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# 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*](https://cdn.dal.ca/content/dam/dalhousie/pdf/research-services/REB/Dal%20REB%20Application%20Instructions%20-%20Prospective%20Research%20%20v2021-02.pdf).

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

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

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| **Project Title:** |

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| **1.1** **Research team information** | | | | | | | |
| Lead researcher  (at Dalhousie) | Name |  | | | | | |
| Email (@dal) |  | | Phone | | |  |
| Banner # |  | | Academic Unit | | |  |
| Co-investigator names, affiliations, and email addresses |  | | | | | | |
| Contact person for this submission (if not lead researcher) | Name |  | | | | | |
| Email |  | | | Phone |  | |
| Study start date |  | | Study end date | |  | | |

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| **1.2** **For student submissions** (including medical residents and postdoctoral fellows) | | | |
| 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: | | | |

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| **1.3** **Other reviews** | | | | |
| Other ethics review (if any) for this research | | Where? |  | |
| Status? |  | |
| Scholarly/scientific peer review (if any) |  | | | |
| Is this a variation on, or extension of, a previously approved Dal REB submission? | | | | [ ] No  [ ] Yes Dal REB file #\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **If yes**, describe which components of the current submission are the same as the previously approved submission (list section numbers), and which components are different from the previously approved submission (list section numbers). You may also use highlighting to clearly indicate revised text. | | | | |

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| **1.4** **Funding**  [ ] Not Applicable | | |
| Funding (list on consent form) | Agency |  |
| Award Number |  |
| Institution where funds are/will be held | [ ] Dalhousie University  [ ] Other: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Was a Dal release of funds agreement issued for this award? | | [ ] Yes Date of RoF Agreement: \_\_\_\_\_\_\_\_\_\_\_\_ |

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| **1.5 Attestation(s).** The appropriate boxes *must* be checked for the submission to be accepted by the REB |
| **[ ]** I am the **lead researcher** (at Dalhousie) named in section 1.1. I agree to conduct this research following the principles of the Tri-Council Policy Statement *Ethical Conduct for Research Involving Humans* ([TCPS](https://ethics.gc.ca/eng/policy-politique_tcps2-eptc2_2022.html)) 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://tcps2core.ca/welcome)) online tutorial.  [ ] Yes [ ] No  For Supervisors (of student / learner research projects):  **[ ]** I am the **supervisor** 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](https://ethics.gc.ca/eng/policy-politique_tcps2-eptc2_2022.html) 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://tcps2core.ca/welcome)) online tutorial.  [ ] Yes [ ] No |

## SECTION 2. PROJECT DESCRIPTION

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| **2.1 Lay summary** |
| 2.1.1 In **plain language**, describe the rationale, purpose, study population and methods to be used. Include a summary of background information or literature to contextualize the study. What new knowledge, or public or scientific benefit is anticipated? [maximum 500 words]  [ ] This is a pilot study.  [ ] This is a fully developed study. |
| 2.1.2 Phased review. 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. Refer to the [guidance document](https://cdn.dal.ca/content/dam/dalhousie/pdf/research-services/REB/Dal%20REB%20Application%20Instructions%20-%20Prospective%20Research%20%20v2021-02.pdf) before requesting a phased review.  [ ] Not applicable |

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| **2.2** **Research question** |
| State the research question(s) or research objective(s). |

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| **2.3** **Recruitment** |
| 2.3.1 Identify the study population. Describe and justify any inclusion / exclusion criteria. Also 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. |
| 2.3.3 If you require permission, cooperation, or participation from a community, organization or company to recruit your participants, describe the agreement obtained from the relevant group(s). Attach correspondence indicating their cooperation and/or support (required). Describe any other community consent or support needed to conduct this research. (If the research involves Indigenous communities complete section 2.11).  [ ] Not applicable |

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| **2.4** **Informed consent process** |
| 2.4.1 Describe the informed consent process:  A) How, when and by whom will the study information be conveyed to prospective participants? How will the researcher ensure prospective participants are fully informed?  B) Describe how consent will be documented (e.g. written signature, audio-recorded, etc).  [ ] Append copies of all consent information that will be used (e.g. written consent document, oral consent script, assent document/script, etc).  *Note: If the research will involve third party consent (with or without participant assent), and/or ongoing consent, ensure these are described above.* |
| 2.4.2 Discuss how participants will be given the opportunity to withdraw their participation (and/or their data) and any time (or content) limitations on this. If participants will not have opportunity to withdraw their participation and/or their data explain why. |
| 2.4.3 If an alteration/exception to the requirement to seek prior informed consent is sought, address the criteria in TCPS article [3.7A](https://ethics.gc.ca/eng/tcps2-eptc2_2022_chapter3-chapitre3.html#7a). If the alteration involves deception or nondisclosure, also complete section 2.4.4.  [ ] Not applicable |
| 2.4.4 Describe and justify any use of deception or nondisclosure and explain how participants will be debriefed.  [ ] Not applicable |

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| **2.5** **Methods, data collection and analysis** |
| 2.5.1  A) Where will the research be conducted?  B) What will participants be asked to do?  C) What data will be collected using what research instruments? *(Note that privacy and confidentiality of data will be covered in section 2.6)*  D) How much of the participant’s time will participation in the study require?  [ ] Append copies of all research instruments (questionnaires, focus group questions, standardized measures, etc)  [ ] This is a clinical trial (physical or mental health intervention) – ensure section 2.12 is completed |
| 2.5.2 Briefly describe the data analysis plan. Indicate how the proposed data analyses address the study’s primary objectives or research questions. |
| 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. |

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| **2.6** **Privacy and confidentiality** |
| 2.6.1  A) Describe who will have knowledge of participants’ identities.    B) Describe the level of identifiability of the study data (anonymous, anonymized, de-identified/coded, identifying) (see [TCPS Chapter 5A – types of information for definitions](https://ethics.gc.ca/eng/tcps2-eptc2_2022_chapter5-chapitre5.html)).  C) Specify which members of the research team (or others) will have access to participants’ data and for what purpose.  D) Describe measures to ensure privacy and confidentiality of study documents and participant data during the data collection and analysis phase. *[Note that plans for long term storage will be covered in 2.6.2*]   * Address: handling of documents/data during data collection; transportation or transfer of documents/data; storage of documents/data (during the study). * If a key-code will be maintained, describe how it will be kept secure. * For electronic data, describe electronic data security measures, including file encryption and/or password protection [as applicable](https://cdn.dal.ca/content/dam/dalhousie/pdf/research-services/REB/Protecting%20Electronically%20Stored%20Personally%20Identifiable%20Research%20Data%20-%202021-08.pdf). * For hard copy documents, describe physical security measures (specify location).   [ ] This research involves personal health records (ensure section 2.13 is completed) |
| 2.6.2 Describe plans for data retention and long-term storage (i.e. how long data will be retained, in what form and where). Will the data eventually be destroyed or irreversibly anonymized? If so, what procedures will be used for this? Discuss any plans for future use of the data or materials beyond the study currently being reviewed.  [ ] This research will be deposited in a data repository (ensure section 2.14 is completed) |
| 2.6.3  Describe if/how participant confidentiality will be protected when research results are reported:  A) For quantitative results - In what form will study data be disseminated?  [ ] Only aggregate data will be presented  [ ] Individual de-identified, anonymized or anonymous data will be presented  [ ] Other. If “other”, briefly describe dissemination plans with regard to identifiability of data.  [ ] Not applicable, only qualitative data will be presented  B) For qualitative results - Will identifiable data be used in research presentations/publications? If participants will be quoted, address consent for this and indicate whether quotes will be identifiable or attributed.  [ ] Not applicable, only quantitative data will be presented |
| 2.6.4 Address any limits on confidentiality, such as a legal duty to report abuse or neglect of a [child](https://novascotia.ca/coms/families/changestoCFSA/Duty-to-Report.pdf) or [adult in need of protection](https://nslegislature.ca/sites/default/files/legc/statutes/adult%20protection.pdf), and how these will be handled. Ensure these are clear in the consent documents. (See the [guidance document](https://cdn.dal.ca/content/dam/dalhousie/pdf/research-services/REB/Dal%20REB%20Application%20Instructions%20-%20Prospective%20Research%20%20v2021-02.pdf) for more information on legal duties and professional codes of ethics).  [ ] Not applicable |
| 2.6.5 Will any information that may reasonably be expected to identify an individual (alone or in combination with other available information) be accessible outside Canada? And/or, will you be using any electronic tool (e.g. survey company, software, data repository) to help you collect, manage, store, share, or analyze personally identifiable data that makes the data accessible from outside Canada?  [ ] No  [ ] Yes. If yes, refer to 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), and describe how you comply with the policy (such as securing participant consent and/or securing approval from the Vice President Research and Innovation). |

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| **2.7 Risk and benefit analysis** |
| 2.7.1 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. Risks to privacy from use of identifying information should be addressed. If applicable, address third party or community risk. (If the research involves Indigenous communities also complete section 2.11) |
| 2.7.2 Identify any direct benefits of participation to participants (other than compensation), and any indirect benefits of the study (e.g. contribution to new knowledge). |

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| **2.8 Provision of results to participants and dissemination plans.** |
| 2.8.1 The TCPS encourages researchers to share study results with participants in appropriate formats. Describe your plans to share study results with participants and discuss the process and format. |
| 2.8.2 If applicable, describe how participants will be informed of any material incidental findings – a discovery about a participant made in the course of research (screening or data collection) that is outside the objectives of the study, that has implications for participant welfare (health, psychological or social). See [TCPS Article 3.4](https://ethics.gc.ca/eng/tcps2-eptc2_2022_chapter3-chapitre3.html#4) for more information.  [ ] Not applicable |
| 2.8.3 Describe plans for dissemination of the research findings (e.g. conference presentations, journal articles, public lectures etc.). |

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| * 1. **Research Team** |
| 2.9.1 Describe the role and duties of all research team members (including students, RA’s and supervisors) in relation to the overall study. |
| 2.9.2 Briefly identify any previous experience or 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.). |

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| **2.10 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 |

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| **2.11** **Research involving Indigenous peoples**  Consult TCPS [Articles 9.1 and 9.2](https://ethics.gc.ca/eng/tcps2-eptc2_2022_chapter9-chapitre9.html#1) in determining whether this section is applicable to your research.  [ ] Not applicable – go to 2.12 |
| 2.11.1 If the proposed research is expected to involve people who are Indigenous, describe the plan for community engagement (per TCPS Articles [9.1 and 9.2](https://ethics.gc.ca/eng/tcps2-eptc2_2022_chapter9-chapitre9.html#1)). If community engagement is not sought, explain why the research does not require it, referencing TCPS article 9.2. |
| 2.11.2 State whether ethical approval has been or will be sought from [Mi’kmaw Ethics Watch](https://www.cbu.ca/indigenous-affairs/mikmaw-ethics-watch/) and if not, why the research does not fall under their purview. If the research falls under the purview of other Indigenous ethics groups, state whether ethical approval has been or will be sought. |
| 2.11.3 Describe plans for returning results to the community and any intellectual property rights agreements negotiated with the community with regard to data ownership (see also 2.11.4 if applicable). Append finalized versions of applicable research agreements. |
| 2.11.4 Does this research incorporate OCAP (Ownership, Control, Access, and Possession) principles as described in TCPS [Article 9.8](https://ethics.gc.ca/eng/tcps2-eptc2_2022_chapter9-chapitre9.html#8)?  [ ] Yes. Explain how.  [ ] No. Explain why not. |

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| **2.12** **Clinical trials**  [ ] Not applicable – go to 2.13 |
| 2.12.1 Will the proposed clinical trial be registered?  [ ] No. Explain why not.  [ ] Yes. Indicate where it was/will be registered and provide the registration number. |
| 2.12.2 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](https://ethics.gc.ca/eng/tcps2-eptc2_2022_chapter11-chapitre11.html)). If placebo is used with a control group rather than standard treatment, please justify. |
| 2.12.3 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 |
| 2.12.4 Discuss any plans for blinding/randomization. |
| 2.12.5 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 (refer to TCPS [Articles 11.6, 11.7, 11.8](https://ethics.gc.ca/eng/tcps2-eptc2_2022_chapter11-chapitre11.html#6))? 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? |

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| **2.13** **Use of personal health information**  [ ] Not applicable |
| 2.13.1 Research using health information may be subject to Nova Scotia’s [*Personal Health Information Act*](http://novascotia.ca/dhw/phia/). Describe the personal health information ([definition explained in the guidance document](https://cdn.dal.ca/content/dam/dalhousie/pdf/research-services/REB/Dal%20REB%20Application%20Instructions%20-%20Prospective%20Research%20%20v2021-02.pdf)) 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. |
| 2.13.2 Will there be any linking of separate health data sets as part of this research?  [ ] No  [ ] Yes  If yes:  A) Why is the linkage necessary?  B) Describe how the linkage will be conducted (it is helpful to append a flow diagram)  C) Does that linkage increase the identifiability of the participants? |
| 2.13.3 Describe reasonably foreseeable risks to privacy due to the use of personal health information and how these will be mitigated. |

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| **2.14** **Data Repositories**  [ ] Not applicable |
| 2.14.1 Identify and describe the data repository in which the research data will be deposited. What is its focus, who are its target users, who can access deposited data and under what circumstances? For how long will the data be kept in the repository? |
| 2.14.2 Describe the data set to be released to the repository. If there is personal and/or sensitive information in the data, describe how you will prepare the data for submission to the repository and mitigate risks to privacy. Identify all fields that will be included in the final data set (include as an appendix). |
| 2.14.3 Is agreeing to have one’s data deposited a requirement for participation in the study? If yes, provide a justification. If no, indicate how participants can opt in or out. |

## SECTION 3. APPENDICES

**Appendices Checklist.** Append all relevant material to this application in the order they will be used. This may include finalized versions of:

[ ] Reference list

[ ] Permission or support/cooperation letters (e.g. School Board, care facility, anyone whose cooperation or permission you need to recruit participants or conduct research)

[ ] Research agreements (required for research involving Indigenous communities)

[ ] 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 and/or study results templates

[ ] List of data fields included in data repository

[ ] Confidentiality agreements

**Consent Form Templates**

Sample consent forms are provided on the [Research Ethics website](https://www.dal.ca/dept/research-services/responsible-conduct-/research-ethics-/resources-.html) and may be used in conjunction with the information in the [*Guidance*](https://cdn.dal.ca/content/dam/dalhousie/pdf/research-services/REB/Dal%20REB%20Application%20Instructions%20-%20Prospective%20Research%20%20v2021-02.pdf) document to help you develop your consent form.