**standard consent form**

REBS 1 & 2

GENERAL GUIDELINES FOR INFORMED CONSENT FORMS (ICF) (REBs 1 & 2s)

Please note that a well-presented ICF that is in accordance with REB 1 & 2 standards will facilitate the approval process. ICFs that do not adhere to REB standards will result in potential delays. Please adhere to the following formatting requirements:

1. Consent forms should be written at a Grade 6-9 level of understanding. (Where the population has an understood minimal educational level, i.e., academics or professionals, an argument for a higher readability can be made). Please use a readability index, such as [hemingwayapp.com](file:///C%3A%5CUsers%5CAppData%5CLocal%5CMicrosoft%5CWindows%5CINetCache%5CContent.Outlook%5CAppData%5CLocal%5CMicrosoft%5CWindows%5CINetCache%5CContent.Outlook%5CAppData%5CLocal%5CMicrosoft%5CWindows%5CINetCache%5CDownloads%5Chemmingwayapp.com), to confirm the level.
2. Use plain language explaining technical terms and jargon. Use non-scientific terminology and remove emotive terms.
3. Type size should be no smaller than the type on this page. e.g., Arial 12 point can be used.
4. Use headings, small paragraphs and spaces between the paragraphs.
5. Use non-pejorative language throughout; use the active voice wherever possible.
6. Write out all acronyms the first time they appear in the consent form.
7. Spelling, grammar and formatting must be corrected before it is submitted for review.
8. Use second person pronouns for the information letter part of the consent form (you/your). Use first person pronoun (“I”) for only the final “consent statement” portion of the form.
9. Use ‘participant’ throughout the consent form rather than ‘patient’ or ‘subject’.
10. Explain the whole research process in a way that participants can understand. Put yourself in the place of the participant when composing your information sheet.

Blue font: instructions

Black font: required language

Red font: insert as applicable or suggested language

Green font: suggested language for data repository

*In each section, replace the instructions (in blue) with information from your study. In some cases sample language is listed (in red), you may use this language, or replace with your own explanation. Sample language for deposit into a data repository is listed in green. Any required language is listed in black. Throughout the consent form, use simple, non-technical terms, and address potential participants directly, with second-person language throughout.*

**To be on Departmental or University Letterhead**

**PARTICIPANT CONSENT FORM**

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

Contact Information

Principal Investigator:

Name & Affiliation

Mailing Address

Phone:

Email:

Research/Study Coordinator: (if needed; insert same contact info as above)

Supervisor (must be included if the PI is a graduate student, otherwise delete)

Name & Affiliation

Mailing Address:

Phone:

Email:

*Students should refrain from putting their personal telephone numbers and email addresses. Only institutional contact information should be provided.*

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, at a 6th-9th grade reading level why this person might qualify for the research study. (i.e.* You are being asked to be in this study because…*) 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.*

*A brief statement about the “purpose” of the Information Sheet can be listed here.* (i.e. The goal of this study is to (investigate/understand/explore/prove)….

**What is the reason for doing the study?**

*Describe the purpose of the study at a 6th – 9th grade reading level. Clearly state what the purpose of this SPECIFIC study is 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).*

**What will I be asked to do?***The first part of this section should describe the study OVERALL, including the following information. Make sure to use third-person (you will be asked to…):*

* *i.e., You will be taking part in (one/two/three) (in-person/online) (interview/survey/group discussion) about….*
* *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.*
* *For interviews/focus groups, indicate the number of interviews, length, format and how interviewees are selected.*
* *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 (online or in person) and how the surveys are confidentially returned.*
* *If the study will be conducted virtually, 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.*
* *Where recording 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.*
* *If interviews are transcribed, explain how this process will take place (who? Where it will be stored)*
* *Describe the procedures for returning transcripts or member-checking or data verification purposes. Indicate how these will be returned and the timeline for doing so.*
* *Make sure to describe only those study activities related to what is required of the participant (i.e., do not describe what other participants may be asked to do or describe activities not related to the research.*
* With your consent, study information will be stored in a secure data repository to facilitate future research

**What are the risks and discomforts?** *Include information on any known risks or discomforts that may result from participation in the study. The risks outlined in this section should directly match the risks indicated in Section 3.1 of the Main Application Form, including the strategies to mitigate those risks.*

* *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, add a statement that,* “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?**

*Describe any direct benefits to the participant first, followed by potential general benefits (e.g., to the group of patients to which the individual belongs, or to medical knowledge). If there is no anticipated direct benefit to the participant from the study, state this at the beginning of the section. 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.*

*Please note incentives such as cash, gift cards, and other material rewards are not considered benefits of participation, and should be included in the section “Will I be paid to be in the research?”*

**Do I have to take part in the study?**  *This section should stress the voluntary nature of the study.* “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 (indicate timeframe for withdrawal from study). After that point we cannot remove you from the study because (explain the reasons). To withdraw from the study please contact (PI or contact name & email/phone number here)

Even if you remain in the research study, you may choose to withdraw some or all of your responses by contacting (contact name) by (deadline). We are unable to remove your answers after that time because (give reasons for non-withdrawal such as: has become part of the data set, thesis will be written, or other reason).

*For studies involving questionnaires/surveys or interviews participants should be advised that they do not have to answer any questions that they are not comfortable with.*

*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.*

*Where data withdrawal is not possible, i.e., anonymous surveys, this should be stated.* Due to the anonymous nature of participation, you can withdraw your data up until the time of submission. Simply close your browser/do not submit your data and nothing will be recorded. Once you have submitted your data it is not possible for it to be removed.

*For studies that involve the use of 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 (*describe the alternate task and instructions for its completion*). 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 the (study team, research coordinator, etc.).

**Will I be paid to be in the research?** *(Include only if applicable)* A *clear statement must be made about any reimbursement the participant will receive for being in the study (i.e., parking costs, food, $$ for time, course credit etc.) Be sure to indicate if these amounts are to be pro-rated for various time intervals. Important: An incentive is money paid for participation, while reimbursement is compensation for out-of-pocket expenses.*

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*NOTE: The REB will take into consideration the nature and amount of payments (i.e., the payments alone should not serve as sufficient inducement for the participant to volunteer).*

*A clear statement regarding what will happen to the payment if the participant withdraws from the study prematurely should also be provided. Note that receipt of compensation/incentives should not be contingent on completion of all study tasks. Participants should still be entitled to receipt of the incentive if they withdraw or where possible, a pro-rated amount. If you choose to withdraw from the study partway through participation you are entitled to the incentive or a portion thereof.*

*Studies employing the use of a lottery or prize draw must include the odds of winning the prize and a skill testing question.*

**What happens if I am injured because of this research?** (where applicable)

*There are certain circumstances where the compensation clause is not needed. For example, 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.*

If you become ill or injured as a result of being in this study, you will receive necessary medical treatment, at no additional cost to you. By signing this consent form, you are not giving up any of your legal rights or releasing the investigator(s), institution(s) and/or sponsor(s) from their legal and professional responsibilities.

**Will my information be kept private?** *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, indicate that alternate names will be used and provide the participant the option to use their own name. (i.e., 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, please say so in the interview. If you would like us to use your real name, please indicate this on the signed consent form 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 the storage is outside of Canada, include the following phrase “Because your information is stored outside of Canada it may be subject to the privacy legislation of those territories which may include access by governmental agents.”*

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. (Describe 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 (NOTE: It is recommended that graduate students store a copy of their data on their supervisor’s secure Google Drive)

*Focus Group Research: Include a statement indicating that while you will strive to protect the confidentiality of the data you cannot guarantee that others from the group will do the same.*

*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, *[name repository here],* to facilitate re-use of the data by approved researchers. Any personal information (i.e., your name, address, telephone number) that could identify you will be removed or changed prior to sharing study data with other researchers. Any researcher who wants to use this data must have the new project reviewed by an ethics board and sign an agreement ensuring your confidentiality and restricting data use only to the approved project. 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*[enter Investigator and/or study coordinator numbers here}*

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

*Declare any actual or potential conflicts of interest with respect to remuneration received from the funding agency for conducting or being involved with any part of the study and/or the possibility of commercialization of research findings*. *If the study is being “sponsored”, list the agency/company that is sponsoring the study, as well as the fact that the Investigator is receiving funding to conduct the study.* “The study is being conducted/sponsored by the [name of research group, e.g., NCIC/industry sponsor/granting agencySSHRC/]. The Institution and Principal Investigator are getting money from the study sponsor to cover the costs of doing this study. You are entitled to request any details concerning this compensation from the Principal Investigator.”

*For Survey Research: See* [*Information Letter Template - Survey Implied Consent*](https://www.ualberta.ca/research/research-support/research-ethics-office/forms-cabinet/forms-human.html)

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

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 investigators 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**

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Pseudonym (if necessary)

Name of Participant

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Signature of Participant Date

**SIGNATURE OF PERSON OBTAINING CONSENT**

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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.