*black text on a white background

University of Prince Edward Island*

***The italicized text is only for guidance. Delete all italicized text when doing your own consent form. Text that is not italicized is approved for use.***

*This consent document template is intended to provide an overview and examples of the basic content required. Further details may be added if/where needed depending on the specific study. Please adapt the style, content and language of the form for your study and your participants. Where several groups of individuals will take part in different components of the research, separate consent forms should be developed for each group to keep the description simple and specific.*

*Please consult Chapter 3 (‘The Consent Process’) of the Tri-Council Policy Statement 2* (<https://ethics.gc.ca/eng/tcps2-eptc2_2018_chapter3-chapitre3.html>*) for further guidance, including to ensure that your form meets the requirements listed in Articles 3.1 and 3.2.*

*Ensure the consent document content is consistent with the information provided in the application form. Use ordinary language, understandable by a layperson. Although there is no perfect number, and it will depend on your specific sample, a Flesch-Kincaid reading level of grade 8 (https://goodcalculators.com/flesch-kincaid-calculator/) is suggested for a general, English-speaking population. Please verify spelling and grammar. The consent document should be written in the second person. Participant is ‘you’, not ‘I’ or ‘they’. If acronyms are used, they must be written out in full the first time they are used, with the acronym in parentheses.*

**Participant Information Letter and Consent Form –** *this must appear at the top of the form. Identify appropriately if there is more than one consent form (i.e., more than one group of participants).*

**Researchers:** *Insert your name and title/student status, institution, department, telephone and email, and that of co-investigators (if applicable).*

**Supervisor:** *If the researcher is a student (including PDF), the supervisor’s name, department, telephone, and email appear here.*

**Title of Project:** *Title should appear as written on the cover page of the application form. An alternate title may be used if the actual title would influence participant responses or otherwise appropriate.*

**Sponsor(s):** *If the project is funded, identify the funding source(s). Providing fund numbers is not necessary.*

***The bolded headings below are meant as a guide for the type of information needed. It is strongly recommended that they be used but they are not mandatory and may be adapted to accommodate individual studies as needed.***

**Introduction**

*State clearly that this is research and participation is voluntary.*

We invite you to take part in a study being conducted by *[Lead Researcher]* and *[student, postdoc, co-researcher]* at the University of Prince Edward Island. It is entirely your choice to take part or not. There will be no negative impact on you *[your studies/your employment/your performance evaluation/the services you receive]* if you decide not to participate. The information below tells you about what you are being asked to do and about any benefit, risk, inconvenience, or discomfort that you might experience. Please take the time to read this carefully and to understand it.

You can discuss any questions you have about this study with *[researcher name]*. You can keep a copy of this information letter and consent form. Please ask as many questions as you like if you want more details about anything mentioned here, or information not included here. If you have questions later, please contact *[Lead Researcher Name]*.

This project has been reviewed by the UPEI Research Ethics Board and complies with Tri-Council guidelines for research involving human participants.

**Purpose of the Study:** *Begin with information that indicates this is an invitation to participate in a research study****.*** *Describe the purpose of the study in clear and simple language that a layperson will understand (or appropriate for the target participant group). Avoid technical jargon and theoretical concepts that participants are unlikely to be familiar with. No more than a short paragraph of text should be necessary.*

*When applicable, any real, potential or perceived conflicts of interest on the part of the researchers, their institutions or the research sponsors must be declared.*

**Who can take part in this Study?** *Clearly and in simple terms state any inclusion and/or exclusion criteria. If any screening activities are planned, these should also be described, including what happens to the screening data if the participant does not proceed further with the study (i.e., will it be immediately destroyed?).*

**What will you be asked to do?** *In plain language,**describe all procedures, research activities, methods of recording, location, and approximate time commitments. Describe anything the participant needs to bring or other preparations required of the participant. This description should only include the activities that the participant will experience.* ***Informed consent is not possible unless it is clearly explained to participants what they will be asked to do.*** *If you are requesting to photograph, video-record or audio-record participants, or if notes on participant body language and non-verbal communication will form part of the research, state this clearly and explain why this is necessary. Indicate how such recordings or observations will be used. If participants will be asked to complete a questionnaire or survey, give examples of the types of questions that will be asked, and be very clear when personal and sensitive questions are included. If there will be a follow up (e.g., a second part to the study), indicate how this will be accomplished (e.g., how will participants be selected and contacted?). Indicate that participation in the follow up is completely voluntary. If you are conducting a focus group or group session of any kind, indicate how many people will be participating.*

**What if you decide not to or decide to stop participating?**Participation is voluntary. *Include statements that a person may decline to answer any question/take part in any procedure, and may withdraw from the study, for any reason, as well as how they stop participating (e.g., contacting the researcher, closing the browser, etc.). Clearly indicate any limitation to withdrawal (e.g., “Data will be de-identified one month after data collection is completed. Once de-identified, data can no longer be withdrawn” OR “As participation is anonymous, withdrawal is not possible after the study session is concluded”, etc.). If applicable, include a statement that whether they choose to participate or not will not result in any loss of benefit to which they are otherwise entitled (e.g., grades will not be affected/current or future services received through an agency will not be affected). Explain what will happen to their information if the participant decides to withdraw (i.e., it will be destroyed unless they give permission otherwise). If applicable, describe the circumstances under which the researcher might terminate someone’s participation in the study. If there is to be deception or incomplete disclosure of the purpose of the study for any reason, participants should be told that they will be given additional information about the study after their participation is complete i.e., a debriefing.*

*There can be no language used that suggests they are waiving any of their legal rights.*

**What information will be collected and what will happen to it?** *If no personal identifying information is to be collected (e.g., names, health numbers, student ID numbers, email addresses, etc.), and the participant will be truly anonymous (identity not known to the research team), state this clearly. Otherwise (including if you are interviewing someone or videotaping or audiotaping), you cannot say their participation is anonymous, rather it is confidential if it will not be shared beyond those noted on the research team. If you are conducting a focus group or group session of any kind, include a statement that participants are encouraged and reminded to maintain confidentiality – not sharing what was discussed or who was present outside the group – but that the research team cannot guarantee confidentiality in these settings.*

*Provide a description of the type of information you will be collecting clearly and in terms that are easily understood. Explain how the data (especially personal data) that they will be providing will be kept secure including how and where it will be securely stored (note that two levels of data security are required e.g., locked file cabinet, password protected file on a computer, coded with key kept separate etc.), for how long (UPEI Policy requires at least five years) and who will have access to it (i.e., (e.g., principle investigator, research assistants or students under the supervision of the PI, etc.). Anyone not on the research team paid to transcribe or otherwise work with the data should sign a confidentiality agreement and this should be stated to participants.*

*In addition, the limitations of confidentiality should be stated clearly. As applicable to the nature of the study, where there are limits to confidentiality such as duty to disclose suspected child abuse or neglect, or where there is reason to suspect imminent serious harm to the participant or others, or in any other situation where the researcher will break confidentiality, this must be stated. A description of what the researcher will do in such a situation needs to be provided. If using US-based software or websites for data collection and/or storage, note to participants that the data can be accessed by Homeland Security as per the US Patriot Act and data confidentiality can therefore not be guaranteed. However, the risks associated with the use of this service are similar to those associated with the use of many e-mail and social media platforms.*

*If you wish to audio or video-record the participant, indicate this clearly and clarify whether the recordings will be disseminated in public presentations or are solely for the use of the researcher. If participants will have the option to review their transcript for accuracy, and to suggest any changes or withdraw components, describe this process (how and when they will receive the transcript, what to do and by when if they want to change or withdraw any content).*

The UPEI Research Ethics Board may access your data to make sure that the study is done ethically. They will not share it with anyone.

**Potential Risks:** *Researchers should not categorically state that there is ‘no risk’ associated with a study. This suggests a guarantee that is not possible given the inherent uncertainty involved in research. Where the harms or discomforts are no greater than those that are related to common experiences of everyday life, they may be described as ‘minimal’.**Include a statement such as “*There are no expected risks to you by taking part in this research beyond what you might have in everyday life*”* ***or*** *address potential risks, harms, or inconveniences to the participant as described in the application and the likelihood of occurrence****.*** *This refers both to discomfort associated with physical procedures as well as the possibility of emotional or psychological distress caused by interview or survey content. Where there is a possibility of economic repercussions, damage to relationships, or loss of privacy, these should be described. The steps that will be taken by the researcher to minimize these risks should be stated. If applicable, include referrals for counseling and other services they may be provided with or directed to. In some instances, risks may exist for communities associated with the study (stigmatization, community discord). These should also be discussed. If the participant will incur any costs (e.g., travel), describe these.*

**Potential Benefits:** *State the benefits of this research, as applicable: to participants; to a particular group; to the field of knowledge. E.g., “Participating in the study will have no direct benefit for you; however, we hope to learn…” Incentives are not to be listed as a benefit.*

**Incentives/Reimbursement:** *If applicable, describe any incentive you will offer, how and when this will be given, and any information needed from the participant just to receive it (e.g., name and mailing address for gift cards). Describe the pro-rating arrangement if applicable (. If no pro-rating is described, the participant is entitled to the full incentive regardless of extent of participation (i.e., even if they withdraw without completing the study).* 

*If participants are to be reimbursed for expenses incurred in relation to study participation (e.g., parking, transportation costs) this should be stated. Upper limits of reimbursement per person should be clear, so as not to create inappropriate expectations.*

**Study Results:** *Indicate how the results will be disseminated (e.g., academic publications, presentations). If applicable, indicate whether results will be given to participants/communities/organizations/school/ etc., how, and approximately when.*

**Questions or Concerns***: Indicate clearly, who is to be contacted with any questions/clarifications about the project. Personal telephone numbers and email addresses should not be used.*

# *On a separate line:*

# You can contact the UPEI Research Ethics Board at (902) 620-5104 or researchcompliance@upei.ca if you have any concerns about how this study is done. The REB file number is *provide UPEI REB file number*.

*For some research (e.g., online surveys) it is inappropriate to get a signature, because signed consent eliminates what would otherwise be anonymity. For online consent or anonymous participation without signature (revise as appropriate to the study methods):*

**Consent to participate:** Submitting your responses means that you understand this information and agree to participate. Please save or print this letter to keep if you like. *For anonymous consent for mail-in questionnaires, revise as appropriate to hard-copy materials and also describe how to return responses.*

**Participant Consent Form** *for written consent; should be on a separate page from the LOI so the participant may retain information.*

**Title of Project:** *Same as on Participant Information Letter*

**Lead Researcher:** *Insert the name and title/student status, institution, department, telephone and email, and that of supervisor (in the case of student-led research).*

My signature below means that:

* I have read the explanation about this study in the Participant Information Letter.
* I have had any questions answered to my satisfaction by the researchers.
* I may ask questions or for more information before, during, and after my participation.
* I understand that my participation is voluntary, and I am free to withdraw from the study at any time, until *[XX weeks/months after my second interview is complete/submitting my responses/etc.]* by *[emailing the research team]*.
* In agreeing to participate in this study, I do not give up any of my rights or release the researchers from their responsibilities.
* I understand that I can contact the UPEI Research Ethics Board at (902) 620-5104, or by email at researchcompliance@upei.ca if I have any concerns about the ethical conduct of this study.
* I understand that I can keep a copy of the information letter and consent form.
* I understand that my information will be kept confidential within the limits of the law.
* *Any further points required for participation (see explanation below).*
* I agree to take part in this study.

Participant’s Name: (please print)

Participant’s Signature: Date: \_\_\_\_\_

*If some things are optional for participants, consent for those should be sought separately from overall study participation. Do not provide places for consent to specific items if they are not in fact optional. If, for example, in order to participate people must consent to being recorded and/or to the use of their quotes, that would be explained as above, with consent granted when the person consents to study participation. In contrast, if someone could participate but refuse recording (the researcher would take notes) or the use of quotations, those items should be removed from the signature statement above and included as yes/no separate consent items. Some examples are provided below.*

*Yes: \_\_\_ No: \_\_\_ I agree that direct quotes from my interview may be used without identifying me.*

*Yes: \_\_\_ No: \_\_\_ I agree that my interview may be audio- [/video-] recorded*

*Yes: \_\_\_ No: \_\_\_ I agree to being contacted for a follow-up interview, with the understanding that I can always decline the request (please provide email/phone number below).*

*Yes: \_\_\_ No: \_\_\_ I would like to receive a summary of the study results (please provide email/phone number below).*

Participant’s Email/Phone number: *\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*

*The norm is written consent. If consent will be obtained orally (as approved by the REB), this must be documented and justified by the researcher. In addition, consent may be audio or video recorded. When appropriate, a copy of the written consent document (LOI) must be offered to participants.*

*When composing your own consent form be sure to include the version date (month/day/year) in the footer. Change accordingly as revised.*