REB Process Module Transcript

Research Ethics at Huron

Here at Huron, in order to conduct research with human participants, all research proposals involving human participants must receive approval by the Huron University College Research Ethics Board (HUC REB). This is a committee of Academic Council that functions to ensure research is consistent with the Tri-Council Policy Statement, to educate Huron faculty, staff and student researchers on how to meet or exceed these standards, and to support researchers in their endeavors. Huron's research ethics board is responsible for protecting the participants of research, and ensuring they are not exposed to any unnecessary harms, risks or discomforts. This is done by adopting a review process that assesses the risks and benefits of research participation from the perspective of the participant.

All researchers at Huron, both faculty members and students, are expected to uphold the Tri-Council Policy Statement throughout the entirety of the research process. For more information, see Huron's Research Ethics Board Policy and Procedures document as well as Huron's Research Ethics page, both of which are provided in the "Linked Resources" tab where this module is located on OWL.

Concept of Proportionate Review

We are now going to talk about two of the principles that guide the research ethics review process. The first is the concept of proportionate review. A proportionate approach to research ethics review starts with an assessment of the magnitude and probability of harms and aims to strike an appropriate balance between recognition of the potential benefits of research, and protection of participants from research-related harms. Therefore, in order for a research project to receive ethics approval from a research ethics board, it must have an appropriate balance of potential benefits and potential harm to participants.

The proportionate approach to research ethics review is intended to direct the most intensive scrutiny, time and resources, and correspondingly, the most protection, to the most ethically challenging research. Especially in the context of limited resources, the more potentially invasive or harmful the proposed research is, the greater care it should receive in its review, and so this implies different levels of REB review for different research proposals.

Concept of Minimal Risk

Minimal risk research is defined as research in which the probability and magnitude of possible harms implied by participation are no greater than those encountered by participants in those aspects of their everyday life. An example of minimal harm includes research where the only burden to participants is the inconvenience of participating in research. The level of scrutiny a research project receives is determined by the level of risk it poses to participants, therefore, a study with a lower level of risk would receive a lower level of scrutiny by having it be delegated to a single REB member or a non-REB member for review, such as the department or a faculty member. And a project with a higher level of risk would receive a higher level of scrutiny, so it would undergo a full board review. A proper ethical analysis of research should consider both the foreseeable risk, and the available methods of eliminating or mitigating the risk.

When considering whether your research entails more than minimal risk, you should ask the questions; “what is the magnitude of the potential harm participants could experience from this research?” as well as “what is the probability that this harm may occur?”. Harm can be physical, emotional, social, economic, etc. in nature, so it is important to consider the potential harm that could occur in each of these areas as a result of your research. Let’s look at an example of a research design that entails participants completing an anonymous survey remotely. While on the surface one might think this design is risk free, there may be potential harm to participants. For example, if the survey asks participants questions of a sensitive or intrusive nature (ie. substance use, sexual behaviours, etc.), participants may experience emotional harm by reading/answering the question. If a sensitive question is not necessary to the research question, it should be removed to reduce the likelihood of harm. If a sensitive question is necessary to the study, measures should be taken to attempt to mitigate the risk of harm. One method of doing this may be to include help resources in your debriefing statement, to aid participants who may have experienced emotional harm as a result of participation in your study. Again, it is important to consider the potential harms that may be unique to your study from the perspective of the participant, not from the perspective of the researcher.

See Chapter 2 Section B of the TCPS 2 for more information regarding the proportionate approach to research ethics review and the concept of minimal risk.

Ethics Review Process

The ethics review process for a research study differs slightly depending on the context of your research (e.g. curricular, extra-curricular, or course-based), and we will touch on those differences, however they generally follow this procedure:

The first step is the completion of the ethics application as well as all relevant attachments such as the letter of information, recruitment script, data collection instruments, etc. with the support of the faculty supervisor. The faculty member serves as the Principle Investigator or PI, and the student as the co-PI for the sake of the REB application, as the faculty member is ultimately responsible for the ethical conduct of student research.

The second step is to submit these completed documents to Huron's research ethics board via email, based on the stated schedule of deadlines found on Huron's Research Ethics page under "Deadline Submission Dates". This means you will have to map out your research accordingly to meet these stated deadlines.

Next the submitted application is reviewed by the REB, either by the whole board for research with a higher level of risk, or in a delegated review for projects involving a lower level of risk. You can expect to hear back from the REB within 2 weeks of the deadline date, with the response either being approval, or, more typically, a list of queries from the REB to the researcher.

The researcher then submits responses to the queries, and sends back any revised documentation as necessary, to the REB.

This response may generate further queries from the REB that the researcher must address, and once these are satisfied then approval will be granted, and the researcher is free to begin the study.

Finally, one year from the approval date the researcher is expected to submit an Annual Review or Termination report to huronreb@uwo.ca, and a reminder to do this will be sent out by the REB in advance. In the case of student projects, the faculty member as the PI typically submits this report.

Categories of Student Research

Now that you are familiar with the general process of an REB review we are going to look at some of the distinctions between each type of student research.

The first type is extra-curricular student research, which includes student research that forms part of a faculty member's research program, an RA position, or student research conducted as part of a CURL Fellowship or grant or other extra-curricular, non-academic credit context. Extra-curricular research must always undergo the HUC REB review process described previously, with students having to complete a regular application with the HUC REB and have a faculty supervisor serve as the Principle Investigator (PI).

The second type of student research is curricular research projects which includes an Honors thesis or an independent study. Curricular research projects also must always undergo HUC REB review, where the faculty supervisor serves as the PI, and the student serves as the co-PI and completes the regular application.

The third type of student research is course-based pedagogical projects, which includes embedded research-like assignments as part of a course, where there are no publication or dissemination plans of objectives beyond the course grade. These projects do not need full HUC REB approval; however, students must still receive notification or acknowledgment via the course instructor. In the case of course-based research, the course instructor is responsible for setting up the in-course process for ethical review to ensure student projects adhere to the TCPS 2 guidelines, in whatever form makes sense in the context of the course.

What are some ethical issues that commonly arise from research at Huron?

We have already touched on some other ethical issues in research throughout these modules, but there are a few more that are important to discuss. The first is the issue of **sampling.** One issue that arises from research at Huron is that often the sample being used for research are university students, because they are the most accessible population to academics. While it is convenient to the researcher, this means that research is only being conducted on one specific population – young adults with post-secondary levels of education – therefore the results obtained cannot be generalized to those with different demographics, which means that these populations are not benefiting from research to the extent that students are.

The next issue that can arise is through the **description of procedures and research process.** For the Research Ethics Board to be able to assess the ethical soundness of a research study, they need to have a clear understanding of the study design. The Research Ethics Board is interdisciplinary, meaning its' members come from different backgrounds and may not all be familiar with discipline-specific language. Therefore, it is important when writing your research proposal to avoid using discipline-specific

jargon, and instead convey the information in a way that someone not in your field can understand clearly. The purpose of ethical review is to assess the risks that the study may pose to participants, not to assess the study's merits, so using complicated language is not necessary, and may even hinder or delay the process of obtaining ethical approval.

Another potential ethical issue is the **management of your research data.** The ethical obligations a researcher has does not end once all data has been collected, it is also the responsibility of the researcher to ensure that participants data stays protected throughout the entire lifecycle of the information, that being its collection, use, dissemination, retention, and/or disposal. Protection of identifiable information is an expectation of all individuals conducting research at or with the support of Western University. Identifiable information of participants is information that can identify an individual alone or in combination with other available information. The context of your research can determine what information is considered identifiable, for example, in some samples age could potentially identify a participant if the sample only contained one participant of that age. Therefore, it is important to consider all of the information you will be collecting and determine whether there is a possibility that it may identify a participant.

Traditionally, data may have been locked in a cabinet to which only the principal investigator had the key, but now more than ever data is being collected and kept digitally. One issue that arises with collecting data virtually is that it may be vulnerable to unauthorized access, therefore taking measures such as storing electronic files on a secure Western sanctioned server such as OWL or Qualtrics, or on an encrypted and password protected device is important. Chapter 5 Section C. Safeguarding Information of the TCPS is useful to help guide your thinking about how you will protect participants data in your research, and it includes what research ethics boards are looking for in their assessments.

It is also important that along with keeping information safeguarded that you also keep it organized and, in a place where you can access it, as if it is requested in the future if your data is subjected to independent scrutiny, it is your responsibility to provide this information to prove its authenticity. More information about open access data management are provided on the OWL page under the "Data Management" tab.