



Huron University College Research Ethics Board Policy and Procedures

(October 2015; revised May 2018; July 2019; July 2020)

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 (2018)*, 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 Ethics 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 should be listed as co-applicants. (For procedures related to student research,

see Section 5.0 Student Research, 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. Researchers are also expected to be familiar with relevant Huron policies including:

- **Statement of Principles on Research Involving Indigenous Communities,**
- **Statement of Principles on Equity, Diversity, and Inclusion in Research,** and
- **HUC Academic Integrity in Research: Policy and Procedures.**

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 should be made according to the schedule below. Deadline dates falling on a weekend will move to the next business day. PIs will be notified of HUC REB approval or recommendations within 2 weeks following submission. Approval, if granted, will be accompanied by a REB number that can be quoted in other correspondence. Submissions made in July-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)
September 1
November 1
January 5
March 1
May 1
June 1
<i>*Submissions in July-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, and provides links to relevant Western Research guidance documents. 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 forms part of a course-based pedagogical project at Huron University College, and involves minimal risk, does not require research ethics approval from the HUC REB. In this case, the course instructor must submit a **Course-Based Research Ethics Review** form to the HUC REB. For further discussion please see Section 5.0 Student Research, below. Undergraduate research projects conducted as part of a thesis or independent study, or which are undertaken through CURL Fellowships or any other extra-curricular, non-course credit project, and which involve human participants, require a full HUC REB submission. 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, Thames Valley District School Board, or at other universities) has already approved the research project, the PI must, nonetheless, submit an application to the HUC REB with the approval by the outside agency attached. Such applications are likely to receive an expedited delegated approval, but PIs should not assume that such submissions will receive an automatic approval. PIs must wait for HUC REB approval before beginning the project. Any approval documents from other agencies must be appended to the HUC REB application or forwarded to the HUC REB when received.

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 TCPS 2 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). 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. In the case of a conflict of interest, the Chair will appoint the delegated review to a committee member without a conflict. 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 by submitting an **Amendment Request** form 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.

The LOI of any protocol run by the current Chair of the HUC REB will allow concerns with the conduct of the study to be directed to the relevant Dean's Office (FT or FASS) instead of, or in addition to, 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. Reminders regarding renewal will be sent in advance, with the project considered closed at the Expiry Date listed on the **Approval Notice**. 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

The HUC REB identifies three categories of, and related processes for, student research activities involving human participants:

1. Extra-Curricular Student Research Projects: 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 must be reviewed by the

HUC REB and must have a current Huron faculty member as a PI. On extra-curricular 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. The PI must report any adverse incidents to the HUC REB using the **Unanticipated Problem Report** and is responsible for submitting an **Annual Project Review or Termination Report** no later than the anniversary of the date on which approval was granted.

2. Curricular Student Research Projects: Student research conducted for academic credit that is intended to reflect the definition of ‘research’ in TCPS 2 Article 2.1 (“an undertaking intended to extend knowledge through a disciplined inquiry or systematic investigation”), and which incorporates measures to disseminate results (publication, thesis/dissertation, other discipline-specific knowledge mobilization strategies) must be reviewed by the HUC REB and must have a current Huron faculty member as PI. This category includes thesis projects and independent studies. On curricular student research projects, the student must serve as co-PI, and should 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. The PI must report any adverse incidents to the HUC REB using the **Unanticipated Problem Report** and is responsible for submitting an **Annual Project Review or Termination Report** no later than the anniversary of the date on which approval was granted.
3. Course-Based Pedagogical Projects: Student research projects conducted in course, as part of a course assignment designed by the course instructor, with data, data analysis, and final report intended solely for the purpose of meeting a course requirement, does not require HUC REB review. Instead, the course instructor is responsible for establishing and communicating ethical guidelines within the context of the course, and accepts responsibility for managing any unanticipated or adverse outcomes. The research must be acknowledged by the HUC REB using the **Course-Based Research Ethics Review** form, which must be completed by the course instructor in advance of student conduct of the project. In cases where the course-based project would entail more than minimal risk, the course instructor should contact the HUC REB. The course instructor must report any adverse incidents to the HUC REB using the **Unanticipated Problem Report**. Course-Based Pedagogical projects are closed at the end of the course dates provided. A form must be submitted for each new iteration of the course project.

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 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 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

This research requires ethics review when it is:

- conducted 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 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

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)

For further guidance, please consult the following resources:

- “REB Requirements for Student Research and Pedagogical Activities” (Western Research, November 2018)
https://www.uwo.ca/research/docs/ethics/Guidance_Document_Student%20Research_and_Pedagogical_ActivitiesNov162018.pdf
- “Distinguishing Between Quality Assurance/Improvement, Program Evaluation & Research” (Western Research, September 2018)
https://www.uwo.ca/research/docs/ethics/hsreb_guidelines/Distinguishing_Between_QA_QI_PE_Research_10Sept2018.pdf
- Huron Research Ethics Training Modules (available via Huron CURL OWL page. Email huronreb@uwo.ca for access)
 - Overview of Research Ethics
 - TCPS Principles
 - REB Process
 - Conducting Ethical Research During COVID-19