**standard consent form**

HEALTH studies

GENERAL GUIDELINES FOR INFORMED CONSENT FORMS (ICF)(HREB Health Panel)

Please note that a well presented ICF that is in accordance with HREB standards will facilitate the approval process. ICFs that do not adhere to HREB 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., physicians, an argument for a higher readability can be made). Please use a readability index, such as [hemingwayapp.com](file:///C:\Users\AppData\Local\Microsoft\Windows\INetCache\Content.Outlook\AppData\Local\Microsoft\Windows\INetCache\Content.Outlook\AppData\Local\Microsoft\Windows\INetCache\Downloads\hemmingwayapp.com), to confirm the level.
2. Use plain language explaining medical 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. Times New Roman 12 point can be used.
4. Use headings, small paragraphs and spaces between the paragraphs
5. When reference is made to regulatory authorities having access to information please include Health Canada before other foreign regulatory agencies like FDA.
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’.

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 INVESTIGATOR Letterhead**

**PARTICIPANT CONSENT FORM**

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

**Principal Investigator:** *[include phone number]*

**Research/Study Coordinator:**

**Why am I being asked to take part in this research study?** *Describe, at a 6th-8th grade reading level why this person might qualify for the research study. (i.e.* You are being asked to be in this study because you have XX*) 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.* This form contains information about the study. Before you read it, a member of the study team will explain the study to you in detail. You are free to ask questions about anything you do not understand. You will be given a copy of this form for your records.

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

*Describe the purpose of the study at a 6th – 8th grade reading level. Clearly state what the purpose of this SPECIFIC study is and what the study hopes to answer.*

*Key points to include in this section, when applicable:*

* *For non-invasive 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:*

* *Provide an estimation of the time required to participate in the study; where more than one procedure will occur, provide the time for each procedure as well as the overall time commitment.*
* *explain the difference between standard therapy and the study procedures(if applicable);*
* *If randomization will be used – what this means and how will this be done.* You will be assigned at random, (like flipping a coin OR like rolling a dice), to one of *XX number* groups. You will have a *[specify 1 in 2, 3 in 4, 50%, etc]* chance of being in the intervention group and *[specify 1 in 2, 3 in 4, etc]* chance of being in the control group. *Participants in the control group should be offered the chance of receiving the intervention at study completion.*
* *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.*
* *Access to medical records is considered part of the study procedures and should first be mentioned here, along with a brief description of the variables to be extracted and how they will contribute to the data analysis.*
* With your consent, allow storage of study information in a secure data repository to facilitate future research

*THEN: Describe the procedures chronologically using simplistic language, short sentences (1-3) lines and short paragraphs (less than 6 sentences). The use of subheadings may help to organize the section and increase readability. Explain study procedures ONLY ONCE and only describe those activities related to what will be required of the participant (i.e., do not describe what other participants may be asked to do or describe procedures that are part of standard care)*

**How long will I be in this study?** *Explain the duration of the study or how long the study will last. This will help participants decide if they have the time to participate.*

Participation will take a total of about [specify time and duration].

*When appropriate, include estimates of the different aspects of the study and state that the study will involve long-term follow-up and specify time frames.*

***Examples*:**

* You will be in this study for XX days.
* Your participation in this study will last \_\_\_.
* Participation in this study will require about XX hours of your time.
* This study will require approximately XX hours of your time for each study visit.
* There will be a total of XX study visits over six months.
* You will be in the [insert clinic/center name] for a total of XX days.

**What are the risks and discomforts?** *Include information on any known risks or discomforts that may result from participation in the study.*

* *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 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.”

*If applicable, please add details related to COVID risks of any in person visits, and any strategies to minimize and mitigate transmission.*

**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.*

*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?”*

***Example****:* There may not be any direct benefit to you from participating in this study. However, this study will help the researchers learn more about [procedure/drug/intervention/device]. Hopefully this information will help in the treatment of future patients with [disease/condition] like yours.

**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 at any time, and it will in no way affect the care or treatment that you are entitled to.”

*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.*

**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, extra credit etc.) Be sure to indicate if these amounts are to be pro-rated for study visit completion.*

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

*A clear statement regarding what will happen to the compensation if the participant withdraws from the study early should also be provided.*

*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?**

*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 whether records will be kept confidential. If records will not be confidential, describe how records will be presented, and whether they will be archived.*

During the study we will be collecting data about you. We will do everything we can to make sure that this data is kept private. No data relating to this study that includes your name will be released outside of the researcher’s office or published by the researchers. 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. (If applicable add the following) We will also put a copy of this consent form in your clinical records, so that doctors you see in the future will know you were in this study.

*For studies employing virtual platforms, describe how the data is downloaded from the platform and securely stored.*

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

list: study sponsor (either a Pharmaceutical Company or the University of Alberta if the study is Investigator Initiated), members of the Research Ethics Board, Health Canada, and/or other foreign regulatory agencies.

*For studies that employ the use of health information (as defined by HIA):* The investigator or their study staff may need to look at your personal health records or at those kept by other health care providers that you may have seen in the past (i.e. your family doctor). Any personal health information that we get from these records will be only what is needed for the study.

By signing this consent form you are saying it is okay for the study team to collect, use and disclose information about you from your personal health records as described above.

After the study is done, we will still need to securely store your health data that was collected as part of the study. *Choose one of the following as applicable: If this is a study being conducted under Health Canada:* In Canada, the law says we have to keep the data stored for 15 years after the end of the study. *OR if not:* At the University of Alberta, we keep data stored for a minimum of 5 years after the end of the study.

*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]. For greater than minimal risk, include 24 hour night/emergency phone numbers.*

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. This office has no affiliation with 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 agency/]. The Institution and study doctor 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 Anonymous Surveys: 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.

**SIGNATURE OF STUDY PARTICIPANT**

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name of Participant

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of Participant Date

**SIGNATURE OF PERSON OBTAINING CONSENT**

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name of Person Obtaining Consent Contact Number

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature Date

**SIGNATURE OF THE WITNESS**

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name of Witness

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of Witness Date

*Under the International Conference on Harmonization, Good Clinical Practice (ICH GCP 4.8.9), where it is known that the participant cannot read (e.g., visually impaired or illiterate), the signature of an impartial witness independent of the trial must be obtained. The witness must be present for the consent process. The witness signature reflects that they believe the participant was presented with sufficient information to assure a truly informed consent.*

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