



PROCEDURES FOR THE ETHICAL REVIEW OF RESEARCH INVOLVING HUMAN PARTICIPANTS

As per *Policy for the Ethical Review of Research Involving Human Participants (VPRGS-3)*

These Procedures are related to the *Policy for the Ethical Review of Research Involving Human Participants (VPRGS-3)* and reflect current practices concerning:

Mandate, Composition and Quorum of the Concordia University Human Research Ethics Committee (UHREC).....	2
Composition and Mandate of the UHREC College of Ethics Reviewers	4
Mandate and Composition of the University Human Research Ethics Appeal Board (UHREAB)	4
Mandate of the Ethics Unit	5
Initial Ethics Review Process	5
Negative Decisions, Requests for Reconsideration, and Appeals	7
Continuing Ethics Review Process	7
Collaborative Research Teams	8
Miscellaneous UHREC processes	9

PROCEDURES FOR THE ETHICAL REVIEW OF RESEARCH INVOLVING HUMAN PARTICIPANTS

Page 2 of 9

Mandate, Composition and Quorum of the Concordia University Human Research Ethics Committee (UHREC)

The mandate of UHREC is to review the ethical acceptability of research involving human participants conducted within the jurisdiction or under the auspices of the University, that is, by its students, faculty and staff, regardless of whether the research is funded or not, or where the research is conducted.

The UHREC will review all faculty and staff research, as well as course-based and student research where the risk to participants is greater than minimal. Research where the risk to participants is greater than minimal is reviewed at face-to-face meetings of the UHREC. Minimal risk faculty and staff research is reviewed by expedited review by members of UHREC.

Minimal risk student research conducted exclusively for pedagogical purposes may be reviewed according to procedures established by each academic department.

The Vice-President, Research and Graduate Studies shall appoint the members of the UHREC, including a Chair and a Vice-Chair, normally for three-year terms.

The UHREC shall be composed of at least five (5) members, including men and women, and, at a minimum:

- One (1) representative from each of the University's Faculties (Arts and Science, Engineering and Computer Science, Fine Arts and the John Molson School of Business). Faculty representatives shall be chosen such that the committee has appropriate expertise to review research from the full range of disciplines and methodologies at Concordia.
- One (1) member knowledgeable in ethics
- One (1) member knowledgeable in the relevant areas of law. This member must not be a member of the University's Office of the General Counsel or the University's Insurance/Liability Specialist
- One (1) community member with no affiliation with the University
- One (1) medical doctor with relevant knowledge and expertise in medical and health related research

PROCEDURES FOR THE ETHICAL REVIEW OF RESEARCH INVOLVING HUMAN PARTICIPANTS

Page 3 of 9

Each member is appointed to only one of the roles listed above.

If the UHREC reviews a research project that requires expertise not available from its members, it shall consult ad-hoc advisors from within the University or the external community. Such advisors shall not be counted in the UHREC quorum or vote on UHREC decisions.

Members may be nominated either as regular or alternate members of UHREC. Regular members are expected to attend all UHREC meetings and to contribute to performing expedited reviews. Alternate members are asked to attend UHREC meetings when a regular member is unable to attend, and to contribute to performing expedited reviews.

Before participating in the activities of the UHREC, new members shall attend an orientation session on research ethics and the University's relevant policies and procedures.

If research requires approval of the full committee, it shall not be reviewed unless there is quorum at the committee meeting. Quorum is defined as follows:

- At least five members are present
- At least two Faculty representatives are present. The faculty members present must have sufficient knowledge and expertise in the relevant disciplines and methodology to assess the research under review, unless other members present have such knowledge or expertise
- At least one community representative is present
- At least one member knowledgeable in ethics is present
- At least one member knowledgeable in relevant areas of law is present
- If medical research is being reviewed, at least one medical doctor is present

Ordinarily, the UHREC will reach decisions by consensus. Where it may be difficult for UHREC members to reach consensus, the decision of the UHREC shall be by simple majority of members present at the meeting.

PROCEDURES FOR THE ETHICAL REVIEW OF RESEARCH INVOLVING HUMAN PARTICIPANTS

Page 4 of 9

Composition and Mandate of the UHREC College of Ethics Reviewers

The UHREC College of Ethics Reviewers will review the ethical acceptability of minimal risk student research conducted within the jurisdiction or under the auspices of the University.

In consultation with the Office of Research, the chair of each academic department whose students conduct research involving human participants shall appoint members of the department to serve on the UHREC College of Ethics Reviewers for one-year terms.

The UHREC College of Ethics Reviewers shall review protocols by expedited review. If members of the UHREC College of Ethics Reviewers review a research project that requires expertise beyond their own, they may consult ad-hoc advisors or refer the study to the UHREC.

Mandate and Composition of the University Human Research Ethics Appeal Board (UHREAB)

The Mandate of UHREAB is to review, upon request from the researcher, negative decisions of the UHREC, that is, decisions where the study is assigned a status of Conditional Approval, Queries or Not Approved, and any requests for reconsideration have been rejected.

The Vice-President, Research and Graduate Studies shall appoint a University Human Research Ethics Appeal Board (UHREAB) on an ad-hoc basis.

The UHREAB shall consist of at least four (4) members, including, at a minimum, one (1) external community member, one (1) member knowledgeable in ethics, and one (1) member familiar with the research area in question.

Researchers may request an appeal of a negative decision by writing to the Vice-President, Research and Graduate Studies requesting that the decision be reviewed by the UHREAB.

The researcher and the chair of the UHREC may submit any relevant documentation to the UHREAB and appear before the UHREAB.

The UHREAB may reverse, modify or maintain the decision of the UHREC.

PROCEDURES FOR THE ETHICAL REVIEW OF RESEARCH INVOLVING HUMAN PARTICIPANTS

Page 5 of 9

Mandate of the Ethics Unit in the Office of Research

The Mandate of the Ethics Unit is to:

- Advise researchers of ethical requirements around research involving human participants and applicable laws, regulations and internal and external policies
- Assist researchers in submitting their studies for ethics review
- Manage the ethics review process and maintain documentation of the process to demonstrate compliance
- Provide administrative support to UHREC
- Liaise with other units in the Office of Research

Initial Ethics Review Process

Researchers must obtain a Certificate of Ethical Approval that covers their research before conducting activities involving human participants.

Researchers must apply for a Certificate of Ethical Approval by submitting a Summary Protocol Form (SPF) and all supporting documentation to the Ethics Unit. If the research implies greater than minimal risk to participants, the researcher must demonstrate that it has been reviewed for scholarly merit. Funding through a competitive peer-review process, successful defense of a thesis or dissertation proposal, or a Scholarly Review Form are accepted as evidence of such review.

Researchers may consult with the Ethics Unit or the chair or vice-chair of UHREC for guidance on procedures or substantial issues at any time.

The Ethics Unit will initially assess if studies submitted for review are minimal risk or greater than minimal risk. Studies assessed as minimal risk will be assigned for expedited review, which are reviews conducted by at least one member of the UHREC, or of the UHREC College of Ethics Reviewers as appropriate. Studies assessed as greater than minimal risk will be reviewed by UHREC at a convened meeting. If a study is initially assessed as minimal risk, but the reviewer assesses it as greater than minimal risk, or if the reviewer feels that the study involves ethical issues that should be examined by the full committee, it will be reviewed by UHREC at a convened meeting.

PROCEDURES FOR THE ETHICAL REVIEW OF RESEARCH INVOLVING HUMAN PARTICIPANTS

Page 6 of 9

UHREC may determine that certain categories of research must be reviewed by the full committee even though they could qualify as minimal risk.

The UHREC or UHREC College of Ethics Reviewers shall assign each study one of the following statuses:

- a. **Approved:** a Certificate of Ethical Acceptability is issued and any research funds are released.
- b. **Approved with Comments:** a Certificate of Ethical Acceptability is issued, and any research funds are released. The approval also includes comments that the reviewers felt should be brought to the attention of the researcher.
- c. **Conditional Approval:** it was determined that the study could be approved if certain specific conditions are met. If the study was reviewed by expedited review, the Ethics Unit validates that the conditions have been satisfied. If the study was reviewed by the full committee, the chair or vice-chair validates that the conditions have been satisfied. Only when the conditions have been met will a Certificate of Ethical Acceptability be issued and any research funds released.
- d. **Queries:** it was determined that additional information was required to complete the review, or that substantial changes would have to be made for the research to be deemed acceptable. If the study was reviewed by expedited review, the reviewer who initially assessed the study reviews the researcher's responses and assigns the study a new status as appropriate. If the study was reviewed by the full committee, the responses are assessed by the full committee, and a new status is assigned as appropriate.
- e. **Not Approved:** it was determined that the study as proposed is not acceptable.

PROCEDURES FOR THE ETHICAL REVIEW OF RESEARCH INVOLVING HUMAN PARTICIPANTS

Page 7 of 9

Negative Decisions, Requests for Reconsideration, and Appeals

If a study is assigned a status of Conditional Approval, Queries, or Not Approved, the researcher may request reconsideration of specific points or the decision as a whole. The request must be made in writing, and it should provide the reasons for the request.

If a study was reviewed by expedited review and the reviewer assigns the study a status of Not Approved, the study will be referred to the full committee. The UHREC will review the study and assign the status that it determines is appropriate.

If a study is assigned a status of Conditional Approval, Queries or Not Approved, and the issues cannot be resolved through requests for reconsideration, the researcher may appeal the decision to the UHREAB.

Continuing Ethics Review Process

The Certificate of Ethical Acceptability must be renewed before it expires. Certificates of Ethical Acceptability will be valid for one year unless it is determined that more frequent continuing review is required.

In order to renew their approval, researchers must submit a Request for Renewal of Ethics Approval one month before their Certificate of Ethical Acceptability expires. The Request for Renewal describes the progress made since the previous review and any administrative changes to the research or anticipated changes for the coming year. Administrative changes are any changes that do not directly affect participants.

If no changes or administrative changes are requested, the Request for Renewal is reviewed by the Ethics Unit. If the requested changes are of minimal risk, the Request for Renewal is reviewed by the chair or vice-chair. If the requested changes are greater than minimal risk, such as significant changes to the research which generate a drastic increase in risk or in the ethical implications of the study, the Request for Renewal is reviewed by the Full Committee.

A Certificate of Ethical Acceptability may be renewed for up to five years. After five years, a new SPF must be submitted for review.

PROCEDURES FOR THE ETHICAL REVIEW OF RESEARCH INVOLVING HUMAN PARTICIPANTS

Page 8 of 9

If researchers wish to make a substantial change to their study, it must be approved before it is implemented. A substantial change is any change that directly affects participants, and includes changes that impact the study's methodology, risk level, eligibility criteria or ethical considerations related to the study. To request approval of a substantial change, researchers must submit an amendment request that provides the rationale for the change and a revised SPF in which changes are clearly shown.

Amendment requests are reviewed by the chair or vice-chair, except if they involve a change in the risk level that is greater than minimal, in which case it is reviewed by the full committee.

Requests for Renewal and amendment requests may be assigned the same statuses as studies submitted for initial review, and the procedures for processing studies once they have been assigned a status are the same as for initial review. Negative Decisions, requests for reconsideration, and appeals with regards to Requests for Renewal and amendment requests are also handled in the same way as for initial review.

When a Request for Renewal is approved, a new Certificate of Ethical Acceptability is issued. Approval of amendment requests is communicated to the researcher in writing, and it does not entail a prolongation of the approval period.

Unanticipated issues

If unanticipated issues arise in the course of research and they could have an impact on the risk to participants or other ethical implications, the researcher must report them to UHREC as soon as reasonably possible. UHREC will review reports of such issues and may recommend relevant changes to the study.

Collaborative Research Teams

If a Concordia researcher is part of collaborative research teams and the principal investigator is based at another institution, the research will normally be reviewed at the principal investigator's institution. In this case, the Concordia researcher may submit the documents reviewed by the principal investigator's institution, as well as the approval issued by that institution, to UHREC in lieu of an SPF. The initial review process is the same as for an SPF.

PROCEDURES FOR THE ETHICAL REVIEW OF RESEARCH INVOLVING HUMAN PARTICIPANTS

Page 9 of 9

The researcher must also submit the equivalent of any requests for renewal, amendment requests, or reports of unanticipated issues from the principal investigator's institution. The review process for these documents is the same as for the Concordia documents.

Miscellaneous UHREC Processes

Researchers shall submit their SPFs to the UHREC well in advance of the time they expect to begin their research activities. The UHREC, in turn, is expected to respond to the SPF submissions in a timely manner, for student protocols this will normally take 3 to 4 weeks from and Faculty protocols will normally take 4 to 6 weeks. These processing times also depend on factors such as complexity and risk level, completeness of the application, and the response time of researchers to comments and concerns..

Members of the UHREC shall comply with the University's *Policy on Conflicts of Interest in Research (VPRGS-5)*, whether such conflicts of interest are real, potential or only apparent. UHREC members shall not review their own SPFs. Furthermore, UHREC members must disclose to other UHREC members possible conflicts of interests arising out of personal relationships, multiple roles, financial interests and other factors. They shall abstain from making decisions in cases where conflicting roles or interests exist and in cases where their judgment is likely to be, or may be perceived to be, biased or prejudiced.

The UHREC will operate in accordance with the principles of natural justice. Correspondingly, they will provide and keep a record of written and reasoned accounts of their criticisms, comments, dissents and inquiries to researchers. They will honour realistic requests of researchers to appear before them.

Approved by Faculty Deans, September 1, 2012

Revised version approved by Faculty Deans, February 17, 2016