

INFORMED CONSENT FORM (ICF) TEMPLATE - REB1 & REB2

For Anonymous Surveys: See [Informed Consent Form Template - Implied Consent \(Survey\)](#)

INSTRUCTIONS: A well presented Informed Consent Form (ICF) that is in accordance with this template and the instructions below will facilitate the approval process.

1. Consent forms should be written at a Grade 6-9 level of understanding. In some contexts (i.e., participants are academics or professionals, etc.), an argument for a higher readability can be made. Please use a readability index, such as hemingwayapp.com, to confirm the level.
2. Formatting:
 - Font size should be no smaller than the font on this page (e.g., Arial 12 point).
 - Use headings, small paragraphs and spaces between the paragraphs.
 - The footer should contain the 1) a version date 2) page number, and 3) Ethics ID: Pro000XXXXX.
 - The header should contain the institutional letterhead or institutional logo.
3. Grammar:
 - Use plain, non-scientific language. Explain technical terms and avoid jargon.
 - Write out all acronyms the first time they appear in the consent form.
 - Avoid language which may express negative or disrespectful connotation or other emotive terms.
 - Use second person pronouns for the information letter part of the consent form (you/your) so that you are addressing the potential participant directly.
 - If applicable, use 'participant' rather than 'patient' or 'subject'.
4. Explain the whole research process in a way that participants can understand. Put yourself in the place of the participant when composing your consent.
5. Prior to submission, please ensure the following:
 - This instructional box is deleted.
 - The header and footers are updated.
 - The font colour of the finished consent should be black.
 - Spelling, grammar and formatting have been corrected.
 - Note: Microsoft Word is preferred format when uploading documents for REB review.

Blue font: *Instructions*

Black font: Required language

Red font: Suggested language, insert as applicable

Green font: Suggested language for data repositories

In each section, replace the instructions (in blue) with information from your study. In some cases suggested language is listed (in red), you may use this language, or replace with your own explanation. Suggested language for deposit into a data repository is listed in green. Any required language is listed in black.

PARTICIPANT CONSENT FORM

Title of Study: *Should match the title on the ethics application.*

Principal Investigator: Dr. XXX
Assistant Professor
School of XXX
University of Alberta
Edmonton, AB
(780) 492-0000 ext. XXXX
XXXX@ualberta.ca

Supervisor(s): *(If applicable)*

Research Coordinator(s): *(If applicable)*

Co-investigator(s): *(If applicable)*

- 1) *Supervisor contact information must be included if the Principal Investigator is a student.*
 - 2) *Students should refrain from putting their personal telephone numbers and personal email addresses. Only institutional contact information should be provided.*
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You are being invited to take part in a research study. Before you take part, a member of the study team is available to explain the project and you are free to ask any questions about anything you do not understand. You will be given a copy of this form for your records.

Why am I being asked to take part in this research study?

Describe why the reader might qualify for the research study. For example: "You are being asked to be in this study because XXX."

Also, provide a brief explanation about why the research is being done so that the participant can understand why a particular phenomenon is being studied. For example: "The goal of this study is to XXX."

What is the reason for doing the study?

This section should describe the purpose of this specific study and what the study hopes to find.

Key points to include in this section, when applicable:

- *For interventional studies, clearly explain what the standard treatment(s) is/are and what basis exists for the experimental intervention.*

- Indicate if the research is part of a larger multi-site project and when appropriate, also include the approximate number of participants in the study (overall and at this site).
- For studies which use partial disclosure or deception, inform the participant that more information will be provided at the time of debriefing. For example, “For now, we must remain vague about the specifics of what we are investigating. At the conclusion of the study, you will be debriefed about our specific hypotheses in more detail.”

What will I be asked to do?

This section should describe the study methods and procedures, including the following information.

- *OVERALL description first, i.e., “You will be taking part in (one/two/three) (in-person/online) (interview/survey/group discussion) about XXX”. Make sure to describe only those study activities related to what is required of the participant. Do not describe what other participants may be asked to do or describe activities not related to the research.*
- *Provide an estimation of the time required to participate in the study; where more than one interaction will occur, provide the time for each interaction as well as the overall time commitment.*
- *Where personal records, documents or other artifacts will be accessed, indicate how these are collected, whether individually identifying information is collected and whether there will be possible linkage with other data. If applicable, indicate how these will be returned to the participant.*
- *If photo, video or artwork is being used explain how it will be collected and if/how it will be returned to the participants.*
- *For surveys, describe how they are completed (i.e., online or in person) and how the surveys are confidentially returned.*
- *For interviews/focus groups/sharing circles, indicate the number of interviews, length, format and how interviewees are selected.*
- *If the study will be conducted virtually (i.e., virtual interview/focus group/sharing circles), describe the platform that will be used and indicate if audio/video recording will take place. Participants should be allowed to turn off their cameras. If video recording is essential to the research this should be stated.*
- *If interviews or focus groups are conducted using Zoom Cloud Recording: “The session may be recorded using the Zoom Cloud service to allow for accurate transcription. The recording will be downloaded to a secure University server and deleted from Zoom once saved. However, Zoom maintains backup systems in the United States, and although deleted recordings are removed from your researcher’s account, copies may persist for a period of time in Zoom’s internal backups. The University cannot access or delete those backups, and they may be subject to U.S. laws.”*
- *Where recordings will be used, specify whether audio or video recording will take place or both. Participants should be allowed to turn off any recording device should they so choose, with the exception of where it may not be possible, i.e., focus groups/sharing circles.*
- *If interviews are transcribed, explain how this process will take place (i.e., By who? Where it will be stored?) NOTE: If the transcriber is not a member of the research team, then they should sign a Confidentiality Agreement or be contractually obligated not to share the information. This practice should be reflected in Section 5.3 of the Application Form.*

- Describe the procedures for returning transcripts or member-checking or data verification purposes. Indicate how these will be returned to the participant and the deadline for the participant to complete the member-checking. Explain what happens to the data if the member checking is not received by the deadline (i.e., original version will be used).
- If the study has plans to use a data repository, include the following: “With your consent, [anonymized, identifiable, etc.] study information will be stored in a secure data repository to facilitate future research.”

What are the risks and discomforts?

This section should include information on any known risks or discomforts that may result from participation in the study. The risks and mitigation strategies outlined in this section should directly match those indicated in Section 3.1 of the Application Form.

- Where risks are identified, outline the process for mitigating those risks (i.e., referral to counselling where the potential for psychological distress is possible).
- If there are no known risks associated with the research, this should be stated.

The following statement should be included at the end of this section in all consent forms: “It is not possible to know all of the risks that may happen in a study, but the researchers have taken all reasonable safeguards to minimize any known risks to a study participant.”

For studies involving an intervention, the following statement should be included, “If we find out anything new during the course of this research which may change your willingness to be in the study, we will tell you about these findings.”

What are the benefits to me?

This section should describe any direct benefits to the participant first, followed by potential scientific/scholarly benefits. The benefits outlined in this section should directly match the benefits indicated in Section 3.2 of the Application Form.

NOTE: Incentives such as cash, gift cards, prize draws, course credits and other material rewards are not considered benefits of participation, and should be included in the section titled “Will I be paid to be in the research?”.

If there are no direct benefits to the participant as a result of participation in the study, the following statement should be included, “While there may not be any direct benefit to you, results from this study may help us learn about XXX and may benefit others in the future.”

Do I have to take part in the study?

This section should stress the voluntary nature of the study.

*Explain how the participant can stop their participation prior to completing the study tasks. The **participation withdrawal** practices outlined here should directly match the participation withdrawal practices as outlined in Section 4.5 Question 5.0.*

Being in this study is your choice. If you decide to be in the study, you can change your mind and stop being in the study *[enter timeframe for withdrawal from study]*. After that point we cannot remove you from the study because *[enter/explain the reasons]*. To withdraw from the study please contact *[enter Principal Investigator and/or study coordinator contact here]*.

In the event of opting out of the study, describe how the withdrawal of data will be handled. Specify what can be done and until what point of the research such withdrawal can occur.

*Explain if/how the participant can request that their data be withdrawn from the research after they have participated. The **data withdrawal** practices outlined here should directly match the data withdrawal practices as outlined in Section 4.5 Question 6.0.*

*Where data withdrawal is possible, the following information should be included, “Even if you remain in the research study, you may choose to withdraw some or all of your responses by contacting *[enter Principal Investigator and/or study coordinator contact here]* by *[enter deadline/timeframe here]*. We are unable to remove your answers after that time because *[enter reasons for non-withdrawal here, such as: the data has been anonymized, thesis will be written, or other reason]*.”*

Where data withdrawal is not possible (i.e., anonymous surveys or focus group/sharing circle discussions), explain why data withdrawal is not possible (i.e. due to the anonymous nature of the survey data withdrawal is not possible after submission, due to the nature of the group discussion removing your contributions may result in a transcript that does not make sense, etc). Explain the last point where participants can redact their data from research analysis.

For studies involving questionnaires/surveys or interviews/focus groups/sharing circles, participants should be advised that they do not have to answer any questions that they are not comfortable with, “You may refuse to answer questions that you do not want to answer.”

*For studies that use student participant pools: Your participation in this study is completely voluntary. If you choose not to participate in today’s session, you may complete an alternate educational activity *[insert description of the alternate task and instructions for its completion where applicable]*. Should you choose to participate in the research activity, you may decide at any time after you have begun, to withdraw and still receive credit without having to complete the alternate activity. Discontinuation will not affect your academic status. If you complete the study and wish to have your data withdrawn for any reason, please contact *[insert Principal Investigator and/or study coordinator contact information]*.*

Will I be paid to be in the research?

Include this section only if applicable. This section should include a clear statement about any compensation and/or reimbursements the participant will receive for being in the study (i.e., parking costs, food, \$\$ for time, course credit, etc.). NOTE: An incentive is money paid for participation, while reimbursement is compensation for out-of-pocket expenses.

A clear statement regarding what will happen to the payment if the participant withdraws from the study prematurely should also be provided. The participant should not suffer any disadvantage for withdrawing, nor should any payment due prior to the point of withdrawal be

withheld. If the research project uses a lump-sum incentive for participation, the participant is entitled to the entire amount. The compensation/incentives should not be contingent on completion of all study tasks however a payment schedule can be used where participants are paid in proportion to their participation. If you choose to withdraw from the study partway through participation, you are entitled to the incentive.

Studies employing the use of a lottery or prize draw must include the approximate odds of winning the prize and apply a skill-testing question to the winner.

What happens if I am injured because of this research?

Include this section only if applicable. There are certain circumstances where the compensation for injury clause is not needed (i.e., research where injury requiring medical care is extremely unlikely, non-interventional studies, and low-risk studies). If there is a potential for harm, there must be a statement regarding possible compensation if the participant is injured as a result of the research.

In the event that you suffer injury as a result of participating in this research, no compensation will be provided to you by [insert name of sponsor/funder], the University of Alberta, or the Researchers. However, you still have all your legal rights. Nothing said in this consent form alters your right to seek damages.

Will my information be kept private?

This section should describe how information will be kept confidential. If records will not be confidential, describe how records will be presented, and whether they will be archived.

During this study we will do everything we can to make sure that all information you provide is kept private. No information relating to this study that includes your name will be released outside of the researcher's office or published by the researchers unless you give us your express permission. Sometimes, by law, we may have to release your information with your name so we cannot guarantee absolute privacy. However, we will make every legal effort to make sure that your information is kept private

For studies using pseudonyms (fake names), indicate that alternate names will be used and provide the participant the option to use their real name. "When your interview is transcribed, we will assign a pseudonym (fake name) to protect your identity. If you would like to choose your own fake-name or if you choose to use your real name, please indicate this on the last page of this document."

For studies employing virtual platforms, describe how the data is downloaded from the platform and securely stored. Explain if/how the data may remain on the virtual platform. If identifiable research data (including recordings) are stored or transmitted using third-party cloud services (e.g., Zoom, Google Drive, Microsoft OneDrive, etc.), researchers must inform participants that these services may store information outside of Canada.

Even when data are deleted by the researcher, copies may persist temporarily in system backups that are not under the University's control. Participants should be advised that "deletion does not equal complete erasure."

Researchers should identify which platform(s) will be used, how data will be downloaded and stored securely, and confirm that University-approved systems are being used.

*If the platform's servers are located outside of Canada, include the following phrase **If data will be collected or stored using online platforms (e.g., Zoom, Microsoft Teams, Google***

Drive, or other cloud services):

“Audio or video recordings, transcripts, or other study data collected or stored using online platforms may be temporarily held on servers outside of Canada. Although the research team will delete recordings or files from the platform once downloaded and transcribed, complete erasure from company backup systems cannot be guaranteed. The University of Alberta does not control how long backup copies are retained or who may lawfully access them under the privacy laws of those countries.”

During research studies it is important that the data we get is accurate. For this reason, your data, including your name, may be looked at by people from the Research Ethics Board.

After the study is done, we will still need to securely store your data that was collected as part of the study. *[Insert description on how the data will be securely stored, including where physical data will be held and the safeguards in place for electronic data, i.e., encrypted, password protected and behind secure firewalls.]* At the University of Alberta, we keep data stored for a minimum of 5 years after the end of the study.

Group Research (focus groups, sharing circles, etc.): Include a statement indicating that while you will strive to protect the anonymity and confidentiality of the data you cannot guarantee that others from the group will do the same. “Please be advised that although the researchers will take every precaution to maintain confidentiality of the data, the nature of group discussion prevents the researchers from guaranteeing confidentiality. You are asked to respect the privacy of your fellow participants and not repeat what is said in the group discussion to others outside of the group.”

Consider the potential for future uses of study data, and data sharing requirements, and advise participants of this possibility. Please indicate whether the data will be held in an identifiable or de-identified state.

For studies wishing to deposit data in a repository: After the study is done, study data will be stored in a secure data repository, [insert name repository here], to facilitate re-use of the data by approved researchers. Any personal information, such as [insert identifiers collected in your research here. For example, “your name, email address, telephone number”], that could identify you will be removed or changed prior to sharing study data with other researchers. Provided they adhere to the policies of the repository and protect confidentiality, this anonymized data may be used by other researchers without further ethics board review. Your data may be linked with other data for research purposes only to increase the usefulness of the data, as subject to scientific and ethical oversight as mentioned above.

What if I have questions?

If you have any questions about the research now or later, please contact *[insert Principal Investigator and/or study coordinator contact information]*

If you have any questions regarding your rights as a research participant, you may contact the University of Alberta Research Ethics Office at ethics@ualberta.ca or (780)492-2615 and quote Ethics ID Pro00XXXXXX. This office is independent of the researchers.

Disclose any actual or potential conflicts of interest related to payment or funding received for conducting the study. This includes any institutional funding, personal remuneration or potential for commercialization of the research. If the study is funded either by a grant or a commercial sponsor, name the funder and/or the sponsor and indicate that the researchers or their institution are receiving funding to conduct the study.

“The study is being funded/sponsored by the [name of funder/granting agency or commercial sponsor]. The Institution and Principal Investigator are receiving funds to cover the costs of doing this study. You are entitled to request any details concerning this compensation from the Principal Investigator.”

How do I indicate my agreement to be in this study?

Please see recommended formatting for signed consent –OR– verbal consent below.

NOTE: For Anonymous Surveys, please see the recommended formatting for implied consent on the [Information Letter Template - Survey Implied Consent](#)

IF USING SIGNED CONSENT:

By signing below, you understand:

- That you have read the above information and have had anything that you do not understand explained to you to your satisfaction.
- That you will be taking part in a research study.
- That you may freely leave the research study at any time.
- That you do not waive your legal rights by being in the study
- That the legal and professional obligations of the researchers and involved institutions are not changed by your taking part in this study.
- **That you agree to the data being stored as part of a data repository (where applicable)**

SIGNATURE OF STUDY PARTICIPANT

Name of Participant

Pseudonym *(Remove if not applicable)*

Signature of Participant

Date

SIGNATURE OF PERSON OBTAINING CONSENT

Name of Person Obtaining Consent

Contact Number

A copy of this consent form has been given to you to keep for your records and reference.

IF USING VERBAL CONSENT:

Potential participants should receive a copy of the consent letter in advance of the research session. The researcher can verbally review the study information with the potential participant at the beginning of the research session and address any questions as needed. The researcher should verify the participants understanding and obtain a verbal attestation from the potential participant of their consent to participate. Documentation of verbal consent should be retained by the research team within their study records.

Your verbal consent will be obtained by a member of the research team at *[insert description of the timing/location of where verbal consent will be obtained]*. By providing your verbal consent, you understand:

- That you have read the above information and have had anything that you do not understand explained to you to your satisfaction.
- That you will be taking part in a research study.
- That you may freely leave the research study at any time.
- That you do not waive your legal rights by being in the study
- That the legal and professional obligations of the researchers and involved institutions are not changed by your taking part in this study.

A copy of this consent form has been given to you to keep for your records and reference.

TO BE COMPLETED BY A MEMBER OF THE RESEARCH TEAM:

Name of Participant

Pseudonym *(Remove if not applicable)*

Date

Name of Person Obtaining Consent

Researcher notes on the verbal consent process/conversation:

