obtained from a person including tissue, blood, urine, sputum and any derivative from these including cell lines. It does not include non-human biological material such as micro-organisms that live on or in a person." [NS, Chapter 3.4, Introduction]
- 'Biospecimens' 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.

² <http://www.nhmrc.gov.au/publications/synopses/e72syn.htm>

³ http://www.austlii.edu.au/au/legis/vic/consol_act/hta1982160/

⁴ <http://www.health.sa.gov.au/autopsy-organs/documents/National%20Code%20of%20Autopsy%20Practice.pdf>

⁵ <http://www.health.vic.gov.au/humantissue/postmortem>

⁶ A Material Transfer Agreement is a legal agreement between two parties that is used to define the terms and conditions under which materials (usually for experimental research) may be transferred from one party to the other.

⁷ Application forms and guidelines for submissions to the Alfred Ethics Committee can be downloaded from <http://www.alfredresearch.org/ethics/applicat.htm> for full and Low Risk applications.