Commit

**University Research Ethics Board (UREB)**



**REB.FORM.005 | Secondary Use of Data Ethics Application**

Secondary use of data/biological materials (e.g. survey data, student records, health records, or biological material surplus to diagnostic exams or surgical procedures) refers to both:

* Retrospectively\* accessing data/samples that has already been collected for a different purpose to answer a research question that is different from the original question, and,
* Re-analyzing an existing research data set with a different research question

\*In order for a study to be considered retrospective, the end date of data collection must be before the date of submission to the UREB.  Therefore, your study will not involve collecting any information prospectively.

**\*\*Both types of secondary use of data require research ethics review.**

If the study exclusively uses data that are publicly available or made accessible through legislation or regulation, it is exempt from REB review (TCPS [Article 2.2](http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter2-chapitre2/)).

|  |
| --- |
| Section A – Ethics File Details |
| 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 |
| Principal Investigatoror Nominated Principal Investigator (see REB.INFO.001 for definitions) | Click or tap here to enter text. |
| Department/Faculty | Click or tap here to enter text. |
| Email Address (MSVU email only) | Click or tap here to enter text. |
| Telephone Number | Click or tap here to enter text. |
| Researcher Category  | Choose an item.If you chose Other, please specify: Click or tap here to enter text. |
| \*Please provide your supervisor’s or MSVU Faculty Sponsor’s information below (if applicable) |
| Supervisor | Click or tap here to enter text. |
| Supervisor’s Email (MSVU email only) | Click or tap here to enter text. |
| 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.\*Note: please use REB.FORM.014 to add, remove or reposition research team members. |

|  |  |  |
| --- | --- | --- |
| 1. | 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. |
| 2. | 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. |
| 3. | 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.\*Note: please use REB.FORM.014 to add, remove or reposition research team members. |
| 1. | 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. |
| 2. | 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. |
| 3. | 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 |
| Research Funding Status | Choose an item. |
| Grantor (select all that apply) | Tri-Council (SSHRC, CIHR, NSERC) [ ] Internal [ ]  Other External [ ] (Please specify other grantors): Click or tap here to enter text. |
| Principal Investigator on Funding | Click or tap here to enter text. |
| Grant Number(s) | Click or tap here to enter text. |
| Grant Title (if different from REB file) | Click or tap here to enter text. |
| 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** |
| 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** |
| 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 aboveClick or tap here to enter text. |
| **Research Team Experience and Qualifications** |
| Does this study require professional expertise/recognized qualifications? (e.g. registered psychologist; first aid certification) | [ ] Yes[ ] NoIf yes, please provide a brief explanation below and indicate if you, or any member of the research team have the required professional expertise/ qualifications.Click or tap here to enter text. |
| 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-1)?)? 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. |
| 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. |
| 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 [ ] NoFor either answer, explain below:Click or tap here to enter text. |
| **Conflict of Interest** |
| 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. |
| 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\*Do not include funded research grant expenses, possible academic promotion or other benefits which are integral to the general conduct of research.  | [ ] 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. |
| How will you manage the conflict with regards to the research? | Click or tap here to enter text. |
| 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. |
| 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 top prevent possible undue influence, coercion or inducement given the power differential. | Click or tap here to enter text. |
| **Scholarly/Peer Review** |
| 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 reviewGraduate Students: Please ensure that you attach a copy of thesis proposal acceptance to this application |

|  |
| --- |
| **Section F - Inclusion of Indigenous Peoples** |
| Will the research questions/hypotheses concern Indigenous peoples? | [ ] Yes[ ] No |
| Will analyses use Indigenous community membership as a variable? | [ ] Yes[ ] No |
| Will interpretation of results refer to Indigenous people, language, history or culture? | [ ] Yes[ ] No |
| If yes to any of the above, please discuss any plans for community engagement, as indicated in the TCPS (Chapter 9). | Click or tap here to enter text. |
| **Append** any existing research agreements concerning the data or samples.  |
| State whether ethical approval has been or will be sought from any Indigenous ethics review group. | Click or tap here to enter text. |
| Describe how results will be returned to the community. | Click or tap here to enter text. |

|  |
| --- |
| **Section G – Original Review Information** |
| 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. |
| Who currently has custody of the records/database/materials to be used ? | Click or tap here to enter text. |
| Have you submitted you proposed research and request for secondary data to the custodian(s)? | [ ] Yes[ ] NoIf no, please provide the anticipated request dateClick or tap to enter a date. |
| Briefly describe the purpose of the original study. Please attach the consent form used when collecting the original data. | Click or tap here to enter text. |
| What is the purpose and rationale of your proposed research? Be sure to explain how the proposed research differs from the original research. Also indicate whether the purpose of the proposed research deviates from what the participants originally gave consent to in the informed consent letter, and if so how. | Click or tap here to enter text. |
| For the current analysis, describe and justify the sample or sub-sample being used (inclusion/exclusion criteria). Explain the process of identifying, selecting and obtaining records (or materials).   | Click or tap here to enter text. |
| Describe the data you will be using and how. (e.g., reviewing videotapes/ transcripts or analyzing a data set) | Click or tap here to enter text. |
| Describe the population or sample included in the original data (or biological material) collection | Click or tap here to enter text. |
| Describe how the data (or materials) were initially gathered, when, and by whom.  | Click or tap here to enter text. |
| If information was collected for research, how were participants recruited? | Click or tap here to enter text. |
| Will the data involve linking data sets (i.e., using data collected from multiple sources)? | [ ] Yes[ ] NoIf yes, explain how participants’ identities could be established or not through data linkage.Click or tap here to enter text. |
| Evaluate the potential harms that might occur as a result of the proposed research. What are the potential benefits? | Click or tap here to enter text. |
| Do you plan to obtain additional consent from the participants | [ ] Yes[ ] NoIf yes, explain how the additional consent will be obtained and attached the proposed consent form. Will you disseminate the results of the study as well? If no, explain why. Also indicate any strategies to be used to allow participants to object and/or communicate to relevant groups about the research (e.g., posting notices where participants may frequent, proxy consent).Click or tap here to enter text. |

|  |
| --- |
| **Section H - Informed Consent**  |
| 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 (e.g., 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 particular circumstances of individual participants. In particular, 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 in light of the new information. In the case of children who begin participation in a project on the basis of consent from an authorized third party, the researcher must seek their autonomous consent if they reach the age of majority during the research, in order for their participation to continue. (TCPS2, Ch. 3, Article 3.3) |
| How was informed consent originally obtained? | [ ] Signed Consent[ ] Online Consent[ ] Oral Consent[ ] Implied (action-relative) Consent[ ] Assent[ ] Parent/Guardian Consent[ ] Other – Specify - Click or tap here to enter text. |
| What were the original parameters of data usage for which participants gave consent?  | Click or tap here to enter text. |
| To what extent does the original consent address the purposes of the current study? \*Attach original consent form if available. | Click or tap here to enter text. |
| Does this study use records or biological materials collected for non-research purposes | [ ] Yes[ ] No*If no, please proceed to Section I below.* |
| Does this research use health information? | [ ] Yes[ ] NoIf yes, this research may be subject to Nova Scotia’s [*Personal Health Information Act*](http://novascotia.ca/dhw/phia/). In accordance with this Act, please explain why the research cannot reasonably be accomplished without access to personal health information.Click or tap here to enter text. |

|  |
| --- |
| **Section I – Data Security and Management Plan** |
| 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 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 ***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. |
| Who will have access to the data? (select all that apply) | [ ] Principal Investigator[ ] Thesis/Project Supervisor or Sponsor[ ] Co-Investigator(s)[ ] Research Assistant(s)[ ] Other (please specify) Click or tap here to enter text. |
| 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. |
| Briefly discuss the data to be captured from records or biological materials, the data fields to be used, or the variables to be used for the proposed analyses. Justify the use of these in relation to the study purposes. Attach any data capture sheet for record review, or list of variables to be used. | Click or tap here to enter text. |
| Describe the data analysis plan. | Click or tap here to enter text. |
| Indicate the level of identifiability of data or biological materials. (It is best practice to collect data at the lowest level of identifiablity possible to meet study objectives.) | [ ] Anonymous/anonymized (data/materials cannot be linked to individuals). [ ] De-identified (a key-code linking data/materials with individuals exists but is not available to the researcher). [ ] Identifiable (information directly or indirectly identifies individuals)If identifiable, specify what direct identifiers (e.g., name, contact information, student number, social insurance number, health number) or indirect (e.g., date of birth, sex, postal code) are being collected. Justify why each item is essential to conduct the research. Click or tap here to enter text. |
| Comment on the expectations that participants have regarding the confidentiality and use of their data for other purposes. | 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 course of the study. | Click or tap here to enter text. |
| Describe the location(s) and safeguards that will be used to securely store all digital sources of electronic data during the course of the study. | Click or tap here to enter text. |
| Indicate how long data will be conserved and the starting time of the conservation 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. |
| Describe how and where the data will be securely stored during the conservation period. | Click or tap here to enter text. |
| 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 J – Privacy, Confidentiality and Anonymity** |
| Will participants be anonymous? (Anonymous means that no link can be established between he participant and the research and that no one, including the research(s) know who participated in the research study.) | [ ] Yes [ ] No |
| Will the confidentiality of participants and their data be protected? (Confidentiality means that no link can be established between the collected data and the participant’s identity.) | [ ] Yes [ ] No |
| 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. |

|  |
| --- |
| **Section K – Dissemination and Future Use of Data** |
| Is it your intention to reanalyze the data **for purposes other than described in this application**? | [ ] Yes [ ] No |
| Have you informed your participants about future use of data collected? | [ ] Yes [ ] No |
| 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 [ ] NoIf yes, please describe below.Click or tap here to enter text. |
| 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. |
| Describe how you will disseminate the results to the participants | Click or tap here to enter text. |
| 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 L – Signature and Agreement |
| My/Our signature(s) below 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. |
| **Signature of Principal Investigator or Nominated Principal Investigator** | Name: Click or tap here to enter text. | 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 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. |
| **Signature of Faculty Supervisor** | Name of Faculty Supervisor: Click or tap here to enter text. | Date: Click or tap to enter a date. |

**Submission Process:**

1. Researchers are asked to submit the application electronically only to 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 refrain from using any special characters (e.g., #; &; etc.).
4. All documents must be clearly labeled and reflect how they are referenced in the application.
5. Note - a **maximum of 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 [**Guidance Documents**](https://www.msvu.ca/research-at-the-mount/research-ethics/policies-procedures-guidelines/):

* REB.INFO.401 – Faculty & Staff
* REB.INFO.402 – Graduate Students
* REB.INFO.403 – Undergraduate Students

***Acknowledgement****:* The University Research Ethics Board wishes to extend its appreciation to the Research Ethics Boards at Dalhousie University, Saint Mary’s University, Health Research Ethics Authority (NL) and the University of Ottawa for permission to embed several aspects of their ethics applications into this current UREB iteration.

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