



Huron University College Research Ethics Board Policy and Procedures

(October 2015; revised May 2018)

1.0 Mandate

Canada's three major granting agencies — the Canadian Institutes of Health Research (CIHR), the Natural Sciences and Engineering Research Council (NSERC), and the Social Sciences and Humanities Research Council (SSHRC) — have developed the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (2014)*, or TCPS 2. The TCPS 2 sets out standards and procedures governing research involving human participants (including the establishment of a research ethics board) at Canadian institutions, such as Huron University College, which receive funding from the Tri-Council. Guiding ethical principles include:

- respect for human dignity
- respect for free and informed consent voluntarily given
- respect for vulnerable persons
- respect for privacy and confidentiality
- respect for justice and inclusiveness
- balancing harms and benefits
- minimizing harm
- maximizing benefits

The Huron University College Research Ethics Board (HUC REB) is a committee of Academic Council that functions primarily to assess consistency of research with the TCPS 2, to review requests for special consideration by researchers, and to educate Huron faculty, staff, and student researchers on how to meet or exceed TCPS 2 standards. The HUC REB aims to conduct its duties in a collegial way that supports and facilitates Huron faculty, staff, and students in their research endeavours.

The HUC REB adheres to the **Terms of Reference** as approved by Academic Council May 2018.

2.0 Procedures for Researchers Making an Application to the HUC REB

All up-to-date HUC REB forms and templates may be found on the Research page of the Huron website. The person requesting the approval shall be deemed the Principal Investigator (PI). PIs applying to the Huron REB should normally be continuing Huron faculty members. Student researchers on non-course related projects (e.g. CURL Fellowships) should be listed as co-

applicants. For procedures related to student research conducted for course credit, see Section 5.0 Student Research Conducted in the Context of an Academic Course, below. Any individuals with status other than Huron faculty or students who wish to make an application for research ethics approval should contact the HUC REB directly.

PIs seeking approval from the HUC REB must familiarize themselves with the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (TCPS 2) and complete the TCPS 2: CORE Tutorial (<http://tcps2core.ca/welcome>) before making a submission. All PIs listed on any submission to the HUC REB are expected to have read and understand the guidelines for ethical conduct of research as described in the TCPS 2.

Following this, a submission must be made using the form entitled **Research Ethics Approval Form for Projects Involving Human Participants at Huron University College** and including relevant attachments. All submissions should be made via email to huronreb@uwo.ca. Incomplete or incorrectly filled out forms will be returned to the applicant for revision. Questions and concerns may be directed to huronreb@uwo.ca.

Submissions to the HUC REB during the regular academic year (September-April) should be made according to the schedule below, updated annually. PIs will be notified of HUC REB approval and/ recommendations within 2 weeks of the closest meeting date following submission. Approval, if granted, will be accompanied by an REB number that can be quoted in other correspondence. Submissions made in June-August will be reviewed as needed, and researchers should anticipate that responses from the HUC REB may take up to 4 weeks.

Submission Deadline Dates (due at 12:00pm)
Monday October 15, 2018
Friday December 14, 2018
Friday February 22, 2019
Monday May 6, 2019
<i>*Submissions in June-August will be reviewed as needed.</i>

2.1. Exemptions from HUC REB Review

In order to assist PIs in deciding whether or not they need to seek approval, Appendix 1 lists types of research that do, and do not, require ethics approval. Researchers are encouraged to inquire directly with the HUC REB if there are any questions regarding the need for an ethics review of their research endeavours.

Research that meets any one of the following descriptions are exempt from requiring further research ethics approval from the HUC REB:

- a) Research that makes use of data collected from human participants which is lodged in publicly-available data banks (e.g. StatsCan), and in which there is no reasonable expectation of privacy in those cases in which individuals can be identified, does not require research ethics approval from the HUC REB.
- b) Undergraduate student research that involves the collection of data from human participants, poses minimal risk, and is conducted in the context of a for-credit course or undergraduate thesis at Huron University College does not require HUC REB approval. Such research must instead receive ethical approval using the **Request for Course-Based Research Ethics Review** (see Section 5.0 Student Research Conducted in the Context of an Academic Course, below). Such projects must be sponsored by a Huron faculty member. Only in cases in which there are concerns about the ethics of the research being proposed will course-based research require a full HUC REB submission. Undergraduate research projects undertaken through CURL Fellowships or any other extra-curricular, non-course credit project) and involving human participants require a full HUC REB submission. In the case of CURL applications, the supervising faculty member must be listed as PI.
- c) Research that has prior approval from the NMREB or HSREB at Western University (Main Campus) or REBs of Western-affiliated colleges (Kings University College or Brescia University College) need not be brought to the HUC REB. This exemption applies only to Western REBs. In cases in which some other agency (e.g., REBs at Fanshawe College or the Thames Valley District School Board) has already approved the research project, the PI must, nonetheless, submit a proposal to the HUC REB with the approval by the outside agency attached. Such proposals are likely to receive an expedited delegated approval, but PIs should not assume that such submissions will receive an automatic approval.

3.0 The Research Ethics Review Process

In accordance with Chapter 1, Section C of the TCPS 2, the HUC REB adopts a proportionate approach based on the general principle that the more invasive the research, the greater should be the care in assessing the research. The *concept of proportionate review* gives practical expression to the general principle that, especially in the context of limited resources, the more potentially invasive or harmful is the proposed and ongoing research, the greater should be the care in its review. A proportionate approach also implies different levels of REB review for different research proposals.

A second guiding principle of research ethics review by the HUC REB is the *concept of minimal risk*. Chapter 2, Section B of the TCPS2 states “a crucial element of the REB review is to ensure that the level of scrutiny of a research project is determined by the level of risk it poses to participants” (p. 9), where “proper ethical analysis of research should consider both the foreseeable risk and the available methods of eliminating or mitigating the risk” (p. 21).

A proportionate approach to research ethics review starts with an assessment of the magnitude and probability of harms. Research with minimal risks should normally receive a delegated review, while research with above-minimal risk shall receive a full REB review.

3.1 Full REB Review Process

The HUC REB will meet regularly to review submitted research proposals, according to a published schedule of submission dates (above). The Chair shall be responsible for updating the submission deadline dates at the start of each committee year in July. All members of the HUC REB will normally review all applications for research ethics approval, and will make recommendations for revision as required to ensure compliance with the TCPS 2.

The HUC REB may invite PIs to a meeting to discuss ethical issues arising in the proposed research protocols, and the HUC REB shall accommodate reasonable requests from PIs to participate in discussions regarding their submissions. PIs shall not be present when the REB votes on approval decisions.

It is the responsibility of the PI to address all recommendations made by the REB and ensure that the submitted research protocols as described in the application are complete and up-to-date. The final approved research protocols in the application will remain on file with the HUC REB and may be subject to audit by authorized representatives of Huron and funding agencies.

3.2 Delegated REB Review Process

While a full REB review process is the default for research projects involving human participants, in cases where it is determined that the research is of minimal risk applications may be eligible for a delegated review. A delegated review does not require a meeting of the full HUC REB.

A delegated review is an expedited research ethics review by the Chair of the HUC REB or one of the members of the HUC REB who has been designated by the HUC REB Chair. Applications may be indicated as appropriate for delegated review by the PI (in Section 3 of the **Research Ethics Approval Form**), and/or conducted at the discretion of the Chair of the HUC REB based on a review of the submitted application.

Delegated review is only available in cases that fulfill at least one of the following criteria:

- a) The proposed research is confidently expected to involve only minimal risk (as defined by the TCPS 2, Chapter 2).
- b) Research protocols that have received prior approval by the HUC REB, or other Western REB process within the last 5 years.
- c) Minimal risk changes to already approved research project.
- d) Annual renewals of approved minimal risk research.
- e) Annual renewals of more than minimal risk research where the researcher will no longer involve new interventions to current participants, renewal does not involve recruitment of new participants, and the remaining research activities are limited to data analysis.

If a question arises as to whether a submission qualifies for delegated review, the HUC REB Chair will make the final determination.

4.0 Continuing Ethics Review

In accordance with TCPS 2, Article 2.8, ongoing research shall be subject to continuing ethics review. Any substantial changes to the research plan or protocols described in the originally approved application must be reported to the Chair of the HUC REB without delay.

Any unanticipated events that occurs in the conduct of research at HUC that have or may increase the level of risk to participants, or have other ethical implications must be reported to the HUC REB using the **Unanticipated Problem Report** without delay. In the case of unanticipated events increasing risk to participants, all research must cease immediately until further notice from the HUC REB.

PIs are required to submit an **Annual Project Review or Termination Report** no later than the anniversary of the date on which approval was granted. If not a report of termination, this report must be re-submitted using the requisite form on every additional anniversary of the approval date until the report is a report of termination.

Incorrectly filled out, or incomplete forms, will be returned to the applicant for revisions. Failure to comply will result in automatic termination of ethical approval for the project and a refusal by the REB to consider any future requests by that individual for ethical approval. Collection of any additional data after a project has been terminated either by the PI (or by the REB for failure to provide an annual report) will be deemed in violation of the Policy.

5.0 Student Research Conducted in the Context of an Academic Course

Student research projects conducted as a component of an academic course (e.g., course assignment, major research projects for thesis or independent study) and entailing no more than minimal risk will undergo review by the Academic Program Chair or Coordinator on behalf of the HUC REB using the **Request for Course-Based Research Ethics Review**. Student research projects deemed by the Academic Program Chair or Coordinator to entail greater than minimal risk must be reviewed by the HUC REB. Student research that forms part of a faculty member's research program, or student research conducted as part of a CURL Fellowship or grant or other extra-curricular, non-academic credit context should be reviewed by the HUC REB and must have a faculty member as a PI. On extracurricular student research projects, the student may serve as co-PI, and may complete the required **Research Ethics Approval Form**, but the supervising faculty member must sign off as the PI and is ultimately responsible for the conduct of the project.

Where there is no designated Academic Program Chair or Coordinator for a course, or in the case where an Academic Program Chair or Coordinator is not able to conduct a review, the Chair of the HUC REB may form an Ad-Hoc departmental committee for the purposes of conducting a departmental level review.

1. The course instructor shall provide the Academic Program Chair or Coordinator with a brief summary of the research project component of the course. The Academic Program Chair or Coordinator will approve the project (provided there is minimal risk to participants) or refer the research project to the HUC REB for approval.
2. The course instructor shall be responsible for providing an initial review of the student projects originating from the course. This initial review will either result in approval or referral to the HUC REB because of residual research ethical concerns. The course instructor is responsible for ensuring that all student research projects adhere to the ethical guidelines set out by the TCPS 2.
3. The Academic Program Chair or Coordinator shall report the results of all course-based research ethics reviews to the HUC REB at the end of each academic year.

Appendix 1

Research Requiring Ethics Review

All research involving living human participants (see TCPS 2, Article 2.1) must undergo a research ethics review.

The TCPS 2 defines “research” as “any undertaking intended to extend knowledge through a disciplinary inquiry or systematic investigation.”

In accordance with the TCPS 2, the following types of research require ethics review and approval from the HUC REB before the research is started:

- research by Huron faculty members, both full-time and part-time
- thesis and directed studies research conducted by Huron undergraduate students
- research conducted by Huron students, or staff that makes use of University resources or facilities, either on-site or off-site
- research that has already been approved, but subsequently requires significant changes in the original protocol or in collecting, storing, analyzing, or reporting data, or research in which ethical issues have arisen
- research conducted at Huron by non-Huron researchers (e.g., faculty, staff, or students from other institutions, or community groups, organizations, or businesses) acting as principal investigators, regardless if the research has been approved at another institution
- research that involves interviewing a human participant to secure identifiable personal information, whether by face-to-face, telephone, videotaping, or other electronic encounters, or individualized questionnaires
- research involving third-party interviews if the third party is approached directly for interviews or for access to private papers
- research involving naturalistic observation of humans
- research that involves the secondary use of data that was originally collected from human participants for another purpose

The above-mentioned types of research require ethics review regardless of whether the:

- research is funded or not
- funding is internal or external
- participants are from inside or outside the University
- participants are paid or unpaid
- research is conducted inside or outside the University
- research is conducted inside or outside of Canada
- research is conducted by staff or students
- research is conducted in person or remotely (e.g., by mail, electronic mail, fax, or telephone)
- information is collected directly from participants or from existing records not in the public domain
- research is to be published or not
- focus of the research is the participant or a broader issue

- research is observational, experimental, co-relational, or descriptive
- project has been approved elsewhere or not
- research is a pilot study or a fully developed project
- research is to acquire basic facts or applied knowledge
- research is primarily for teaching or training purposes or whether the primary purpose is the acquisition of knowledge

Research NOT Requiring Ethics Review

The following types of research DO NOT require ethics approval:

- research that relies exclusively on publicly available information, when it is legally accessible and appropriately protected by law or where the information is publicly accessible and there is no reasonable expectation of privacy (TCPS 2, Article 2.2)
- research that involves naturalistic observation of people in public places (and there is no intervention staged by the researchers or direct interaction with people; does not include collecting personal information that will be disseminated with visual materials; and where there is no reasonable expectation of privacy among those being observed) (TCPS 2, Article 2.3)
- research that involves the secondary use of anonymous information (pooled data) which cannot be traced to the original research participants (TCPS 2, Article 2.4)
- quality assurance and quality improvement studies, program evaluation, and performance reviews or testing within normal educational requirements (TCPS 2, Article 2.5)
- creative practices in and of themselves (TCPS 2, Article 2.6)