
ALFRED ETHICS COMMITTEE POLICY: USE OF HUMAN TISSUE IN RESEARCH

PURPOSE AND SCOPE

This document describes the Alfred Hospital 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.¹

Ethics Committee 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'
- tissue transferred to and from the Alfred.

This policy is based on the principles described more fully in the following documents.

- **Human Tissue Act 1982**²
- **National Statement on Ethical Conduct in Human Research (2007)**³
The National Statement consists of a series of Guidelines made in accordance with the National Health and Medical Research Council Act 1992. Section 15 details the use of human tissue for research. The Human Research Ethics Handbook provides further detail and commentary on the National Statement⁴.
- **National Code of Ethical Autopsy Practice**⁵
On 1 August 2001 Australian Health Ministers directed the Australian Health Ministers' Advisory Council (AHMAC) to establish a subcommittee to continue the work recently completed by the Australian Health Ethics Committee (AHEC) on organs retained at autopsy. The Code will be a public document and will inform families and the community. Advice for informing and involving families has been developed.
- **Victorian Government Policies and Practices in Relation to Post-Mortem Examinations**⁶
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 tissue in research must be in accordance with the National Statement on Ethical Conduct in Research Involving Humans. 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 Alfred must be carried out in accordance with the Ethics Committee requirements outlined in this document.

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

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

Transfer of tissue between Alfred tissue banks and an external tissue repository is subject to a Materials Transfer Agreement (MTA)⁷ that complies with Bayside Health specifications.

PROCEDURE

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 ethics committee.

Applicants seeking Ethics Committee approval to use human tissue in research must complete and forward to the Ethics Committee 'Module 1 Core application form', 'Module 3 Use of human tissue samples', 'Module 6 Alfred-specific financial details' and any other module/s relevant to their particular research.⁸

The specific requirements for Ethics Committee approval for the use of discarded human tissue, whole human organs and tissue obtained at autopsy, museum specimens, tissue banks or genetic testing are described in separate sections below.

Consent

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

1. Applications for approval of research projects in which unconsented tissue **held at the Alfred** will be used must include a request for waiver of the consent requirement addressing the factors identified in section 15.8 of the National Statement on Ethical Conduct in Research Involving Humans (1999), see Appendix A. The Committee will then assess the merits of each request.
2. Applications for approval of research projects in which unconsented tissue will be used where the tissue is **held external to the Alfred** must include a request for waiver of the consent requirement addressing the factors identified in section 15.8 of the National Statement. Such applications must also include:
 - (a) 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,
 - (b) 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 tissue in order to comply with Alfred or national standards. The Committee will then assess the merits of each application on a case-by-case basis.

Transfer of tissue

Where tissue is to be obtained from an external source by an Alfred researcher for use in research at the Alfred, 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 Human Research Ethics Committee at any other site(s) must be submitted to the Alfred committees before the research can proceed.

Where tissue to be used in an Alfred research project is to be obtained from an external tissue bank and is to be transferred to the control of Alfred tissue banks, the transfer of tissue shall be subject to a Materials Transfer Agreement (MTA). The MTA must be completed in accordance with the policies and procedures of the Alfred tissue banks and must document the formal transfer of authority from the external institution to the Alfred tissue banks with respect to management of the tissue.

Where tissue is to be provided by Alfred tissue banks for use in research at another site(s), whether or not as part of collaborative research, approval by the Alfred 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 tissue from Alfred tissue banks to the control of another site shall be subject to a Materials Transfer Agreement (MTA) completed in accordance with the policies and procedures of the Alfred tissue banks and which documents the formal transfer of authority from the Alfred to the external institution with respect to management of the tissue.

APPLICATION TO USE DISCARDED TISSUE IN RESEARCH

Applicants should complete the '[Application to use discarded tissue in research](#)' form, and follow the directions for submission.

The review and approval of applications to utilise discarded tissue from surgical operations, when permission has been provided by the patient, may be delegated to an appointed senior medical officer. The appointed senior medical officer will assess the application to ensure compliance with Ethics Committee guidelines and if Ethics Committee criteria are met, approve the application. Approval is usually granted for a two-year period. Researchers are required to submit a progress report to the senior medical officer on the anniversary of their approval. Researchers can apply for an extension of approval if required.

The appointed senior medical officer will report to the Ethics Committee every twelve months.

APPLICATION TO USE WHOLE HUMAN ORGANS AND TISSUE OBTAINED AT AUTOPSY

Applicants should complete the '[Application to use discarded tissue in research](#)' form, and follow the directions for submission.

The review and approval of applications to utilise discarded tissue from autopsy, when permission has been provided by the next of kin, may be delegated to an appointed senior medical officer. The appointed senior medical officer will assess the application to ensure compliance with Ethics Committee guidelines and if Ethics Committee criteria are met, approve the application. The appointed senior medical officer will report to the Ethics Committee every twelve months.

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 ethics committee 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 use, 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 of 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.

APPLICATIONS TO CONDUCT GENETIC RESEARCH

Applicants should read 'Section 16 Human Genetic Research' of the National Statement on Ethical Conduct in Research Involving Humans.⁹

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

In addition, applicants will need to complete 'Module 4 Human genetic research'.

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 Ethics Committee directly. 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 the Ethics Manager.

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REFERENCES

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

Human Research Ethics Handbook
http://www.nhmrc.gov.au/hrecbook/02_ethics/06.htm

Human Tissue Act 1982
<http://www.dms.dpc.vic.gov.au>

National Code of Ethical Autopsy Practice
<http://www.dhs.sa.gov.au/autopsy-organs/code.asp>

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.dhs.vic.gov.au/phd/postmortem/>

NOTES

¹ For the purposes of this document:

- '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.
- 'Research' includes activities other than diagnostic, biochemical, or pathological examinations performed as a component of patient care, audit type activities and calibration of equipment. It includes the evaluation of new diagnostic, prognostic or biological techniques in a series of patients.
- 'Unconsented' tissue is tissue for which consent to its use in research was not obtained at the time of collection.

² <http://www.dms.dpc.vic.gov.au>

³ <http://www.nhmrc.gov.au/publications/synopses/e72syn.htm>

⁴ http://www.nhmrc.gov.au/hrecbook/02_ethics/06.htm

⁵ <http://www.dhs.sa.gov.au/autopsy-organs/code.asp>

⁶ <http://www.dhs.vic.gov.au/phd/postmortem/>

⁷ A Materials 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.

⁸ Application forms and guidelines for submissions to the Alfred Ethics Committee can be downloaded from <http://www.alfredresearch.org/ethics/applicat.htm>

⁹ <http://www.health.gov.au/nhmrc/publications/humans/part16.htm>

APPENDIX A

National Statement on Ethical Conduct in Research Involving Humans Part 15 - Use of Human Tissue Samples

Respect for persons

Institutional responsibility

Where consent would be required

Where the requirement for consent could be waived

Confidentiality

Samples of tissue, including blood and other body fluids, are collected from persons in hospitals and other health care institutions in a variety of circumstances. Samples collected for diagnostic purposes in the course of treatment may also be used for teaching or quality assurance activities and for research. Directors of Pathology have traditionally exercised, and should continue to exercise, discretion in the use of clinical samples in the interpretation and development of laboratory procedures. After the original purpose for which samples were collected has been achieved, the residual tissue may be discarded. Hospitals and pathology laboratories are required by law to retain archival samples for diagnostic or forensic purposes. Accordingly, most hospitals have collections of stored samples, the use of which in research may lead to important advances in the understanding and treatment of disease.

The principles of ethical conduct and review described in 1. Principles of Ethical Conduct and 2. Human Research Ethics Committees of this Statement should govern all such research.

This Statement refers to such tissue samples as are referred to above but excludes fetal tissue, reproductive tissue and tissue from autopsy to which additional guidelines or legislation may apply. ^{Footnote 7}

Where human tissue is to be used in any research, researchers and Human Research Ethics Committees (HRECs) need to be satisfied that the research proposal conforms to the guidelines below. The additional ethical issues that arise in genetic research that uses human tissue need to be addressed in conformity with 16. Human Genetic Research.

Respect for persons

15.1 The fundamental ethical principle to be observed in the use of human tissue samples for research is respect for the person and this is reflected in:

- (a) the provision to the donor of full information about the purposes of the sampling, and/or the plan of the research proposal;
- (b) consent by the donor to the use of the sample;
- (c) the professional removal of samples to be used;
- (d) provision for appropriate and secure storage of tissue samples;
- (e) provision and maintenance of appropriate and secure systems to ensure confidentiality and privacy in the recording, storage and release of data; and
- (f) accountability in the care and usage of such samples.

15.2 It is important for institutions or organisations in conjunction with their HRECs to determine when consent should be sought for the use of tissue in research or when a waiver of the requirement for consent may be considered.

Institutional responsibility

15.3 Institutions or organisations at which research involving the use of human tissue samples is conducted, should develop policies about the conduct and ethical approval of such research which conform to relevant legislation and are consistent with this Statement. Those policies need to provide guidance to researchers and HRECs in relation to soliciting or accepting voluntary donations of, and specifying conditions for, the use of human tissue samples in research. In their development, relevant considerations include:

- (a) the source, nature and cultural or religious sensitivity of the sample;
- (b) the original reason for its collection; and
- (c) the purpose of the research.

Where consent would be required

15.4 Where human tissue samples are collected for purposes including research, consent for their use in research is generally required.

15.5 Consent should:

- (a) be voluntary; and
- (b) be specific to the purpose for which the tissue is to be used; and
- (c) follow the provision of full information about the project, including advice as to whether, after completion of the research for which consent is given, tissue samples are to be stored.

15.6 Where it is proposed that human tissue samples previously collected and stored with consent for research be used for a research purpose different from that of the previously approved research, consent for the use of the tissue samples in the new research should generally be obtained. An HREC may waive the requirement for consent in conformity with paragraph 15.8.

15.7 Where it is proposed to use tissue samples which have been:

- obtained for or held in storage following, or in association with, clinical investigations;
- held in archives or banks; or
- removed in the course of a clinical procedure and not required for any clinical purpose, in research that may lead to harm, benefit or injustice to a donor of such tissue, consent of those donors should normally be obtained.

Where the requirement for consent could be waived

15.8 An HREC may sometimes waive, with or without conditions, the requirement for consent. In determining whether consent may be waived or waived subject to conditions, an HREC may take into account:

- the nature of any existing consent relating to the collection and storage of the sample;
- the justification presented for seeking waiver of consent including the extent to which it is impossible or difficult or intrusive to obtain specific consent;
- the proposed arrangements to protect privacy including the extent to which it is possible to de-identify the sample;
- the extent to which the proposed research poses a risk to the privacy or well being of the individual;
- whether the research proposal is an extension of, or closely related to, a previously approved research project;
- the possibility of commercial exploitation of derivatives of the sample; and
- relevant statutory provisions.

Confidentiality

15.9 Wherever human tissue samples or related information are gathered in the course of a professional relationship, professional confidentiality must be observed. Identification of samples must be limited to the minimum necessary to achieve the stated objectives of the study. If the study may produce information relevant to the health and well being of the person from which it was derived, the HREC may require procedures to allow participants to be identified to facilitate appropriate follow-up.

Footnote

⁷ For guidelines on fetal tissue see *Supplementary Note 5 - The human fetus and the use of human fetal tissue (1983)*.