

# RESEARCH ETHICS BOARDS

# APPLICATION FORM

**Prospective Research**

This form should only be used if new data will be collected. For research involving only secondary use of existing information (such as health records, student records, survey data or biological materials), use the *REB Application Form – Secondary Use of Information for Research.*

This form should be completed using the *Guidance for Submitting an Application for Research Ethics Review* available on the [Research Ethics website](http://www.dal.ca/dept/research-services/responsible-conduct-/research-ethics-/apply-for-reb-approval.html) (application instructions).

## SECTION 1. ADMINISTRATIVE INFORMATION [File No: office only]

|  |
| --- |
| Indicate the preferred Research Ethics Board to review this research:[ ] Health Sciences OR [ ] Social Sciences and Humanities |

|  |
| --- |
| Project Title: |

|  |
| --- |
| **1.1** Research team information  |
| Dalhousie researcher name |  |
| Banner # |  | Department |  |
| Email (@dal) |  | Phone |  |
| Study start date |  | Study end date |  |
| Co-investigator names and affiliations |  |
| Contact person for this submission (if not lead researcher) | Name |  |
| Email |  | Phone |  |

|  |
| --- |
| **1.2** For student submissions: |
| Degree program |  |
| Supervisor name and department |  |
| Supervisor Email (@dal) |  | Phone |  |
| Department/unit ethics review (if applicable). **Undergraduate minimal risk research only**. |
| Attestation: [ ] I am responsible for the unit-level research ethics review of this project and it has been approved. Authorizing name: Date:  |

|  |
| --- |
| **1.3** Other reviews: |
| Other ethics reviews (if any)  | Where | Status |
| Funding, if any (list on consent form) | Agency |  |
| Award Number |  |
| Peer review (if any) |  |

|  |
| --- |
| **1.4** Attestation(s). The appropriate boxes *must* be checked for the submission to be accepted by the REB) |
| **[ ]** I am the **lead researcher**. I agree to conduct this research following the principles of the Tri-Council Policy Statement *Ethical Conduct for Research Involving Humans* ([TCPS](http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/Default/)) and consistent with the University [*Policy on the Ethical Conduct of Research Involving Humans*](http://www.dal.ca/dept/university_secretariat/policies/human-rights---equity/ethical-conduct-of-research-involving-humans-policy.html).I have completed the TCPS Course on Research Ethics ([CORE](http://www.pre.ethics.gc.ca/eng/education/tutorial-didacticiel/)) online tutorial. [ ] Yes [ ] NoFor Supervisors (of student / learner research projects):**[ ]** I am the **supervisor** for this research named in section 1.2. I have reviewed this submission, including the scholarly merit of the research, and believe it is sound and appropriate. I take responsibility for ensuring this research is conducted following the principles of the [TCPS](http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/Default/) and University [Policy](http://www.dal.ca/dept/university_secretariat/policies/human-rights---equity/ethical-conduct-of-research-involving-humans-policy.html).I have completed the TCPS Course on Research Ethics ([CORE](http://www.pre.ethics.gc.ca/eng/education/tutorial-didacticiel/)) online tutorial. [ ] Yes [ ] No |

## SECTION 2. PROJECT DESCRIPTION

|  |
| --- |
| **2.1** Lay summary |
| 2.1.1 In lay language, describe the rationale, purpose, study population and methods. Include the background information or literature to contextualize the study. Mention what new knowledge is anticipated, and whether this is a pilot project or fully developed study. [500 words] |
| 2.1.2 If a phased review is being requested, describe why this is appropriate for this study, and which phase(s) are included for approval in this application.[ ] Not applicable |

|  |
| --- |
| **2.2** Research question  |
| State the hypotheses, the research questions or research objectives. |

|  |
| --- |
| **2.3** Recruitment |
| 2.3.1 Identify the study population. Describe how many participants are needed and how this was determined. |
| 2.3.2 Describe recruitment plans and append recruitment instruments. Describe who will be doing the recruitment and what actions they will take, including any screening procedures. Describe and justify any inclusion / exclusion criteria.  |
| 2.3.3 Describe any community or organizational permissions needed to recruit your participants (attach support letters). Describe any other community consent or support needed to conduct this research. (If the research involves Aboriginal participants, please complete section 2.10).[ ] Not applicable |

|  |
| --- |
| **2.4** Informed consent process |
| 2.4.1 Describe the informed consent process, including any plans for ongoing consent (how and when the research will be described to prospective participants, by whom, how the researcher will ensure prospective participants are fully informed). If non-written consent is proposed, describe the process. Address how any third party consent (with or without assent) will be managed. Append copies of all consent/assent documents, including oral consent scripts. |
| 2.4.2 Discuss how participants will be given the opportunity to withdraw (their participation and/or their data) and any limitations on this. [ ] Not applicable |
| 2.4.3 If an exception to the requirement to seek prior informed consent is sought, address the criteria in TCPS article [3.7A](http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter3-chapitre3/#toc03-1b).[ ] Not applicable |

|  |
| --- |
| **2.5** Methods and analysis |
| 2.5.1 Describe the study design, where the research will be conducted, what participants will be asked to do and the time commitment, what data will be recorded using what research instruments (append copies). [ ] This is a clinical trial (physical or mental health intervention) – ensure section 2.11 is completed |
| 2.5.2 Describe plans for data analyses. |
| 2.5.3 Describe any compensation that will be given to participants and how this will be handled for participants who do not complete the study. Discuss any expenses participants are likely to incur and whether/how these will be reimbursed. |
| 2.5.4 Describe and justify any use of deception or nondisclosure and explain how participants will be debriefed.[ ] Not applicable |
| 2.5.5 Describe the role and duties of local researchers (including students and supervisors) in relation to the overall study. Identify any special qualifications represented on the team relevant to the proposed study (e.g. professional or clinical expertise, research methods, experience with the study population, statistics expertise, etc.). |

|  |
| --- |
| **2.6** Privacy & confidentiality  |
| 2.6.1 Describe any provisions for ensuring privacy and confidentiality (or anonymity). Describe who will have access to data and why, how data will be stored and handled in a secure manner, how long data will be retained and where. Discuss any plans for data destruction and/or de-identification.[ ] This research involves personal health records (ensure section 2.12 is completed) |
| 2.6.2 Describe how participant confidentiality will be protected when research results are shared. Discuss whether participants will be identified (by name or indirectly). If participants will be quoted address consent for this, including whether quotes will be identifiable or attributed.  |
| 2.6.3 Address any limits on confidentiality, such as a duty to disclose abuse or neglect of a child or adult in need of protection, and how these will be handled. Detail any such limits in consent documents. [ ] Not applicable |
| 2.6.4 Will any information that may reasonably be expected to identify an individual (alone or in combination with other available information) be accessible outside Canada? This includes sharing information with team members, collecting data outside Canada, use of survey companies, use of software.[ ] No[ ] Yes. If yes, describe how you comply with the University [*Policy for the Protection of Personal Information from Access Outside Canada*](http://www.dal.ca/dept/university_secretariat/policies/governance/protection-of-personal-information-policy-.html), such as securing participant consent and/or securing approval from the Vice President Research. |

|  |
| --- |
| **2.7** Provision of results to participants  |
| 2.7.1 The TCPS encourages researchers to share study results with participants in appropriate formats. If you plan to share study results with participants, discuss the process and format. [ ] Not applicable |
| 2.7.2 If applicable, describe how participants will be informed of any incidental findings – unanticipated results (of screening or data collection) that have implications for participant welfare (health, psychological or social). [ ] Not applicable |

|  |
| --- |
| **2.8** Risk & benefit analysis  |
| 2.8.1 Discuss what risks or discomforts are anticipated for participants, how likely risks are and how risks will be mitigated. Address any particular ethical vulnerability of your study population. If applicable, address third party or community risk. Risks to privacy from use of identifying information should be addressed. |
| 2.8.2 Identify any direct benefits of participation to participants (other than compensation), and any indirect benefits of the study (e.g. contribution to new knowledge) |

|  |
| --- |
| **2.9** Conflict of interest  |
| Describe whether any dual role or conflict of interest exists for any member of the research team in relation to potential study participants (e.g. TA, fellow student, teaching or clinical relationship), and/or study sponsors, and how this will be handled.[ ] Not applicable |

|  |
| --- |
| **2.10** Research with Aboriginal peoples [ ] Not applicable – go to 2.11 |
| 2.10.1 If the proposed research involves Aboriginal peoples, describe the plan for community engagement (per TCPS Articles [9.1 and 9.2](http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter9-chapitre9/#toc09-1c)). Attach supporting letters, research agreements and other relevant documents, if available. If community engagement is not sought, explain why the research does not require it, referencing article 9.2. |
| 2.10.2 State whether ethical approval has been or will be sought from Mi’kmaw Ethics Watch or other Indigenous ethics review group(s), and if not, why the research does not fall under their purview. |
| 2.10.3 Describe any plans for returning results to the community and any intellectual property rights agreements negotiated with the community, with regard to data ownership. If there are specific risks to the community involved, ensure these have been addressed in section 2.8.1.  |

|  |
| --- |
| **2.11** Clinical trials [ ] Not applicable – go to 2.12 |
| 2.11.1 Does the proposed research require clinical trial registration, in keeping with national and international regulations? [ ] No. Please explain why not.[ ] Yes. Please indicate where it was registered and provide the registration number. |
| 2.11.2 If a novel intervention or treatment is being examined, describe standard treatment or intervention, to indicate a situation of clinical equipoise exists (TCPS [Chapter 11](http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter11-chapitre11/)). If placebo is used with a control group rather than standard treatment, please justify.  |
| 2.11.3 Clearly identify the known effects of any product or device under investigation, approved uses, safety information and possible contraindications. Indicate how the proposed study use differs from approved uses. [ ] Not applicable |
| 2.11.4 Discuss any plans for blinding/randomization. |
| 2.11.5 What plans are in place for safety monitoring and reporting of new information to participants, the REB, other team members, sponsors, and the clinical trial registry? These should address plans for removing participants for safety reasons, and early stopping/unblinding/amendment of the trial. What risks may arise for participants through early trial closure, and how will these be addressed? Are there any options for continued access to interventions shown to be beneficial? |

|  |
| --- |
| **2.12** Use of personal health information [ ] Not applicable |
| 2.12.1 Describe the personal health information required and the information sources, and explain why the research cannot reasonably be accomplished without the use of that information. Describe how the personal health information will be used, and in the most de-identified form possible. |
| 2.12.2 Will personal health information be combined with information from other sources to form a composite record (data linkage)? Will the research create individually identifying health information by combining information from two or more databases without the consent of the individuals who are the subjects of the information (data matching)?[ ] No.[ ] Yes. Describe the other information and how linkage will be conducted, and/or why data matching is required. |
| 2.12.3 Describe reasonably foreseeable risks to privacy and how these will be mitigated. |

## SECTION 3. APPENDICES

**3.1 Appendices Checklist.** Append all relevant material to this application. This may include:

[ ] Recruitment documents (posters, oral scripts, online postings, invitations to participate, etc.)

[ ] Screening documents

[ ] Consent/assent documents or scripts

[ ] Research instruments (questionnaires, interview or focus group questions, etc.)

[ ] Debriefing forms

[ ] Permission letters (Aboriginal Band Council, School Board, Director of a long-term care facility)

[ ] Support letters

**3.2 Consent Form**

Sample consent forms are provided on the [Research Ethics website](http://www.dal.ca/dept/research-services/responsible-conduct-/research-ethics-/apply-for-reb-approval.html) and may be used in conjunction with the information in the *Guidance* document to help you develop your consent form.