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| This is a picture of the Mount Saint Vincent University logo | **Research Ethics Board** |

# **REB.FORM.001 – Standard Research Ethics Application**

The UREB uses the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (TCPS2) to guide ethical review. The three core principles of the TCPS2 - **Respect for Persons, Concern for Welfare, and Justice** – must be kept in mind to ensure a balance between the protection of participants and the value of human dignity, and the legitimate requirements of research. Applying the core principles will also maintain free, informed and ongoing consent throughout the research process and lead to sharing the benefits of the research. These results will help to build and maintain the trust of participants and the public in the research process.

For more information:

* <http://www.msvu.ca/ethics>
* <http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/Default/>

# **Section A – Ethics File Details**

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| Date of Application | Click or tap to enter a date. |
| Title of Research Study | Click or tap here to enter text. |
| Proposed Study Start Date | Click or tap to enter a date. |
| Anticipated Study End Date | Click or tap to enter a date. |

# **Section B – Applicant Information**

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| 1. Principal Investigator or Nominated Principal Investigator - see the MSVU [REB Glossary of Terms](https://www2.msvu.ca/sites/ResearchDocumentCentre/Research%20Ethics%20%20Human/REB.INFO.001%20REB%20Glossary%20of%20Terms.pdf) (REB.INFO.001) | Click or tap here to enter text. |
| 2. Department/Faculty | Click or tap here to enter text. |
| 3. Email Address (MSVU email only) | Click or tap here to enter text. |
| 4. Telephone Number | Click or tap here to enter text. |
| 5. Researcher Category  \*Please provide your supervisor’s or MSVU Faculty Sponsor’s information below (if applicable): | Choose an item.  If you chose Other, please specify:  Click or tap here to enter text. |
| 6. Supervisor | Click or tap here to enter text. |
| 7. Supervisor’s Email (MSVU email only) | Click or tap here to enter text. |
| 8. Supervisor’s Telephone Number | Click or tap here to enter text. |

**Co-Applicants (if applicable)**

**If more space is required, please submit a separate roster.**

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| Name | Click or tap here to enter text. |
| Email Address | Click or tap here to enter text. |
| Institutional Affiliation | Click or tap here to enter text. |
| Name | Click or tap here to enter text. |
| Email Address | Click or tap here to enter text. |
| Institutional Affiliation | Click or tap here to enter text. |
| Name | Click or tap here to enter text. |
| Email Address | Click or tap here to enter text. |
| Institutional Affiliation | Click or tap here to enter text. |

Research Assistant(s); Staff/Student/Other (if applicable)

**If more space is required, please submit a separate roster.**

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| Name | Click or tap here to enter text. |
| Email Address | Click or tap here to enter text. |
| Institutional Affiliation | Click or tap here to enter text. |
| Name | Click or tap here to enter text. |
| Email Address | Click or tap here to enter text. |
| Institutional Affiliation | Click or tap here to enter text. |
| Name | Click or tap here to enter text. |
| Email Address | Click or tap here to enter text. |
| Institutional Affiliation | Click or tap here to enter text. |

# **Section C – Research Funding**

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| 1. Research Funding Status   Funded  Pending Funding  Not Funded |
| 1. For Funded Researcher – indicator the Grantor (Please select all that apply):   Tri-Council (SSHRC, CIHR, NSERC)  Internal  Other External  (Please specify other grantors): Click or tap here to enter text. |
| 1. Principal Investigator on funding (if applicable): Click or tap here to enter text. |
| 1. Grant Number(s) – if applicable: Click or tap here to enter text. |
| 1. Grant Title if different from REB File: Click or tap here to enter text. |
| 1. Funding Period:   Start Date: Click or tap to enter a date.  End Date: Click or tap to enter a date. |

# **Section D – CORE Tutorial Completion**

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| Effective July 1, 2016, all researchers conducting research with human participants and/or their data must complete the CORE Tutorial and submit a copy of their completion certificate with this application (**REB.POL.004**).  All MSVU members of this research team has:  Completed the CORE Tutorial  Copies of all CORE Completion Certificate(s) have been attached to this ethics application |

# **Section E - Researcher Assessment of Risk for the Proposed Study**

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| The TCPS2 defines minimal risk as “…researchin which the probability and magnitude of possible harms implied by participation in the research is no greater than those encountered by participants in those aspects of their everyday life that relate to the research.”  \* The UREB may determine that your assessment of risk is incorrect and may assign a different risk level. The PI will be advised as soon as possible if this occurs as the level of review will change.  Minimal Risk  Exceeds Minimal Risk  Please provide a **brief** explanation for your choice above  Click or tap here to enter text. |
| Research Team Experience and Qualifications |
| 1. Does this study require professional expertise/recognized qualifications? (e.g. registered psychologist; first aid certification)   Yes  No  If yes, please provide a brief explanation below and indicate is you, or any member of the research team have the required professional expertise/ qualifications.  Click or tap here to enter text. |
| 1. Please provide a brief description of previous experience with this type of research by (a) the principal investigator, (b) the research team and/or (c) the people who will have direct contact with the participants and their data. If there has not been previous experience, please describe how the principal investigator/ research team will be prepared.   Click or tap here to enter text. |
| 1. Will the research involve specific cultural groups (e.g., indigenous populations) or work with vulnerable persons (e.g., intellectual or physical disabilities, children, at-risk persons) or collect *sensitive data*[[1]](#footnote-2)?)? Please provide details on the specific population(s) and describe the researcher’s (or research team’s) experience and training in dealing with these considerations.   Click or tap here to enter text. |
| 1. For projects involving community members (e.g., peer researchers) in the collection and/or analysis of data, please describe their status within the research team (e.g., are they considered employees, volunteers or participants?) and what kind of training they have or will receive.   Click or tap here to enter text. |
| 1. Will training be provided for those with access to *sensitive data*?   **Note**: With respect to determining whether data collected is sensitive, the underlying assumptions tend to be that the information being requested may evoke a strong emotional response and it may be threatening or even damaging to the individual to share such information. It is important to carefully think through the likely impact on participants or vulnerable groups of any data collection methods. The Research Ethics Board (REB) recognizes that it is not only research with human participants that raises relevant ethical concerns. Researchers may be assessing sensitive information, the publication or analysis of which may have direct impact on agencies, communities or individuals. For example, collection and use of archives, historical, legal, online or visual materials may raise ethical issues (e.g., for families and friends of people deceased).  Yes  No  For either answer, explain below:  Click or tap here to enter text. |
| 1. Will this research take a participatory approach? (e.g., participatory action research, community-based research)?   Yes  No  If yes, please provide a brief explanation below.  Click or tap here to enter text. |

# **Section F - Conflict of Interest**

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| 1. Describe any real or perceived conflict(s) of interest for any research team member that could affect participant welfare.   Click or tap here to enter text. |
| 1. Will the researcher(s), members of the research team, and/or their partners or immediate family members receive any personal benefits related to this study? Select all that apply.   No Conflict  Financial  Commercial entity benefits  Other – Specify - Click or tap here to enter text.  Please describe the benefits below.  Click or tap here to enter text.  \*Do not include funded research grant expenses, possible academic promotion or other benefits which are integral to the general conduct of research. |
| 1. How will you manage the conflict regarding the research?   Click or tap here to enter text. |
| 1. Please describe any restrictions regarding access to or the disclosure of information during or at the end of the study that the funding agency/sponsor has placed on the researcher(s).   Click or tap here to enter text. |
| 1. Is there any relationship (current, pre-existing or expected) between the researcher(s) and the participants (e.g., instructor/student; manager/employee; co-workers; family members; intimate relationships).   Yes  No  If yes, please describe any safeguards and/or procedures to prevent possible undue influence, coercion or inducement given the power differential.  Click or tap here to enter text. |

# **Section G – Research Study Information**

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| Research Abstract/Summary – In **layperson’s terms**, please provide a summary of your research study. **Max 200 words**  Click or tap here to enter text. |

Research Project Details - \*Please use plain, clear language

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| 1. Describe the project and objectives. (include the research question)   Click or tap here to enter text. |
| 1. Please situate the project in the scholarly literature, providing the rationale for the study (including citations, references)   Click or tap here to enter text. |
| 1. Please describe all methods and procedures that will be used to obtain data and answer the research question   Click or tap here to enter text. |
| 1. What, if any, are the restrictions on the use of research tools (e.g., copyright material, protected tests)?   Click or tap here to enter text. |
| 1. How will the data be analyzed?   Click or tap here to enter text. |
| 1. What is the anticipated contribution of the research?   Click or tap here to enter text. |

Scholarly/Peer Review

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| 1. Article 2.7 (TCPS2) states: “As part of research ethics review, the REB shall review the ethical implications of the methods and design of the research.” Has this project undergone scholarly or peer review?   Yes, if yes, please check one of the following:  The research has been reviewed and approved by the following thesis committee or equivalent (required for thesis research): Click or tap here to enter text.  The research has undergone scholarly review prior to submission for ethics review by the following review committee: Click or tap here to enter text.  The research will undergo scholarly review prior to funding by the following review committee: Click or tap here to enter text.  No, it has not received scholarly/peer review.  Graduate Students Note: ensure that you attach a copy of your signed thesis proposal acceptance to this application |
| 1. Does this research require additional research ethics clearance (e.g., school boards, other universities or hospitals)?   Note: Final approval is contingent upon the researcher’s formal confirmation to the UREB that third party permission and/or clearance has been granted.  \*Append a copy of the clearance, or an expected date of approval.  Yes  No  *If yes, specify agency:*  Click or tap here to enter text. |
| 1. Does this research require additional permissions – (e.g., recruitment permission from offsite locations, data provided by outside agencies)   \*Please append support letters to this document.  Yes  No  *If yes, specify agency:*  Click or tap here to enter text.  Describe how you will establish the consent of third parties.  Click or tap here to enter text. |

Research Location(s)

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| 10.Please identify the locations where data will be collected (participant location)  On Campus or,  Off Campus (please identify below)  Halifax Regional Municipality  Province of Nova Scotia  Canada  Outside of Canada – **Please complete international section.**  Please elaborate on location(s) of research  Click or tap here to enter text. |

International Research

Research that is performed outside the jurisdiction or country of the institution that employs the researcher or with which the researcher is affiliated (staff, students) shall undergo prospective ethics review by both 1/ the REB within the researcher’s institution; and 2/ the REB, where such exists, with the legal responsibility and equivalent ethical and procedural safeguards in the country or jurisdiction where the research is to be done (TCPS 2010, Art 8.3).

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| 1. Is ethical clearance required at the locale(s) to carry out the research?   Yes  No |
| 12. Please explain how additional ethics clearance has been or will be obtained and submit copies of all clearances to the UREB. If ethics clearance is not required, please explain why not.  \*Researchers may wish to include the following information to show that articles of the TCPS have been met where appropriate:   * Relevant information about the rules governing research involving humans and the ethics review requirements at the research site (where any exist); * The names and contact information for the relevant REB or comparable ethics bodies; * The relevant information about the target populations and circumstances that might have a bearing on the research ethics review by the researchers’ home REB.   Click or tap here to enter text. |

Participants and Recruitment

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| 1. Number of participants you plan on recruiting for the study and rationale.   Click or tap here to enter text. |
| 1. Describe any required demographic characteristics.   Click or tap here to enter text. |
| 1. Will all participants be the age of majority in their locale?   Click or tap here to enter text. |
| 1. Please describe your inclusion/exclusion criteria for this study and provide a brief rationale.   Click or tap here to enter text. |
| 1. Please describe how you will determine participants’ capacity to consent to participate in the research.   Click or tap here to enter text. |
| 1. Is parental or guardian consent required?   Yes - If yes, attach Alternate Consent Form  No |
| 1. Is participant assent required in lieu of consent?   Yes  No  If yes, please describe below how assent will be obtained and attach assent form.  Click or tap here to enter text. |
| 1. Please select all methods of recruitment   Posters  Social Media  Online Notices  Participant Pool  Email  Letter  Telephone  Snowball Sampling  Other - Specify - Click or tap here to enter text. |
| 1. Describe each step of how participants will be recruited. Include how contact information will be obtained, who will be recruiting, how participants will be made aware of the study, where recruitment materials will be located, and how participants can express interest.   Click or tap here to enter text.  \*Append all recruitment tools (e.g., flyers, telephone scripts, letters, advertisements, etc.) to this document. |
| 1. Do you require a third-party authorization to recruit? (e.g. schoolboard; indigenous communities, access to premises)? If permission is already granted, please append to this application.   Yes  No  If yes, please describe below how permission has been or will be secured.  Click or tap here to enter text. |
| 1. What are the participant selection procedures? What are the participant inclusion and/or exclusion criteria for your research? How will you inform interested participants if they do not meet the selection criteria?   Click or tap here to enter text. |

Inclusion of Indigenous Peoples

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| 1. Will the research questions/hypotheses concern Indigenous peoples?   Yes  No |
| 1. Will analyses use Indigenous community membership as a variable?   Yes  No |
| 1. Will interpretation of results refer to Indigenous people, language, history or culture?   Yes  No |
| 1. If yes to any of the above, please discuss any plans for Indigenous community engagement, as indicated in the TCPS ([Chapter 9](http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter9-chapitre9/)).   Click or tap here to enter text. |
| 1. State whether ethical approval has been or will be sought from any Indigenous ethics review group.   Click or tap here to enter text. |
| 1. Describe how results will be returned to the community.   Click or tap here to enter text. |

**Append** any existing research agreements concerning the data or samples.

# **Section H - Research Tools, Procedures and Methods**

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| 1. Are any of the following procedures or methods involved in this study? Check **all** that apply.   Analysis of human tissue, samples, body fluids (\**Request for Use of Human Tissue Sample* must be completed and appended to this application)  Audio/video recording (specify) Click or tap here to enter text.  Computer-administered tasks  Ethnography (also includes autoethnography)  Focus Groups  Group Interview(s)  Home Visit(s)  Interview(s) (in person)  Interview(s) (telephone; Skype, web-based technologies)  Invasive physiological measurements (e.g. venipuncture)  Journals/Diaries/Personal Correspondence  Non-invasive physical measurement (e.g., exercise, heart rate, blood pressure)  Observations  Photos and/or PhotoVoice  Questionnaire (email/web)  Questionnaire (in person)  Questionnaire (mail)  Secondary Data  Survey  Other: (specify) Click or tap here to enter text.  \*\*\* Ensure that copies of all research tools such as questionnaire(s), interview guides or other test instruments are appended to your ethics application and marked accordingly, such as Appendix A, B. If reference is made to previous protocols, please provide copies of relevant documentation |
| 1. Describe sequentially, and in detail, all of data collection methods and provide details of any instruments used, as well as and all procedures in which the research participants will be involved (paper and pencil tasks, interviews, questionnaires, physical assessments, physiological tests, time requirements, etc.) Note: Researchers may choose to use a timeline for longer projects or to break the study down into phases, participant groups, or types.   Click or tap here to enter text. |

# **Section I – Participant Incentives, Compensation and Remuneration**

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| 1. Are you offering participants any of the following (select all that apply).   No compensation/Not Applicable  Cash  Draw for gift, cash or gift card  Gift Card  Reimbursement of travel, parking or childcare expenses  Refreshments  Course Credit/Bonus Points  Other – Specify Click or tap here to enter text. |
| 1. Describe all compensation/remuneration and indicate when participants will receive the compensation.   Click or tap here to enter text. |
| 1. What is the monetary value of the compensation?   Click or tap here to enter text. |
| 1. What happens to the compensation if the participant withdraws from the study?   Click or tap here to enter text. |
| 1. Describe what procedures are in place if you need to record participants’ identifying information for Financial Services   Click or tap here to enter text. |

# **Section J – Risk Management and Benefits**

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| 1. Are there any risks to the participant(s)? Select all that apply   Mild Risks  Moderate Risks  High Risks |
| 1. Indicate if the participants might experience any of the following risks (check **all** that apply)   Risk of physical harm (e.g., falling, muscle pain)  Physical discomfort (e.g., tiredness, weakness, nausea)  Psychological or emotional discomfort  (e.g., anxiety, stress, loss of confidence, regret for disclosing personal information)  Legal repercussions for participating in the study  (e.g., possibility of being sued, charged with criminal activity)  Social repercussions  (e.g., possibility of marginalization, being negatively judged by peers or employer)  Economic inconveniences  (e.g., expenses incurred for participation, loss of income during time of participation)  Other inconveniences  (e.g., long travel to research site, time consumed, disruption of family routines)  There are possible risks to participants that are greater than those that the participants might encounter in their everyday life.  There is potential for participants to feel obligated to participate or coerced into contributing to this research (such as regular contact between participants and the researcher, relationships that involve power-dynamics). |
| 1. If you have selected any of the above noted risks, please describe in detail.   Click or tap here to enter text. |
| 1. Describe how the risks will be managed and include the availability of appropriate medical or clinical expertise or qualified people. Explain why less risky alternative approaches could not be used.   Click or tap here to enter text.  \*\*\*Please ensure that you append to this application the list of resources that will be provided to all participants in this study. |
| 1. Discuss any (potential) direct benefits to the participants from their involvement in the project. If there are no direct benefits, please indicate.   Click or tap here to enter text. |
| 1. Discuss the (potential) benefits to society that would justify involvement of participants in this study.   Click or tap here to enter text. |
| 1. Discuss the (potential) benefits to the scientific community that would justify involvement of participants in this study.   Click or tap here to enter text. |

Deception, Debriefing, Incidental Findings

Please note: Deception and/or partial disclosure requires debriefing (see below) and requires secondary consent forms. (secondary consent forms allow the participant to consent to the use of their data when the have been informed of the true nature of the study. Ensure that you append the copies of any debriefing documents as well as the secondary consent form to your application if deception and/or partial disclosure is used.

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| 1. Will **deception** or partial disclosure of any kind be necessary in this study?   Yes  No  If yes, describe the deception and/or partial disclosure and why it is necessary for the study (e.g., what information is withheld from participants).  Click or tap here to enter text.  Describe the magnitude and likelihood of harm.  Click or tap here to enter text. |
| 1. Will participants be debriefed?   Yes  No |
| 1. Please describe when and how participants will be debriefed (if applicable).   Click or tap here to enter text. |
| 1. Describe any risks to participants during debriefing and how they will be mitigated.   Click or tap here to enter text. |
| 1. Do you anticipate any incidental findings? (e.g., unanticipated discoveries that relate to the welfare of the participants or others such as becoming aware of child or elder abuse, imminent harm to participant or others)   \*if yes, ensure that this is addressed in the informed consent.  No  Low Probability  High Probability  If you select low or high, please describe the nature of the finding(s) and how you will manage it.  Click or tap here to enter text. |
| 1. Are there any risks (or safety issues) to the researcher or research team? Select all that apply.   No Risk/Not Applicable  Mild Risks  Moderate Risks  High Risks |
| 1. How will risks (or safety issues) to the researcher or research team be minimized?   Click or tap here to enter text. |

# **Section K - Informed Consent Process**

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| Consent shall be maintained throughout the research project. Researchers have an **ongoing** duty to provide participants with all information relevant to their ongoing consent to participate in the research. Consent encompasses a process that begins with the initial contact (i.e., recruitment) and carries through to the end of participants’ involvement in the project or use of their data. Throughout the process, researchers have an enduring duty to provide participants and REBs with all information relevant to participants’ ongoing consent to participate in the research as well as an ethical and legal obligation to bring to participants’ attention any changes to the research project that may affect them. These changes may have ethical implications or may be germane to their decision to continue research participation or may be relevant to the circumstances of individual participants. Researchers shall disclose changes to the risks or potential benefits of the research. This gives participants the opportunity to reconsider the basis for their consent considering the new information. In the case of children who begin participation in a project based on consent from an authorized third party, the researcher must seek their autonomous consent if they reach the age of majority during the research, for their participation to continue. (TCPS2, Ch. 3, Article 3.3) |
| 1. Who will obtain informed consent from the participants?   Click or tap here to enter text. |
| 1. How will consent be documented, select all that apply   Signed Consent  Online Consent  Oral Consent  Implied (action-relative) Consent  Assent  Parent/Guardian Consent  Other – Specify - Click or tap here to enter text. |
| 1. Describe the procedures for how you will obtain free and informed **signed consent** from the participant or legal guardian.   Click or tap here to enter text. |
| 1. If **signed consent** is not appropriate for this study or cannot be obtained, please justify the alternative method chosen and how free and informed consent will be obtained and documented.   Click or tap here to enter text. |
| 1. Are there any supervisory or trust-based relationships between persons obtaining consent and the participants (e.g., professor-student, patient-doctor, relative, friend)?   Yes  No  If yes, please describe and explain the measures taken to ensure that participants do not feel pressure to participate or perceive they may be penalized for choosing not to participate.  Click or tap here to enter text. |
| Does the study involve participants under the age of 19? Yes – please specify Click or tap here to enter text.  No |
| Participants who do not have capacity to provide consent should be given the opportunity to agree to their involvement in the study. This is done with an appropriate assent text. Please attach a copy of the consent form and the assent form(s). |
| 1. If the participants are minors or for other reasons are not competent to consent, describe the proposed alternative source of consent, including any permission form to be provided to the person(s) providing the alternative consent (assent).   Click or tap here to enter text. |
| 1. How will informed consent and/or assent be determined with minor children or those deemed incapable of giving informed consent?   Click or tap here to enter text. |
| Could participants feel pressure to participate or perceive that they may be penalized for choosing not to participate in the study? Yes  No  If yes, please describe and explain the measures taken to ensure that participants do not feel pressure to participate or perceive they may be penalized for choosing not to participate.  Click or tap here to enter text. |
| 1. Informed Consent is not only the completion of the form but is also an ongoing process. Please describe how you will maintain informed consent throughout the study.   Click or tap here to enter text. |
| 1. What are your procedures/intentions for future use of data and is this clearly communicated to your participants?   Click or tap here to enter text. |

Participant Withdrawal

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| 1. Are participants able to withdraw from the study?   Not applicable  Participants can withdraw  Participants can only withdraw during the study session  Special withdrawal procedures are in place |
| 1. Describe the procedures for a participant to withdraw.   Click or tap here to enter text. |
| 1. What will happen to the data from a participant if they withdraw?   Click or tap here to enter text. |
| 1. Describe any deadlines and/or limitations on withdrawal from the study.   Click or tap here to enter text. |

\*\*\* **Note**: Ensure that all information letters, informed consent, informed assent, etc. are appended and clearly labeled

# **Section L – Privacy, Confidentiality and Anonymity**

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| 1. Will participants be anonymous? (Anonymous means that no link can be established between the participant and the research and that no one, including the researcher(s) know(s) who participated in the research study.)   Yes  No |
| 1. Will the confidentiality of participants and their data be protected? (Confidentiality: An ethical and/or legal responsibility of individuals or organizations to safeguard information entrusted to them, from unauthorized access, use, disclosure, modification, loss or theft - TCPS)   Yes  No |
| 1. Will data be stripped of identifying information?   Yes  No  If yes, please explain how and when.  Click or tap here to enter text. |
| 1. Are there any limits to confidentiality? (select all that apply)   Limits due to the nature of the research activity (e.g., focus groups – the researcher cannot guarantee confidentiality)  Limits due to context – individual participants could be identified because of the nature or size of the sample or because of their relationship with the researcher  Limits due to selection – procedures for recruiting or selecting participants may compromise the confidentiality of participants (e.g., participants are referred to the study by someone outside the research team)  Duty to report (e.g., participant self-harm, harm to others, child or elder abuse)  Other – specify - Click or tap here to enter text.  Please describe how you will manage limits to confidentiality and ensure that this is also addressed in the informed consent.  Click or tap here to enter text. |
| Are you collecting any identifying information which would permit specific research participants to be identified through identifiers (e.g., name, address, social insurance number, personal health number, date of birth, place of residence, unique personal characteristic)? Yes  No  If yes, what identifying information will be collected?  Click or tap here to enter text. |
| Please describe how the identity of the individuals will be safeguarded. If using pseudonyms or codes to remove identifiers, please describe who will have access to codes or pseudonyms to link data to participant identities. Click or tap here to enter text. |
| When disseminating research results, will research participants be quoted? Yes  No  If yes, describe how identifying information will be removed or altered ensuring that quotes do not reveal individuals' identities. In the case where quotes will reveal individuals' identities, please explain the reasons and include this information in the consent form.  Click or tap here to enter text. |
| If research participants are quoted, will they be given the opportunity to review their transcripts? Yes  No  Participants will not be quoted  If yes, please explain how research participants will have access to their transcripts. If sending transcripts via email, please explain the security measures being taken (e.g., encryption, password protection of documents). If no security measures are being contemplated, please inform research participants of the possible security risk in the consent form.  Click or tap here to enter text. |

# **Section M – Research Data Security and Management Plan**

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| The duty of confidentiality includes obligations to protect the data from unauthorized access, use, disclosure, modification, loss or theft. Researchers must provide details to the UREB regarding their proposed measures for safeguarding information, for the full life cycle of information - that is, its collection, use, dissemination, retention and disposal. Physical safeguards include the use of locked filing cabinets and location of computers containing research data away from public areas. Administrative safeguards include development and enforcement of organizational rules about who has access to personal information about research participants. Technical safeguards include use of computer passwords, firewall, anti-virus, encryption and other measures that protect data from unauthorized access, loss or modification.  **\*\*\*Please note** that the term ***data,*** as used in this section, refers to **both** electronic and hard copy versions of data (physical types of data such as notes, questionnaires, consent forms). Your responses should indicate and include all forms of data being used in your study. |
| 1. Who will collect the data?   Click or tap here to enter text. |
| 1. Who will have access to the data? (select all that apply)   Note: Any additional individuals who may have access to the data, who have not signed this form (e.g., research assistants, translators, interpreters) must sign a confidentiality agreement.  Principal Investigator  Thesis/Project Supervisor or Sponsor  Co-Investigator(s)  Research Assistant(s)  Other (please specify) Click or tap here to enter text. |
| Describe the physical location(s) and safeguards that will be used to securely store all non-digital sources of data, such as written records, audio or video recordings, questionnaires, during the study. Click or tap here to enter text. |
| 1. Describe the location(s) and safeguards that will be used to securely store all digital sources of electronic data during the study.   Click or tap here to enter text. |
| 1. Indicate how long data will be retained and the starting time of the retention period (e.g., following publication, completion of project). It is recommended that all data (excluding clinical trial data) be conserved for a minimum of 5 years. Clinical trial data must be stored for at least 25 years.   Click or tap here to enter text. |
| 1. Describe how and where the data will be securely stored during the conservation period.   Click or tap here to enter text. |
| 1. Describe the methods of disposal for all types of data following the conservation period (e.g., shredding, secure deletion).   Click or tap here to enter text. |

# **Section N – Dissemination and Future Use of Data**

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| 1. Is it your intention to reanalyze the data **for purposes other than described in this application**?   Yes  No |
| 1. Have you informed your participants about future use of data collected?   Yes  No |
| 1. Is it your intention to allow the study and data to be reanalyzed by colleagues, students, or other researchers outside of the original research purposes? If this is the case, explain how you will allow your participants the opportunity to choose to participate in a study where their data would be distributed to others (state how you will contact participants to obtain their re-consent).   Yes  No  If yes, please describe below.  Click or tap here to enter text. |
| 1. If there are no plans to reanalyze the data for secondary purposes and, yet, you wish to keep the data indefinitely, please explain why.   Click or tap here to enter text. |
| 1. Describe how you will disseminate the results to the participants.   Click or tap here to enter text. |
| 1. Describe how stakeholders, the public, the academic community will be informed of the results of the study.   Click or tap here to enter text. |

# **Section O – Signature and Agreement**

|  |  |
| --- | --- |
| **Researcher Responsibilities:**   * No research activity with human participants (recruitment or data collection) may take place prior to the PI receiving notification from the UREB that the study has been cleared by the UREB * The researcher must ensure appropriate training for all members of the research team * Researchers must notify the UREB when the study is complete or if the researcher wishes to place the study on hold. This is accomplished by filing REB.FORM.004 – Final Report * All adverse events must be reported promptly to the UREB as per MSVU UREB Policies and Procedures * All privacy breaches and/or unanticipated research events must be reported promptly to the UREB as per MSVU UREB Policies and Procedures * All modification requests for cleared protocols must be reviewed and cleared by the UREB prior to their implementation as per MSVU UREB Policies and Procedures * Researchers must request a renewal extension using REB.FORM.003 30 days prior to expiry * Research studies receive research ethics clearance for an initial one-year period, at which time the researcher must close or renew the study. Renewals may, upon receipt of the appropriate application, be renewed for up to an additional 4 years, at which time, if the research is still on-going, the PI must re-apply with a new application. This re-review shall be delegated normally to the Chair or Vice-Chair | |
| My/Our signature(s) below, and submission of this application, confirms that I/we will ensure that all procedures conducted as part of the project will be conducted in accordance with the Tri-Council Policy Statement on Ethical Conduct for Research Involving Humans (TCPS) found online at <http://www.pre.ethics.gc.ca/eng/index/> as well as all relevant MSVU University Research Ethics Board policies and procedures and agree to comply with the policies and procedures outlined therein. | |
| **Insert** Signature of Principal Investigator or Nominated Principal Investigator | Date: Click or tap to enter a date. |
| **Faculty Supervisor or MSVU Sponsor (if required)**  In the case of student research, as Faculty Supervisor, my signature below, and submission of this application, indicates that I have read and approved the application and proposal, deem the project scientifically valid and worthwhile, and agree to provide continuing and thorough supervision of the student(s). I will ensure that the level of risk inherent to the project is balanced by the level of research experience that the student researcher has. I will provide appropriate oversight to ensure that the research will be conducted in accordance with MSVU UREB's policies/procedures and that it adheres to this cleared protocol and consenting process. | |
| **Insert** Signature of Faculty Supervisor | Date: Click or tap to enter a date. |

Submission Process:

1. Researchers must submit the application electronically to [ethics@msvu.ca](mailto:ethics@msvu.ca)
2. Please note that recruitment and data collection may not begin until a certificate of Research Ethics Clearance has been issued.
3. Researchers may **only** use letters and/or numbers for file names and must refrain from using any special characters (e.g., #; &; etc.).
4. All documents in the appendices must be clearly labeled and reflect how they are referenced in the application.
5. **Note** - **only 2 attachments** are permitted for submission– the application (1) and the combined appendices (2)
6. Application packages shall only be accepted in the form of Word documents (\*.doc or \*.docx) or Portable Document Format (\*.pdf)

For details on specific submission criteria, please see the following Guidance Documents:

* [REB.INFO.401](https://www2.msvu.ca/sites/ResearchDocumentCentre/Research%20Ethics%20%20Human/REB.INFO.401%20Faculty%20and%20Staff%20Submission%20Process.pdf) – Faculty & Staff
* [REB.INFO.402](https://www2.msvu.ca/sites/ResearchDocumentCentre/Research%20Ethics%20%20Human/REB.INFO.402%20Graduate%20Student%20Submission%20Process.pdf) – Graduate Students
* [REB.INFO.403](https://www2.msvu.ca/sites/ResearchDocumentCentre/Research%20Ethics%20%20Human/REB.INFO.403%20Undergraduate%20Student%20Submission%20Process.pdf) – Undergraduate Students

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1. For more information on Sensitive Data, please refer to SOP.REB.127 on the MSVU Research Ethics website. [↑](#footnote-ref-2)