POLICY FOR THE ETHICAL REVIEW OF RESEARCH INVOLVING HUMAN PARTICIPANTS

Effective Date: September 1, 2012
Originating Office: Office of the Vice-President, Research & Graduate Studies

Supersedes/Amends: June 1, 2011
Policy Number: VPRGS-3

PREAMBLE

Originally adopted in 1998 to promote the ethical conduct of research involving humans, the Tri Council Policy Statement: Ethical Conduct for Research Involving Humans is a joint policy of Canada’s three (3) federal research agencies – the Canadian Institutes of Health Research (CIHR), the Natural Sciences and Engineering Research Council of Canada (NSERC), and the Social Sciences and Humanities Research Council of Canada (SSHRC). All University research involving human participants must be conducted in keeping with the Tri Council Policy Statement: Ethical Conduct for Research Involving Humans, with guidelines based on the following three (3) core principles:

• respect for persons
• concern for the welfare of persons
• justice.

PURPOSE

The purpose of this Policy and its related Procedures is to ensure that all members of the University (faculty, students and staff) conducting research (whether funded or not) (“Researchers”) involving human participants do so in ways that respect the dignity and interests of humans affected by their research. Researchers are responsible for complying with the guidelines set forth in the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans as well as with this Policy and its related Procedures, and any other related University guidelines and policies.

SCOPE

This Policy and its related Procedures applies to all Researchers and outlines the principles that govern the ethical review of research involving human participants.
The forms of research involving human participants that are not subject to ethical review can be found in the [Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans](https://www.nim.nih.gov/ethics/tri-council-policy-statements) and include:

- research that relies exclusively on publically available information
- research involving the observation of people in public places
- research that relies exclusively on secondary use of anonymous information, or anonymous human biological materials
- quality assurance or quality improvement studies, evaluations, or testing within normal academic requirements
- creative practice activities
- research conducted by faculty members as an outside professional activity or outside employment as defined in the collective agreement between [Concordia University and the Concordia University Faculty Association](https://www.concordia.ca/)
  (“CUFA Collective Agreement”) so long as the information collected is not disseminated in the public domain in association with the University.

POLICY

1. The Vice-President, Research & Graduate Studies shall have the overall responsibility for the review of this Policy and the Procedures foreseen in this Policy.

2. The [Procedures](https://www.concordia.ca/) related to this Policy address:
   - composition and mandate of the University Human Research Ethics Committee (UHREC)
   - composition and mandate of the UHREC Disciplinary College
   - mandate of the Office of Research (OOR)
   - unfavorable decisions
   - composition and mandate of the University Human Research Ethics Appeal Board (UHREAB)
   - ethical review process
   - annual progress reports
   - collaborative research teams
   - miscellaneous UHREC processes.
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Any amendments to the Procedures as recommended by the Vice-President, Research & Graduate Studies and endorsed by the Chair, UHREC, are subject to the approval of all Faculty Deans.

3. All Researchers conducting research (whether funded or not) involving human participants must submit a Summary Protocol Form for UHREC review, and must obtain the UHREC Certificate of Ethical Acceptability before the research begins. Research funds will not be released until the Certificate of Ethical Acceptability is obtained by the Researcher.

4. Any modifications to an originally approved protocol must be reviewed and approved by the UHREC.

5. The Certificate of Ethical Acceptability will remain valid for one (1) year following its date of approval. For all studies continuing beyond this one (1) year time-frame, an Annual Progress Report must be submitted to the UHREC at the end of the validity period of the Certificate of Ethical Acceptability in order to ensure on-going ethical approval for the life of the research study.

6. If Researchers are in doubt as to whether or not their proposed research is subject to ethical review, they should consult with the relevant members of the UHREC or the OOR.

Adopted by Senate at its meeting of May 18, 2012