RMIT University
Human Research Ethics Committee

Guidelines on Use of Human Tissue in Research.

Purpose
This set of guidelines document the conditions under which human tissue can be used in research conducted at RMIT University.

Scope
These guidelines apply to all staff and students employed or enrolled at RMIT University or any RMIT subsidiary conducting research involving the use of human tissue.

Human tissue includes blood and body fluids provided voluntarily or non-voluntarily for diagnostic and other purposes.

Policy
RMIT Human Research Ethics Committee (HREC) approval for the use of human tissue in research is required. Applications for research involving human tissue may be considered at the school and portfolio level but approval can only be given by HREC. Research involving human tissue is normally considered as being at the highest ethical risk level.

Use of human tissue in research will only be permitted when it is consistent with the principles of ethical conduct described in the National Statement on Ethical Conduct in Human Research (2007). Research involving human tissue must observe the fundamental ethical principle of respect for the tissue donor, including the provision of full information, professional removal of samples, consent and secure storage of data.

Donor consent for the use of tissue is generally required, but the requirement may be waived by the HREC in appropriate circumstances. According to the National Statement consent may be waived in certain circumstances including where:

- The benefits from the research justify any risks of harm associated with now seeking consent.
- It is impracticable to obtain consent.
- There is no known or likely reason that participants would not have consented if they had been asked.
- There is sufficient protection of their privacy.
- There is an adequate plan to protect the confidentiality of data.

Procedure
- Where a research project involves human tissue a detailed scientific protocol will be submitted with the application.
- Issue of consent must be addressed in the application. Application must include details of method of gaining consent or a request for waiver of consent.
- Applications are to be assessed by HREC on a case-by-case basis. Applicants may be requested to provide more information before a final decision is made.
- The applications must include information on how and from where the tissue is being sourced.
- Issues of religious and cultural sensitivity to the collection, storage and use of particular human tissue should also be considered.
- Human Research Ethics approval from the organisation providing the tissue should normally be available before RMIT HREC will grant approval. Where approval from the provider institute is not available at the time of applying RMIT can grant conditional approval.
- All approved applications will be recorded on a database for research using human tissue.

K:\RMIT Ethics\HREC\Web documents\human tissue guidelines.doc
Approved at HREC 06/07
Database
A database including a record of all tissue being used at RMIT will be maintained. The database will include a record of all projects at RMIT involving the use of human tissue in research. Details to be recorded include:
- Project title.
- Primary researcher/investigator.
- School/centre.
- HREC and any other institutional approval.
- Consent conditions.
- Any socio-cultural conditions impinging on use.
- Source of the tissue.
- Method of disposal of tissue.
The database will be maintained by the secretary of HREC.

Other documents