

# 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 previously collected biological materials, use the *REB Application Form – Secondary Use of Information for Research.*

Instructions to complete this form are provided in 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%20-%20%20Prospective%20Research%20%20v%20December%202023.pdf).

## This form makes reference to the TCPS2. It is [linked here](https://ethics.gc.ca/eng/policy-politique_tcps2-eptc2_2022.html) for convenience.

## SECTION 1. ADMINISTRATIVE INFORMATION [File No: office only | v 2023 ]

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| Suggest 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): | First name:  | Last name:  |
| Email (@dal.ca): |  | Phone: |  |
| Banner #: |  | Department: |  |
| Lead researcher’s primary affiliation with Dalhousie: |
| [ ]  Faculty[ ]  PhD Student[ ]  Master’s student[ ]  Undergraduate student[ ]  Medical student | [ ]  Postdoctoral Fellow[ ]  Medical Resident[ ]  Staff[ ]  Medical Staff[ ]  External to Dalhousie  |
| Co-investigator names, affiliations, and email addresses |  |
| Contact person for this submission (if not lead researcher) | Name: |  |
| Email: |  | Phone: |  |
| Banner # if applicable: |  |
| Study start date: |  | Study end date: |  |

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| **1.2** **For student/learner submissions** (including medical residents and postdoctoral fellows) |
| Degree program |  |
| Supervisor name and department |  |
| Supervisor Email (@dal) |  | Phone |  |
| Code for the course in which credit will be received as a result of this research (e.g., REGN 9999):[ ]  Not Applicable |  |
| 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) | Funder |  |
| Award Number |  |
| Institution where funds are/will be held | [ ]  Dalhousie University[ ]  Other: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  |

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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* (TCPS2) 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 TCPS2 Course on Research Ethics ([CORE](http://tcps2core.ca/welcome)) online tutorial. [ ]  Yes [ ]  NoFor Supervisors (of student, postdoc, resident 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 TCPS2 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 TCPS2 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? Is this a pilot study or a fully developed study? [maximum 500 words] |
| **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%20-%20%20Prospective%20Research%20%20v%20December%202023.pdf) before requesting a phased review.[ ]  Not applicable |

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

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| **2.3** **Study Population** |
| **2.3.1** Identify the study population(s) and describe and justify the inclusion and exclusion criteria for participants.  |
| **2.3.2** How many participants are needed to answer the research question or achieve the research objectives? Provide a target range that includes the maximum number of participants for each participant category and data collection method (*e.g.: Interviews with nurses: 10-15. Surveys with farmers: 90-100*). Provide a scholarly rationale (e.g. sample size calculation) for how these numbers were determined.   |

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| **2.4** **Recruitment** |
| **2.4.1** Will you require the cooperation, assistance, or approval of a third party to recruit or access potential participants?[ ]  No, I can do all recruitment without cooperation, assistance or approval from anyone outside the research team. [ ]  Yes, in order to inform potential participants about the study, I will need to work with a third-party to assist with recruitment or approve the study. If yes, describe the required cooperation, assistance, approvals or agreements needed and append written confirmation of their agreement to assist with recruitment and/or their approval of the research (required) and label the corresponding appendices here. **These must be secured and appended before your project will be considered for ethical review**. |
| **2.4.2** What methods will be used to recruit participants? Check all that apply. Append final versions of all materials that will be used during recruitment.[ ]  Posters[ ]  Social Media [ ]  Email or listserv[ ]  Online advertising [ ]  Subject pool (e.g. SONA)[ ]  Word of mouth / in person[ ]  Syllabus or online learning platform[ ]  Phone[ ]  Presentation[ ]  Letter[ ]  Other. Describe:  |
| **2.4.3** Who will conduct recruitment? Please specify by name or position (e.g. research assistant). What will they do?  |
| **2.4.4** What actions will participants take to express interest in the study?  |
| **2.4.5** Describe how participants will be screened to determine eligibility for the study. Append any materials that will be used in screening. If participants will self-screen, state that here.  |

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| **2.5** **Informed consent process** |
| **2.5.1** Describe the informed consent process by completing each of the following sections. Append copies of all consent information/forms that will be used (e.g. written consent document, oral consent script, assent document/script, etc.) and identify the corresponding appendices.  |
| **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.). |
| **C)** If third-party consent will be used, describe who will provide consent for the participant. Describe the process for obtaining assent from the participant. [ ]  *Not applicable. Participants will consent for themselves.* |
| **D)** For longitudinal studies, describe how ongoing consent will be confirmed. Address the possibility that a participant’s capacity to consent may develop, diminish, or fluctuate and how this will be handled (see TCPS2 Articles 3.9 and 3.10).[ ]  *Not applicable, participants only participate at a single time point.* |
| **2.5.2** If the data/materials collected from this research will be kept by the researcher or in a data repository/biobank for potential re-use in future research, describe how participants will be given the opportunity to consent or not consent to potential future use of their data/materials (see TCPS2 Article 3.13) separately from their consent to participate in the research. (Note: participants must be allowed to participate in this research even if they do not want their data/materials stored for future research purposes). [ ]  *Not applicable. Data/biological materials collected from participants will not be used in future research.*  |
| **2.5.3** Discuss how participants will be given the opportunity to withdraw their participation and/or their data and/or their biological materials and any limitations on this (such as time, identifiability of data, progress through stages of research, etc.). If participants will not have opportunity to withdraw their participation and/or their data and/or their biological materials, explain why. |
| **2.5.4** If an alteration/exception to the requirement to seek prior informed consent is sought, address the criteria in TCPS2 Article 3.7A. If the alteration involves deception or nondisclosure, also complete section 2.5.5.[ ]  Not applicable. |
| **2.5.5** Describe and justify any use of deception or nondisclosure. Explain how participants will be debriefed (TCPS2 Article 3.7B).[ ]  Not applicable. |

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| **2.6** **Methods, data collection and analysis** |
| **2.6.1** This section is about the research methods and the tasks participants will be asked to complete. |
| **A)** Where will participants be located during their participation? (If the study takes place online, specify that it is an online study.) |
| **B)** What tasks will participants be asked to do and what research instruments will be used to collect the data? Append all instruments and identify the corresponding appendices here.  |
| **C)** How much of the participant’s time will participation in the study require (including consent and screening processes, debriefing, member-checking, etc.)? |
| **D)** If biological samples will be provided by participants, please describe what samples will be provided, how much/many, and the associated process(es) for collecting them.  [ ]  *Not applicable. No biological samples will be taken as part of this research.* |
| **2.6.2** Will the participants be audio- or video-recorded during data collection? [ ]  No[ ]  Yes. If yes:* State if the recordings are audio only, video only, or a combination.
* Explain why recordings are necessary for the research.
* Identify the tool or software that will be used.
* Explain if participants can opt-out of recording and if they can, what modifications to the data collection process will be needed.
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| **2.6.3** If recordings will be transcribed, state who will do the transcribing and/or if transcription will be done by a computerized program or software (name the program/software). Specify if transcription programs or software are used in the cloud or on a local device only. If a transcriptionist will be hired, append the confidentiality agreement they will be asked to sign and identify the corresponding appendix here.[ ]  *N/A. Transcription is not required for this study.* |
| **2.6.4** Briefly describe the data analysis plan. Indicate how the proposed data analyses address the study’s primary objectives or research questions. Describe and justify the use of all information collected from participants (for example, demographic variables) in the analysis plan. |
| **2.6.5** Describe any incentives that will be offered to participants and how this will be handled for participants who do not complete the study (see TCPS2 Article 3.1 for guidance on incentives). Discuss any expenses participants are likely to incur and whether/how these will be reimbursed. |

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| **2.7** **Privacy and confidentiality**  |
| **2.7.1** This section is about how participants’ data and information will be managed, and how identifiable participants and their data will be during and after this research.  |
| **A)** Describe who will have knowledge of participants’ identities at any point in the research process. |
| **B)** Describe the level of identifiability of the study documents (including screening and consent forms and other administrative documents) and data (anonymous, anonymized, de-identified/coded, identifying) (see TCPS2 Chapter 5A – types of information for definitions) at the following timepoints: * during recruitment, screening, and consent
* during collection
* during analysis and preparation of results
* during long-term storage
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| **C)** Specify which members of the research team (or others) will have access to participants’ data and/or biological materials and for what purpose. |
| **D)** Describe measures to ensure privacy and confidentiality of study documents, participant data and biological materials during the pre-study (e.g. recruitment, screening, consent), data collection and analysis phases. *[Note that plans for long term storage will be covered in 2.7.2*]. Specifically address the following: * Where data/recordings/documents will be stored and the security of such storage.
* How study data/recordings/documents will be securely shared and/or transported between team members.
* If data collection software is used, describe the security measures of that software and if others outside the research team (e.g. a survey company) will have access to the data.
* If a key-code will be maintained, describe how it will be kept secure and separate from study data.
* Confirm that any identifiable data will be encrypted.
* For hard copy documents and biological materials, describe physical security measures and specify storage location.
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| * + 1. This section is about plans for retention and long-term storage of study documents (signed consent forms, screening documents, key-codes, etc.), data, and/or biological materials.

Will all documents/data/biological materials eventually be destroyed?[ ]  No, all documents/data/biological materials will not be destroyed (if ‘no’, complete section 2.8).[ ]  Yes. If yes:1. State when they will be destroyed and provide a rationale for the proposed retention period:
2. Where will they be stored when the study is over (after analysis and dissemination of findings) but before they are destroyed?
3. How will they eventually be destroyed (i.e., method of destruction) and by whom?
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| **2.7.3** Describe if/how participant confidentiality will be protected when research results are reported by answering the following: |
| **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 (complete part B).* |
| **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 (complete part A).* |
| **2.7.4** 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%20-%20%20Prospective%20Research%20%20v%20December%202023.pdf) for more information on legal duties and professional codes of ethics).[ ]  *Not applicable.* |
| **2.7.5** 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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| **2.8 Indefinite retention of research data/biological materials**If study documents/data/biological materials will not be destroyed **and/or** there are possible plans for re-use of the data, complete this section (and ensure section 2.5.2 is complete): [ ]  *Not applicable. The documents/data/materials generated from this study will only be used for this specific research and will be destroyed after this research is complete.* |
| **2.8.1** Discuss the risks and potential benefits of storing documents/data and/or human biological materials long-term for future unspecified research.  |
| * + 1. Who will be the keeper of the documents/data/biological materials?

[ ]  The lead researcher on this project.[ ]  A data repository (identify the repository):[ ]  Other (describe):  |
| **2.8.3** If the custodian/steward becomes unaffiliated with Dalhousie (retires, leaves their position, dies, graduates, etc.), what will happen to the documents/data/materials? [ ]  *N/A, the data/materials are* ***only*** *being stored in a repository/biobank.* |
| **2.8.4** Describe the repository/biobank where the data/materials will be deposited. Indicate the protective measures in place to ensure participants’ data are securely managed.[ ]  *Not Applicable – the researcher will manage all data indefinitely.* |
| **2.8.5** Who will be able to access the data/materials for future use and under what circumstances?  |
| **2.8.6** Describe the type, identifiability, and amount of data and/or human biological materials being stored for potential re-use in the repository. Identify all fields and materials that will be included in the final data set (include as an appendix).  |

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| **2.9 Risk and benefit analysis**  |
| **2.9.1** Discuss what risks or discomforts are anticipated for individual participants, how likely risks are and how risks will be mitigated. Risks to privacy from the collection/use of identifying information should be addressed.  |
| **2.9.2** What people, groups, or communities other than participants in this study might be negatively impacted by the conduct of the research and/or dissemination of research results? How will the researcher mitigate these potential negative impacts? Describe any community engagement that may occur as part of a mitigation strategy. [ ]  *This research involves Indigenous communities (complete section 2.13).* |
| **2.9.3** 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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| **2.10 Provision of results to participants and dissemination plans** |
| **2.10.1** The TCPS2 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.  |
| **2.10.2** Will individual results be returned to participants? [ ]  *Not applicable.*[ ]  No. [ ]  Yes. If yes, explain the format in which results will be given (and append a template for communicating results to participants). Describe how individual results will be shared in a secure and confidential manner. Explain how/if the research team will ensure the individual results are understandable to participants. Discuss any risks to participants of receiving individual results, and how these will be mitigated. |
| **2.10.3** 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, data collection, or analysis) that is outside the objectives of the study, that has implications for participant welfare (health, psychological or social). (See TCPS2 Article 3.4 for more information.) [ ]  *Not applicable.* |
| **2.10.4** If providing genetic results/information to participants, communities, or groups, discuss the plans for providing genetic counselling (TCPS2 13.4)[ ]  *Not applicable.* |
| **2.10.5** Describe plans for dissemination of the research findings (e.g. conference presentations, journal articles, public lectures etc.).  |

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| **2.11 Research Team** |
| **2.11.1** Describe the role and duties of each research team member (including students, RAs and supervisors) in relation to the overall study. |
| **2.11.2** 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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| **2.12 Conflict of interest**  |
| **2.12** 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. Please provide copies of contracts between researchers, institutions and industry sponsors and relevant budgetary information related to this research (TCPS2 12.20).[ ]  *Not applicable.* |

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| **2.13** **Research involving Indigenous peoples** Consult TCPS2 Articles 9.1 and 9.2 in determining whether this section is applicable to your research.[ ]  *Not applicable – go to 2.14.* |
| **2.13.1** If the proposed research is expected to affect the welfare of an Indigenous community, or communities, to which prospective participants belong, describe the plan for community engagement (per TCPS2 Articles 9.1 and 9.2). If community engagement is not sought, explain why the research does not require it, referencing TCPS2 articles 9.1 and 9.2. Append applicable finalized research agreements. |
| **2.13.2** 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. |
| **2.13.3** 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).  |
| **2.13.4** Does this research incorporate OCAP (Ownership, Control, Access, and Possession) principles as described in TCPS2 Article 9.8?[ ]  Yes. Explain how:[ ]  No. Explain why not: |

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| **2.14** **Clinical trials** [ ]  *Not applicable – go to 2.15.* |
| **2.14.1** Will the proposed clinical trial be registered? [ ]  No. Explain why not:[ ]  Yes. Indicate where it was/will be registered and provide the registration number: |
| **2.14.2** If a novel intervention or treatment is being examined, describe standard treatment or intervention, to indicate a situation of clinical equipoise exists (TCPS2 Chapter 11). If placebo is used with a control group rather than standard treatment, please justify.  |
| **2.14.3** 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.* |
| **2.14.4** Discuss any plans for blinding/randomization. |
| **2.14.5** 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 TCPS2 Articles 11.6, 11.7, 11.8)? 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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| **2.15** **Use of personal health information** [ ]  *Not applicable.* |
| **2.15.1** Research using health information may be subject to Nova Scotia’s [*Personal Health Information Act*](http://novascotia.ca/dhw/phia/)or a similar piece of legislation in the jurisdiction where the participants reside. 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%20-%20%20Prospective%20Research%20%20v%20December%202023.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. |
| **2.15.2** 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 may be helpful to append a flow diagram).**C)** Does that linkage increase the identifiability of the participants?  |
| **2.15.3** Describe reasonably foreseeable risks to privacy due to the use of personal health information and how these will be mitigated. |

## SECTION 3. APPENDICES

**Appendices Checklist.** Please label andappend all relevant material to this application in the order they will be used. This may include:

[ ]  Reference list

[ ]  Permission or support/cooperation letters (e.g. from anyone whose cooperation 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.)

[ ]  Contracts, data transfer agreements, material transfer agreements (finalized versions)

[ ]  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 *Application Instructions* document to help you develop your consent form.