

OP8600 RESEARCH ETHICS ADMINISTRATION

Records documenting the activities of the Research Ethics Boards in relation to research proposals involving the use of human subjects.

Includes the review of research proposals.

Also includes developing and reviewing policies regarding ethical issues relating to the use of human subjects in research projects.

Example documents: Research Ethics Application Form, Research Ethics Change Form, Annual Renewal Form, Adverse Event Report Form, Ethics Approval Letter, correspondence.

University Records exist in both physical and electronic formats, such as paper, email or data in a database. Paper records may or may not contain information that is duplicated in an electronic system. For technical reasons the retention assigned to the electronic records may be different from the retention of physical records.

OPR - Director, Research Ethics Compliance

(Unless otherwise assigned, see below)

| NO. | TYPE OF RECORD | Active yr(s) | Semi-Active | Dis-position | Personal Info |
|-----|------------------------------------|--------------|-------------|--------------|---------------|
| 10 | Research Ethics Board Files | AY + 3 | 2 | AR | NO |

Include meeting minutes, meeting agenda package, and annual reports Not used for the review of research ethics applications, see other secondaries under OP8600.

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|----|---|--------|---|---|-----|
| 31 | Health Sciences Research Ethics Board Applications Files | ET + 3 | 7 | D | YES |
|----|---|--------|---|---|-----|

Includes Ethics Submission Form, Information/Consent Form, Study Protocol, Investigator Brochure or Product Monograph, Data Summary and Signature Sheet, Information Sheet, Curriculum Vitae for Investigator, Annual Renewal Form, Research Ethics Amendment Form, Adverse Event Report Form, Ethics Approval Letter

ET Definition: Trial closed or research concluded.

GLOSSARY

FY = Fiscal Year (May 1 to April 30)

AY = Academic Year (September 1 to August 31)

CY = Calendar Year (January 1 to December 31)

ET = Event Trigger

OPR = Office of Primary Responsibility

DP = Special Disposition Plan

AR = Transfer to Archives

D = Destroy / Delete

PIB = Personal Information Bank

OP8600 was approved on 10/06/2008.

| NO. | TYPE OF RECORD | Active yr(s) | Semi-Active | Dis-position | Personal Info |
|---|---|--------------|-------------|--------------|---------------|
| 32 | General Research Ethics Board Applications Files | ET + 3 | 7 | D | YES |
| <p><i>Includes GREB Application Form, Letter of Information, Consent Form, Study Protocol / Outline of Project, Unit REB approval letter, Data Summary and Signature Sheet, Questionnaires / Sample Data Collection Instruments, Research Ethics Change Form, Annual Renewal Form, Adverse Event Report Form, Ethics Approval Letter</i></p> <p><i>ET Definition: Research concluded.</i></p> | | | | | |
| 33 | Course-based Research Ethics Applications Files | ET + 3 | 7 | D | YES |
| <p><i>Used for course-based student research projects. Include application files, GREB's feedback to Unit REBs.</i></p> <p><i>ET Definition: Research concluded.</i></p> | | | | | |
| 34 | Research Ethics Monitoring Program Files | ET + 3 | 7 | D | YES |
| <p><i>Records include site visit checklist, correspondence, site visit reports</i></p> <p><i>ET Definition: Trial closed or research concluded.</i></p> | | | | | |

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