RS55 – Human Research Ethics Clearance

Records relating to ethics clearance for research involving human subjects, including clinical research.

This records class is a Personal Information Bank.

Content & Scope

The University requires all research involving human participants conducted by its students, staff and faculty, on or off-campus, to undergo prior ethics review and clearance through the Office of Research Ethics. Depending on the risk level and type of project, the ethics review may be conducted by the director or managers of the Office of Research Ethics, by the Human Research Ethics Committee, or the Clinical Research Ethics Committee.

The records include the agendas, minutes, and working papers of the research ethics committees, research ethics application files and associated attachments, modifications to the research, results of ethics review, documentation regarding formal and informal appeals of ethics review decisions, reports on adverse events, annual progress reports, and associated correspondence.

Responsible Unit

- Office of Research Ethics
- Researchers

Information Steward

Vice-President, Research & International

Information Confidentiality Classification

Restricted.

Retention

- Office of Research Ethics:
  - Clinical trials: 25 years after data collection is complete or ethics clearance is denied.
  - All other human research: 10 years after data collection is complete or ethics clearance is denied.
- Researchers: retain a copy of the ethics clearance certificate until the corresponding data is destroyed.

Disposition

Archives Selection.

Records which are not selected for the University archives must be securely destroyed at the end of their retention period.
Archival Records

The minutes of research ethics committees are of long-term historical value to the University. Please contact the University Records Manager for further assistance with these records at the end of their retention period.

Authority

- University of Waterloo Act, 1972
- Tri-Council Policy Statement: Ethical Conduct of Research in Humans, Article 1.1
- University of Waterloo Statement on Human Research
- Food and Drug Regulation, C. R. C., c. 870, c.05.012
- Medical Devices Regulations (SOR/98-282)
- Health Canada Guidance for Records Related to Clinical Trials (Guide 0068), 2006

Retention Rationale

The Food and Drug Regulations c.05.012 specifies 25 year retention for records related to clinical trials. Selected records have long-term historical value.

Other Units with Copies

- Committee members.
- Course instructors (for course-based student projects).

Retention of Copies

- Committee members: Until relevant committee decisions have been made
- Course instructors: 1 year after the end of the term in which the project was completed.

Disposition of Copies

Secure Destruction.

Approval Date

14 January 2011