Research Ethics Board

Research Ethics – Human | Frequently Asked Questions (For Researchers)

Important Notice

The information included in the FAQs listed below is for researcher information and guidance purposes only. Each research study possesses unique properties and/or situations that may require additional or different guidance than what is presented. The information throughout this forum is meant to provide general situational advice and does not constitute research ethics compliance in its absolute form. If you have any questions or need further guidance, please contact ethics@msvu.ca.

All research involving human participants (or their data) must obtain REB clearance before recruiting or interacting with human participants. This includes the secondary use of de-identified participant data. Before submitting your research ethics application or exemption request, please review the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS) **and** complete the TCPS 2: CORE (Course on Research Ethics).

Additional information for researchers in general can be found through the Panel on Research Ethics, a Government of Canada resource.

The development of these questions was aided by MSVU's Research Ethics Board (REB) and information from publicly available documents at Canadian Universities, such as Carleton University, Queen's University, and Dalhousie University.

Contents

Pre-Submission of Research Ethics Application

1. If I have research ethics-related questions, or need to submit a research ethics application or other protocol documents, who should I contact?

All research ethics inquiries surrounding your potential or ongoing research study, including applications, supporting documents, and/or continuing research ethics forms should be forwarded to MSVU's Research Ethics Coordinator, Brenda Gagne, at ethics@msvu.ca.

Research ethics forms and applications can be found here, while policies, procedures, and guidelines can be found here and are updated on an on-going basis. Researchers are reminded that the MSVU REB website holds the most up-to-date versions.

2. Do I need to submit a research ethics application when dealing with human participants?

All research involving human participants (or their data) must seek REB clearance before recruiting or interacting with human participants. This includes the secondary use of de-identified participant data. Before submitting your research ethics application or exemption request, please review the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS) and complete the TCPS 2: CORE-2022 (Course on Research Ethics).

For more information on which research activities require REB clearance please review question five (5) of this forum on possible exemptions and review REB.SOP.102. Please contact the Research Ethics Office at ethics@msvu.ca if you have any questions or concerns.

3. Why do I need to submit a research ethics application when dealing with human participants?

The Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans – TCPS instills federal policies and guidelines of three (3) federal granting councils (CIHR, NSERC, and SSHRC) for research with human participants or their data. As such, the UREB ensures that research carried out by MSVU researchers or research involving members of the MSVU community adheres to these policies and guidelines.

Following these policies and guidelines through the UREB allows the MSVU research community to apply and receive Tri-Agency funding. Furthermore, the TCPS and resulting documents created and upheld by the UREB ensures the highest protection for research participants, researchers and their constituents, and the overall institution.

Failure to fulfill the requirements of the TCPS, by the researcher or the institution, may result in recourse by the Agencies, as set out in the Tri-Agency Framework: Responsible Conduct of Research (2021).

4. If I have research ethics clearance through another institution, do I need MSVU research ethics clearance as well?

All research with human participants or their data that is conducted under the auspices of MSVU, either at or affiliated with MSVU, must be granted MSVU REB clearance before recruiting, interacting with, or collecting data from participants. For example, a collaborative study between MSVU, Dalhousie University, and the IWK Health Centre, normally must be reviewed and cleared from all three (3) participating institutions before recruiting and interacting with participants.

If a MSVU researcher requires research ethics clearance and/or has already been granted clearance from another Canadian institution, hospital, or health authority for their study, the researcher would then submit REB.FORM.010 for MSVU REB clearance. If a MSVU researcher requires research ethics clearance at a hospital or health authority for their study, the researcher should obtain clearance from that location prior to submitting the application to the MSVU REB.

5. I do not believe the study I want to conduct requires UREB clearance, what should I do?

There are select instances where UREB review and clearance may not be necessary. This could include research relying exclusively on publicly available information, the observation of people in public places, and overall, where there is no expectation of privacy. However, with the continual rise of accessible information through social media, it is important to understand the terms of service of each site being assessed, understanding users' expectation of information they post, laws and regulations where the research is being

conducted and/or the geographical location of where information is being taken, and the limitations of what is public and private domain.

Please review TCPS – Chapter 2: Scope and Approach for more information and additional guidance. Please contact the Research Ethics Office at ethics@msvu.ca if you have any questions, concerns, or need additional guidance on the appropriate form/application of your potential research study.

If you believe the study does not require UREB clearance, please submit REB.FORM.016 (REB Exemption Request).

6. How do I know whether my study is minimal risk or exceeds minimal risk? If my study exceeds minimal risk, do I have to do anything different for a full-board review?

Most research studies reviewed at MSVU are minimal risk; however, it is dependent on what the study is asking of participants to during data collection. For example, studies utilizing deception or stress inducing manipulations are typically regarded as exceeding minimum risk.

Although not all studies exceed minimal risk based solely on the participant population one is working in, researchers should use caution when conducting research with children, marginalized and Indigenous communities, and those who feature diminished cognitive capabilities and/or are physically incapacitated.

If a study is deemed to exceed minimal risk and a full-board review is needed, you do not have to prepare or send any additional documents. Please review REB.SOP.408 (Full Board Review) and REB.SOP.401 (Delegated Review) for additional guidance.

7. Do my participants need to sign a written consent form?

A written consent form that requires research participants signature before participation in any research-related activities is one of the most common means of documenting the consent process and signed consent is normally the default. However, there are select instances where a range of procedures to gain consent may be more appropriate such as

online surveys, action relative, verbal, etc. The consent process is dictated by the study, the target participant population, ensuring that diverse cultural traditions and practices are respected, and ensuring that written consent before participation does not create barriers between the researcher and participant.

Alternatives, as derived from the TCPS, include oral consent or verbal agreement, a handshake, or the exchange of gifts, among others. Please review Article 3.12 of TCPS Chapter 3: Consent Process and Article 10.2 of TCPS Chapter 2: Qualitative Research.

If written consent is deemed to be inappropriate, alternative processes must be included in the research ethics application. The onus is on the researcher to provide sufficient details and justification to the UREB. Please review REB.SOP.701 (Free and Informed Consent) and REB.SOP.703 (Consent Updates and Ongoing Consent).

8. Do lab volunteers need to be included as team members in the research ethics application?

As each study is unique, so too are the roles of team members and volunteers. Whether a lab volunteer is listed on the research ethics application or not, depends on their access to participants and/or their data. The role they play throughout the research study may require them to be listed in the research ethics application.

All team members and volunteers, whether specifically included in the application or not, must complete CORE Tutorial training, and it is highly recommended for everyone to have completed WHMIS. CORE Tutorial certificates must be included in the research ethics application. Other training may be appropriate for team members and volunteers, depending on the specific study.

Please contact the Research Ethics Office at ethics@msvu.ca if you have any questions or concerns about how best to include team members and volunteers in the research ethics application, and for other possible training modules.

9. I would like to use secondary data that has been de-identified. Do I still need research ethics clearance for this?

UREB clearance is required when using secondary data that has been de-identified. The overall goal is to protect the original participants and their data. For guidance on when UREB clearance is required for secondary use of de-identified data, please review Article 2.4 and 2.5, Section D of Chapter 5, and Section C of Chapter 12 of the TCPS.

If a researcher is planning to use secondary data, please submit REB.FORM.005 (Secondary Use of Data) for UREB clearance.

Submission and Review of Research Ethics Applications

1. How long does it take for the UREB to review research ethics applications?

MSVU's REB normally provide initial comments on research ethics applications (that do not exceed minimum risk) within 3-4 weeks.

The REB makes every effort to review protocols within a timely manner, however, reviews may take additional time depending on the complexity/nature of the study, university closures, end of term (exams/marking) or during periods where there is a high volume of application submissions.

Please review the REB Policies & Guidelines for Conducting Research with Human Participants, specifically, SOPs 401 through 409 and 412, for additional information.

2. I don't agree with the comments made on my research ethics application. What should I do?

The MSVU REB is an interdisciplinary board, and the review of research ethics protocols is a dynamic process whereby reviewers focus on the guiding principles of the TCPS, with heavy focus on protecting the rights of participants. Multiple people review your research ethics application to ensure that a variety of voices and backgrounds are heard. Researchers are encouraged to provide additional clarification or justification in response to the UREB review comments. The Research Ethics Office can always be contacted to discuss any part of the review and processes.

If you feel that someone has made an error or is unjust in the review process, please forward all inquiries to the Research Ethics Coordinator, Brenda Gagne, at ethics@msvu.ca.

3. My study requires research ethics clearance from multiple institutions. If I have been granted research ethics clearance by the MSVU REB and not the other affiliated institutions, can I begin recruiting participants and collecting data?

Each study and collaboration is unique. Depending on what is required from the other institution, i.e., data collection, clinical trials, etc., you may or may not need to wait for research ethics clearance from all institutions. However, if participant engagement (recruitment, data collection) is required among all affiliated institutions, research ethics clearance must be given from each institution before the research process can begin.

- If a MSVU researcher requires research ethics clearance at a hospital or health authority for their study, the researcher is asked to obtain clearance from that location as the first step, and then submit the **REB.FORM.010** application to the MSVU REB to obtain REB Clearance. This will normally be an expedited review.

- If a researcher has been granted research ethics clearance from another institution, please submit the **REB.FORM.010** application to the MSVU REB to obtain REB clearance. This will normally be an expedited review

4. How do I create a survey located on the MSVU LimeSurvey platform?

Please contact MSVU's Research Ethics Coordinator, Brenda Gagne (ethics@msvu.ca), to request a survey ID. Normally, this will be completed once you have been granted research ethics clearance, however there are provisions for a researcher to request access prior to research ethics clearance (in these cases, researcher shall not distribute the survey until research ethics clearance is obtained).

Post-Clearance and Conduction Your Research

1. How long do I have research ethics clearance for?

UREB clearance is granted for one (1)-year from the initial clearance date. Researchers who are continuing their study beyond this year must submit REB.FORM.003 (Annual Report/Request for Renewal) prior to the expiry date. This report must be filled out every year that the study is continuing*.

*Researchers may, with submission of the Annual Report/Request for Renewal, renew their research ethics clearance for up to four (4) additional years (original clearance +4 annual renewals). After five (5) years, the researchers must re-apply to the UREB for review/clearance. This review will be expedited wherever possible.

NOTE: When the study is complete, researchers must submit REB.FORM.004 (Final Report).

2. Who on my research team should have access to the research ethics application once it has been given UREB clearance?

The research ethics application outlines the major objectives, procedures, and goals of the study. It should be paramount that all managers, coordinators, team members, and volunteers review the cleared research ethics application before collecting data with participants.

This will further help undergraduate and graduate students, as well as new researchers, to learn how to best complete a research ethics application while ensuring the highest ethical standards are being demonstrated throughout the entirety of the research process.

3. What if I experience an unanticipated or adverse event, or a privacy breach, during the research process?

Unanticipated issues and problems include those that may increase the level of risk to participants or affect participants welfare, and not anticipated by the Researcher in the research ethics proposal. Unanticipated problems further include those that are unexpected,

related or possibly related to participation in the research, and places research participants or others at a greater risk of harm whether physical, psychological, economic, or social. This could include adverse events. If an unanticipated event arises during the research process, please submit REB.FORM.008 (Unanticipated Research Event).

An adverse event is any untoward medical occurrence or serious non-medical occurrence in a research participant, who has been administered investigational product, including an occurrence which does not have a causal relationship with the product. A local adverse event includes experiences by research participants enrolled by the researcher at the centre under the authority of MSVU's REB. A non-local (external) adverse event includes experiences by research participants enrolled by researchers at other centers or organizations, external to MSVU REB's authority. If an adverse event occurs, please submit REB.FORM.007 (Adverse Event Report).

Please contact the Research Ethics Office at ethics@msvu.ca if you have any questions or concerns, and if you are unsure of which form to submit.

A privacy breach is the unauthorized collection, use, or disclosure of personal information or personal health information. If a privacy breach has occurred, researchers are required to immediately submit REB.FORM.015 (Privacy Breach) and REB.FORM.008 (Unanticipated Research Event). For additional clarification of terms, please review REB.INFO.001 (REB Glossary of Terms).

4. Am I able to change or make amendments to the Principal Investigator after I have been granted research ethics clearance, during the research process?

Researchers can make amendments to MSVU faculty or staff Principal Investigator (PI). Please submit REB.FORM.021. This form can be used regardless of the current stage of research. This form can **only** be used for MSVU faculty or staff PI changes.

5. What happens when my study, or my student's study, is completed?

All research that has received UREB clearance must submit REB.FORM.004 (Final Report) once the study has concluded. The UREB is unable to close the research ethics file for the study without this report.

6. How long should I keep my data once the study is complete? Should my participants be aware of this?

Regulations and best practices for data retention vary and may depend on funding agency, nature of the research, publication requirements or the deposit/sharing or future use of research data.

All researchers should clearly define data retention, destruction, sharing, and deposit requirements in the consent form. It is good practice to inform participants in the consent form whether data may be transferred from MSVU-affiliated database to another professional or personal database. For additional guidance, please review REB.INFO.503 (Sensitive Data).