

# RESEARCH ETHICS BOARDS

# APPLICATION FORM

**Secondary Use of Information for Research**

(including biological materials)

This form should only be used for secondary use of information and biological materials such as health records, student records, survey data, or previously collected biological material. 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](https://ethics.gc.ca/eng/tcps2-eptc2_2022_chapter2-chapitre2.html#2)).

This form should be completed using the [*Guidance for Submitting an Application for Research Ethics Review – Secondary Use of Information.*](https://dal.ca/content/dam/dalhousie/pdf/research-services/REB/Dal%20REB%20Application%20Instructions%20-%20Secondary%20Use%20Research%20v2023-01.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 secondary use 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). |

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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? | [ ] No [ ] 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 [ ] NoFor 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, data/records/biological materials 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 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://dal.ca/content/dam/dalhousie/pdf/research-services/REB/Dal%20REB%20Application%20Instructions%20-%20Secondary%20Use%20Research%20v2023-01.pdf) (section 2.1.2) 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** Information source / Identification |
| 2.3.1 Describe the original/source data (or biological material) collection. Describe how and why the data (or materials) were originally gathered, when, from whom and by whom. If the data or materials were collected for research purposes, how were participants recruited? |
| 2.3.2 Describe how the purpose of the current research builds on, and/or differs from, the purpose for which the information (data/records/biological materials) was originally gathered. |
| 2.3.3 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) from the collection.  |
| 2.3.4 Who is the steward/custodian of the source data (or biological materials) collection?  |
| 2.3.5 Has your proposed research been approved by the steward/custodian(s) of the records/data/materials? [ ] Yes Date: *Attach permission and/or letters from the data steward/custodian(s).*[ ] No Anticipated date of approval: If no, explain why approval could not be granted prior to submission of this REB application: |
| 2.3.6 Inclusion of Indigenous peoples Will the research questions/objectives 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 these, describe the plan for community engagement, as indicated in [TCPS Articles 9.20-9.22](https://ethics.gc.ca/eng/tcps2-eptc2_2022_chapter9-chapitre9.html#20) and complete section 2.3.7. State whether ethical approval has been or will be sought from an Indigenous ethics review group. Describe how results will be returned to the relevant community/communities. Append the finalized research agreements concerning the data or samples. |
| 2.3.7 If yes is checked in 2.3.6, 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. [ ] Section 2.3.6 is not applicable |

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| **2.4** Informed consent process |
| 2.4.1 If data or biological materials were originally collected for research purposes, how was informed consent originally obtained from participants? Indicate the information uses for which participants originally gave consent. To what extent does the original consent address the purposes of the current study? Attach original consent form if available.[ ] Not applicable, uses records or biological materials collected for non-research purposes (ensure 2.4.2 is complete). |
| 2.4.2 Will consent be obtained from individuals prior to using data (or biological materials)?[ ] Not applicable, uses pre-existing research dataset (ensure 2.4.1 is complete).[ ] Yes. Explain informed consent process in detail and append consent form(s).[ ] No. Explain why this would be impossible or impracticable, and why it is unlikely to adversely affect the welfare of individuals to whom the information relates (referring to each of the criteria described in TCPS [5.5A](https://ethics.gc.ca/eng/tcps2-eptc2_2022_chapter5-chapitre5.html#5a) or [B](https://ethics.gc.ca/eng/tcps2-eptc2_2022_chapter5-chapitre5.html#5b) and/or [12.3A or B](https://ethics.gc.ca/eng/tcps2-eptc2_2022_chapter12-chapitre12.html#3a)). |

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| **2.5** Data collection and analysis |
| 2.5.1 Briefly discuss the data to be captured from the original/source data (or biological material) collection, the data fields to be used, or the variables to be used for the proposed analyses. Justify the use of each of these in relation to the study purposes. Append any data capture sheet for record review, or list of variables to be used.  |
| 2.5.2 Briefly describe the data analysis plan. Indicate how the proposed data analyses address the study’s primary objectives or research questions. |

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| **2.6** Privacy and confidentiality |
| 2.6.1 A) Indicate the level of identifiability of the original/source data (or biological material) held by the steward/custodian: [ ] Anonymized (all identifiers have been removed and a key-code linking data/materials with individuals does not exist).[ ] De-identified/coded (a key-code linking data/materials with individuals exists but is not accessible).[ ] Identifying (information directly or indirectly identifies individuals).B) Who will access the source data (or material) to extract the data or samples for this research? Explain their role or qualifications. If there is identifying information in the source data, how will the privacy of individuals whose data/samples are stored in the collection be protected during this data access?  |
| 2.6.2A) Indicate the level of identifiability of the data (or samples) that will be extracted from the source data (or biological material) collection for use in this research. It is best practice to collect data at the lowest level of identifiability possible to meet study objectives.[ ] Anonymized (all identifiers will be irreversibly removed and there will be no key-code linking data/materials with individuals)[ ] De-identified/coded (a key-code linking data/materials with individuals will exist but will not be accessible to the researchers).[ ] Identifying (information could directly or indirectly identify individuals). Specify what direct (name, contact information, student number, social insurance number, health number etc.) or indirect (date of birth, sex, postal code, etc.) identifiers are being collected. Justify why each item is needed to conduct the research.B) Specify which members of the research team will have access to extracted data (or biological materials) and the level of identifiability of the information to which they will have access. Describe why this is necessary. |
| 2.6.3 Research using health information may be subject to Nova Scotia’s [*Personal Health Information Act*](http://novascotia.ca/dhw/phia/). In accordance with this Act, if personal health information (defined in [guidance document](https://cdn.dal.ca/content/dam/dalhousie/pdf/research-services/REB/Dal%20REB%20Application%20Instructions%20-%20Secondary%20Use%20Research%20v2021-02.pdf)) will be used please explain why the research cannot reasonably be accomplished without this information. [ ] Not applicable, the research does not use personal health information. |
| 2.6.4 Will there be any linking of separate data sets as part of this research? [ ] No[ ] YesIf 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? If so, describe reasonably foreseeable risks to privacy and how these will be mitigated. |
| 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). |
| 2.6.6 Data security during the study: Describe how and where study documents and data (both hard copy and electronic) and materials will be collected, handled, transported or transferred and stored during the data collection and analysis phase. In particular, indicate the steps that will be taken to protect the security of any directly or indirectly identifiable information, especially if it is shared with others. Include physical security and [technological security](https://cdn.dal.ca/content/dam/dalhousie/pdf/research-services/REB/Protecting%20Electronically%20Stored%20Personally%20Identifiable%20Research%20Data%20-%202021-08.pdf). If there are codes to be used that link the data/samples to information that could identify participants (names, addresses etc.), security of these codes should be described. |
| 2.6.7 Data security during long term storage: How long will study data or materials be retained after the study is completed? How will they be secured during this time? 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 2.10 is completed) |

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| **2.7** Provision of results to participants and dissemination plans. |
| 2.7.1 The TCPS encourages researchers to share study results with participants in appropriate formats. If applicable, describe your plans to share study results with participants and discuss the process and format. [ ] Not applicable |
| 2.7.2 If applicable, describe how participants will be informed of any [material incidental findings](https://ethics.gc.ca/eng/tcps2-eptc2_2022_chapter3-chapitre3.html#4) – 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). [ ] Not applicable |
| 2.7.3 A) Describe plans for dissemination of the research findings (e.g. conference presentations, journal articles, public lectures etc.). B) In what form will study data be disseminated?[ ] Only aggregate data will be presented[ ] Individual de-identified data will be presented[ ] Other. If “other”, briefly describe dissemination plans with regard to identifiability of data. |
| 2.7.4 Discuss any potential for risk to individuals, or to communities/collectives (e.g. geographic communities, schools, professions, ethnic groups, etc.) as a result of dissemination of the research findings and how this will be mitigated. |

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| **2.8** Research Team |
| 2.8.1 Describe the role and duties of all research team members (including students, RA’s and supervisors) in relation to the overall study. |
| 2.8.2 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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| **2.9** Conflict of interest |
| Describe whether any dual role or conflict of interest exists for any member of the research team in relation to the individuals whose data or biological materials are being used (e.g. teaching or clinical relationship, program provision), and/or to study sponsors, and how this will be handled.[ ] Not applicable |

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| **2.10** Data Repositories[ ] Not applicable |
| 2.10.1 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?  |
| 2.10.2 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).  |
| 2.10.3 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. This may include finalized version of:

[ ] Reference list

[ ] Steward/custodian permission letters, support/cooperation correspondence

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

[ ] Original and/or new consent documents

[ ] Data capture sheet/list of data fields, variables, survey items

[ ] Flow diagram outlining data collection and linkages

[ ] List of data fields included in data repository

**Consent Form Templates (if applicable)**

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-%20Secondary%20Use%20Research%20v2021-02.pdf) document to help you develop your consent form.