Instructions for Informed Consent Form Development

The informed consent form (ICF) is one component of the informed consent process. Further guidance may be found in the HREB Guidelines for Consent for Research found under the Attachments tab in the Researcher Portal.

Brief instructions to consent authors are highlighted in this colour and/or [enclosed in square brackets]. This text should be removed prior to REB submission, i.e. not included in the consent form for participants.

Edit the text examples as necessary to make the language specific to the study question since many statements throughout the template are generic.

Examples are not given for every study situation. Consent authors should review all examples in a section, even if the example is for a different study type, to identify language that may apply to their study.

Participant Study Calendars: Consider providing an easy-to-read-and- understandable participant study calendar. A participant study calendar may be included as an appendix or included in the main consent document.

Eliminate repetitive information.

Define all acronyms when they first appear and limit their use.

Use the term ‘study doctor’ when referring to physicians involved in the clinical trial, to ensure there is no confusion with the treating or primary care doctors.

Please delete this instruction page from the consent forms prior to REB submission.

(Insert your letterhead)

Consent to Take Part in Research

TITLE:

RESEARCHER(S): Phone Number:

SUPERVISOR(S): [if applicable]

SPONSOR/FUNDER: **[if applicable]**

You have been invited to take part in a research study. Taking part in this study is voluntary. You may choose to take part or you may choose not to take part in this study. You also may change your mind at any time. **If applicable include**: If you decide to stop participating in the study, the researcher/study doctor will discuss other options with you. Whatever you choose it will not affect your [usual care/employment] and you will not lose any benefits to which you are entitled.

This consent form has important information to help you make your choice. It may use words that you do not understand. Please ask the [researcher(s)/study staff] to explain anything that you do not understand. It is important that you have as much information as you need and that all your questions are answered. Please take as much time as you need to think about your decision to participate or not, and ask questions about anything that is not clear. You may find it helpful to discuss it with your friends and family. The [researcher/study staff] will tell you about the study timelines for making your decision.

1. Why am I being asked to join this study?

Give a brief statement of why this particular person was considered as a possible candidate for the trial. Explain in lay language main purpose/goals of the study. Describe the background information relevant to the study.

Example
You are being invited to join this study because [explain the main features of the population to which the research applies]. This study is being done to find out more information about [describe research topic].

2. How many people will take part in this study?

Briefly describe where the study is being done, (e.g. Newfoundland, Canada, North America, world-wide) and how many people are expected to take part in total and at the local site.

Example:
This study will take place in in several cities in Canada. The study will enroll a total of 500 people. We expect to enroll about 10 patients at this site/clinic/hospital.

3. How long will I be in the study?

Briefly summarize in one or two sentences, how many visits will be required, how long the visits will last, and the duration of the study.

Example:
You will be expected to come to [location] for two in-person interviews over the next 4 months. Each interview will take 1-2 hours.

4. What will happen if I take part in this study?

Describe all the **research study** procedures that are used in the study. Clearly identify and explain the procedures that are mandated by the study proposal.

Example:
If you agree to take part in this study, the following procedures will take place:

- Questionnaires: You will be provided with a questionnaire(s) [provide information about the number and timing of questionnaires e.g., before you begin the study and then every 8 weeks for a year]. The purpose of the questionnaire(s) is/are [include description of purpose e.g., to understand how the study intervention and illness affects your quality of life]. Each questionnaire will take about [indicate estimated time to complete in minutes) to complete. The information you provide is for research purposes only. Some of the questions are personal. You can choose not to answer questions if you wish. [If the questions are of a sensitive nature, include potential for emotional distress in the Risks section and what type of help will be provided if this happens.]
- Interviews: You will be asked to participate in [specify how many interviews if more than one, provide information about timing e.g., before you begin the study and then every X weeks/months]. During this interview, you will speak with/meet with a member/members of the research team [and specify others if applicable]. Each interview will be about [specify length of time in minutes or hours] and will take place [specify location]. You will be asked to provide information about [explain topics of discussion e.g., your experiences with condition/intervention]. You can choose not to answer questions if you wish. [If the questions are of a sensitive nature, include potential for emotional distress in the Risks section and what type of help will be provided if this happens.]

- Audio recording used: You will be audio/video recorded during the [specify e.g., interview(s)/focus group].The audio recording will be transcribed (written down) after the interview/focus group and will be analyzed by the research team. The transcription will be done by [e.g., members of the study team, a professional transcription service]. Your name or any other identifying information will not be included during the recording, except your voice. The audio recording will be destroyed after it has been transcribed and checked for accuracy [if otherwise state it here and explain].
- Video recording used**:** The interview/focus group [or other procedure, as applicable] will be video recorded. [Explain what parts of the participant will be video recorded. Will it include their face? What will be done to remove the identifiable information from the video, if any? How will the videos be analyzed, for what purpose, and by whom?]

- Database Studies: The researchers will collect information about you from [specify source of information e.g., your medical chart] and enter this information into an electronic database. The data will be securely stored, and will be maintained by [specify responsible individual/group]. The database can only be accessed by people who are involved in research. Please talk to the research team if there is information that you do not feel comfortable sharing.
  If the database information will be entered into secondary databases(s), this must be specified (including the reason and who the data will be shared with). **For example**: Information about you kept in this database may be shared with national and international research partners and may be entered into other national and international databases. The data will be securely stored, and will be maintained by [specify responsible individual/group]. The sharing of this information is meant to [specify purpose e.g., allow researchers to work together and increase worldwide research efforts]. The information provided to them will not include information that can directly identify you, such as your name, address or phone number.
- Focus Groups: You will be asked to participate in [specify how many) focus group(s). If more than one focus group, provide information about timing e.g., before you begin the study and then every X weeks/months. A focus group is a small group of representative people who are asked to speak about their opinions as part of the research. A moderator will organize the focus group(s). Each focus group discussion will be about [specify length in minutes or hours] in length and will take place [specify location]. You will be asked to speak about [explain topics of discussion e.g., your experiences with condition/intervention].
- Participant Diaries: You will be asked to keep a diary of [identify information to be recorded]. You will be asked to return the diary to this centre.
- Specimen collection: Describe the mandatory sample collection, including the sample type and amount and manner/safety of acquisition, purpose of the research (including any commercial use), measures employed to protect privacy and minimize risk, and length, method, and location of storage. **For example**: You will have blood samples taken by inserting a needle into a vein in your arm. [Specify amount of blood to be collected and timing e.g. About 1 tablespoon will be taken at every study visit, or x times a year]. These blood samples will be sent to a laboratory in [city, country] where they will be examined to [explain the purpose e.g. confirm your diagnosis or test your kidney and liver function]. To protect your identity, the information that will be on your samples will be limited to [specify which identifiers will be on the samples e.g. study code, initials]. Once these tests have been completed, any leftover samples will be destroyed. [If there is an optional future use purpose include: unless you wish to give permission for other future research purposes, in which case you will be given a separate optional consent form to sign.]

5. Are there risks to taking part in this study?

All potential risks, discomforts or inconveniences of being in the study – physical, emotional, social – should be explained. Any social, legal, group or community risks should also be included here.
If there is a risk that a participant would be emotionally disturbed, the investigator must be qualified to deal with this situation or must describe the procedure for addressing the situation. A list of available resources is expected to be included for this situation.

If there is a risk of identifying a participant, describe what measures are in place to protect against this occurring.

Examples:
Interviews/Questionnaires: During the questionnaires and/or the interview, you may become uncomfortable or experience some anxiety, emotional and/or psychological distress due to the nature of the questions. You can skip questions, take a break or stop answering at any time. The following resources are available for you to contact for psychological support:
If applicable include, If your responses indicate that there is a serious risk of harm to yourself or others, confidentiality will be broken in order to protect you or another person. If we feel that you need urgent care as result of participating in this research study we will intervene according to routine clinical care practices.

Use of images:
If unique features like birth marks or tattoos are captured in the photos taken for this study, there is a potential risk of loss of your confidentiality.

Audio Recording:
There is a potential risk of loss of your confidentiality because even though your name will not be part of the audio recording or the transcription, your voice may still be identifiable as your voice. If anyone mentions identifiers (e.g., your name), during the recording, this may identify you.
Focus Group:
Although the researchers will take every precaution to maintain confidentiality of the data, the nature of focus groups prevents the researchers from guaranteeing confidentiality. It is possible that some focus group members may repeat things said in the meeting. The researchers will ask participants to respect the privacy of fellow participants and treat all information shared with the group as confidential.

Blood Sampling:
There is a possibility of pain, bruising, swelling or infection related to the blood draw. These discomforts are minimal and brief.

Inconvenience of time:
There is an inconvenience of time. Each study visit will take about (## minutes/hours, for a total of ## minutes/hours) for the entire research study.

Confidentiality risk (for all studies):
Despite protections being in place, there is a risk of unintentional release of information. Researchers will make every attempt to protect your privacy.

6. What are the possible benefits of participating in this study?

There may not be direct benefit to you from taking part in this study.
If applicable, include: We hope that the information learned from this study can be used in the future to benefit other people with (disease/condition).

7. If I decide to take part in this study, can I stop later?

Note: requiring a written notification is not acceptable. It is the study team's responsibility to document the request. Verbal notification is sufficient. Parents/patients should not be asked to go through the additional burden of writing a letter for documentation purposes.

It is your choice to take part in this study, participation is voluntary. You can change your mind at any time during the research study. The study team may ask why you are withdrawing for reporting purposes, but you do not need to give a reason to withdraw from the study if you do not want to. Withdrawal from the study will not have any effect on the care you [or your family, if applicable] will receive. If you decide to leave the study, you can contact your researcher/study doctor. They will discuss other options with you.

Please describe the process for withdrawal and any limitations to the withdrawal. **You may select an option from the sample language below or edit to suit the study:**

- You may choose to withdraw from the study treatment but continue to have follow up study visits. Your researcher/study doctor or designate will discuss what study procedures will be carried out if you choose this option. The researcher/study staff will continue to access your medical records and use your medical data and study information as described in this consent form for the purposes of this study.
- You may choose to withdraw from study treatment and study procedures but allow the researcher/study team to contact you regularly according to the study visit schedule and to access your health records and use your health data and study information as described in this consent form for the purposes of this study.
- You may fully withdraw from this study. This means that the researcher/study staff will no longer access your health records or use your data for research and all data collected about you will be destroyed. If applicable, Any remaining biologic samples will also be destroyed. We will no longer contact you for any reason. Any data that has already been merged with other data and analyzed cannot be destroyed or removed from the study. This is because we have to preserve the study's scientific integrity. However, your data will not be used in future research.
- You may withdraw from this study. The study team will have a discussion with you about what will happen to the information about you [and/or your samples] already collected. Your study doctor will notify the sponsor who will ensure that the information/samples are [returned to the hospital from which they were obtained if needed, or destroyed]. You can request withdrawal of your specimens until [insert expected time point], at which point the code that links you to your sample will be removed. It won't be possible to return samples after this because the researchers will not know which sample is yours.
- You have the right to request the destruction of your information [and/or samples] collected during the study, or you may choose to leave the study and allow the investigators to keep the information already collected about you until that point.

If your participation in this study includes enrolling in any optional studies or long term follow-up, you will be asked whether you wish to withdraw from these as well.

8. What about new information?

It is possible that during the study we will get new information that may affect your willingness to remain in the study. If this happens, you will be notified about the new information in a timely manner.

You will be asked whether you want to continue taking part in this study and you may be invited to sign a new consent form, if you decide to continue in the research study.

9. What are my rights when participating in a research study?
Edit as required

You have the right to receive all information that could help you make a decision about participating in this study, in a timely manner. You also have the right to ask questions about this study at any time and to have them answered to your satisfaction.

Your rights to privacy are legally protected by federal and provincial laws that require safeguards to ensure that your privacy is respected.

Signing this form gives us your consent to be in this study. It tells us that you understand the information about the research study. When you sign this form you do not give up any of your legal rights against the study doctor, sponsor or involved institutions for compensation, nor does this form relieve the study doctor, sponsor or their agents of their legal and professional responsibilities.

You have the right to be informed of the results of this study once the entire study is complete. Describe how the study results will be provided (i.e. Section 16.1 of the application).

You will be given a copy of this signed and dated consent form prior to participating in this study.

10. What about my privacy and confidentiality?

Edit as applicable for your study

Protecting your privacy is an important part of this study. If you decide to participate in this study, the [researchers/study staff] will collect and use information from your [health/medical] records. They will only collect and use the information they need for this study, including:
Edit as necessary.

- gender
- date of birth (Describe format collected. Preferably year of birth only)
- new or existing medical tests or procedures and medical conditions
- sensitive information about HIV and genetic testing, or treatment for drug or alcohol abuse or mental health problems
- medications
- information from study interviews and questionnaires

The personal health information or personal information collected about you will have your directly identifiable information removed (i.e., name, MCP) and replaced with a code or with a "study number". There will be a master list linking the code numbers to names. The [researcher/study doctor] is responsible for keeping it separate from the samples and personal health information. If applicable, This link will not be available to the [Sponsor/Funding agency/Coordinating centre].

Study information collected during the study will kept at this site and stored in a secure, locked place that only the study staff will be able to access. After the study closes, study information will kept as

long as required by law, which could be xx years or more. This information will be stored [name the appropriate location]. [Name the appropriate person/role] is the person responsible for keeping it secure.

Study information sent to the sponsor, and companies working for the sponsor, will be stored in a secure central database. When the results of this study are published or presented at scientific meetings, your name and other personal information will not be used in the publication.

All information that identifies you will be kept confidential, and to the extent permitted by applicable laws, will not be disclosed or made publicly available, except as described in this consent document. Every effort to protect your privacy will be made. Even though the risk of identifying you from the study data is very small, it can never be completely eliminated. If there is a breach of your privacy resulting from your participation in this study you will be notified.

If data or samples will be sent outside of Canada:
Your study information and/or samples, will be sent outside of Canada so there is a possible increase in the risk of identifying you from the study data because the laws in other countries dealing with protection of information may not be as strict as in Canada. However, all study data and/or samples that are transferred outside of Canada will have your directly identifying personal information removed (such as your name, address, medical health number or contact information). Any information will be transferred in compliance with all relevant Canadian privacy laws. By signing this consent form, you are agreeing to the disclosure of your coded information to organizations located outside of Canada.

For studies using smartphones, apps or applicable technology, please provide details on the security/privacy/limits to the confidentiality.

If email will be used for study purposes (e.g., distribution of questionnaires, etc.), please add:
Communication via e-mail is not absolutely secure. We do not recommend that you communicate sensitive personal information via e-mail.

11. Who will see my personal information?

Edit as applicable for your study

Note: If there will be disclosure of personal identifiers, i.e., disclosed on any research-related information/documents including samples or scans, or as part of the unique identifier, these disclosures must be justified in the REB application and approved. Please ensure that you are aware of institutional and REB policies with respect to the disclosure of personal identifiers.
Representatives from the following organizations may come to look at the study records and your personal health information under the supervision of the study staff to check that the information collected for the study is correct and to make sure the study followed the required laws and guidelines:
Edit as needed

- Sponsor Name, the company that makes the (product) and its representatives and partner companies;
- Representatives of the Health Research Ethics Board

- Representatives of Health Canada, group of people who oversee the use of drugs in research in Canada, and (if applicable) other regulatory bodies such as the United States Food and Drug Administration (FDA).

We may continue to review your health records that you have consented for the study to access for a period of time after your last study visit in order to check that the information we collected is correct.

If identifiable data will be sent outside the institution:
This study requires the transfer of identifiable information to [insert name of institution/individual] for the purposes of [specify purpose]. The following information will be transferred:

- Specify identifiable information to be transferred
- Indicate how this identifiable information will be protected, used, and disclosed.

Your access to records
You have the right to see the information that has been collected about you for this study. If you wish to do so, please contact your study doctor.

12. Commercialization:

It is possible that a commercial product may be developed as a result of this study. You will have no right to any products that may be created as a result of this study or any future research studies using this research study data. You will not receive royalties from any products that may be created as a result of this study or any future research studies.

13. Declaration of financial interest, if applicable

Describe any conflict of interest that exists or may appear to exist as it relates to any of the investigators, study staff or member of their immediate family. NOTE: A conflict of interest exists if there is a potential benefit to the investigator(s), study staff or member of their immediate family beyond the professional benefit from academic achievement or presentation of the results. Examples include, but are not limited to, speaker's fees, travel assistance, consultant fees, honoraria, gifts, and intellectual property rights such as patents. A declaration of conflict of interest should include the identity of the person with the conflict of interest, the type of incentive or inducement, and its source.

A conflict of interest can occur when a person or group has more than one interest. In research, the people who run or work on studies must tell you if they have a conflict of interest.

If there are no conflicts, state:
There are no conflicts of interest to declare related to this study.

If a conflict exists, see below example language
Dr. X, declares that he/she [may/will] gain financially by being involved in this study because he/she will be paid by [insert name of sponsor/agency] for his/her time and effort during the study. This may create a competing interest or conflict of interest.

OR

As a result of his/her participation in this study, Dr. X [has received/may receive] one or more of the following benefits from [insert name of sponsor/agency]: [speaker's fees, travel assistance, industry-initiated research grants, investigator-initiated research grants, consultant fees, honoraria, gifts, intellectual property rights such as patents, etc.]. This may create a competing interest or conflict of interest.

OR

The spouse of Dr. X owns shares in the company [insert name of company/sponsor] that is sponsoring the study and may benefit financially if the outcome of the study shows that the product helps patients. This may create a competing interest or conflict of interest.

14. What about questions or problems?

If you have any questions about taking part in this study, you can meet with the doctor/principal investigator who is in charge of the study. That person is:

[Principal Investigator's Name and Phone Number]
[Or you can speak to my supervisor(s): Name and Phone Number]

You can also talk to someone who is not involved with the study at all. They can tell you about your rights as a participant in a research study. This person can be reached through:

Ethics Office at 709-864-8871
Email: info@hrea.ca
Web: www.hrea.ca

Signature Page

My signature on this consent form means:

- I have had enough time to think about the information provided and ask for advice if needed.
- All of my questions have been answered and I understand the information within this consent form.
- I understand that my participation in this study is voluntary.
- I understand that I am completely free at any time to refuse to participate or to withdraw from this study at any time, without having to give a reason, and that this will not change the quality of care that I receive.
- I understand that it is my choice to be in the study and there is no guarantee that this study will provide any benefits to me.
- I am aware of the risks of participating in this study.
- I do not give up any of my legal rights by signing this consent form.
- I understand that all of the information collected will be kept confidential and that the results will only be used for the purposes described in this consent form.
- I allow access to health records and transfer of specimens and related personal health information as explained in this consent form [include as applicable].
- I understand that my family doctor [will/may] be informed of my study participation [include as applicable].
- I agree, or agree to allow the person I am responsible for, to take part in this study [include as applicable].
- [Insert any other research specific clauses that may be important to reiterate.]

Signature of participant	Printed name	Day Month Year
Signature of person authorized as substitute decision maker **[If applicable]**	Printed name	Day Month Year
Signature of person conducting the consent discussion	Name printed	Day Month Year

To be signed by the investigator:

I have explained this study to the best of my ability. I invited questions and gave answers. I believe that the participant/substitute decision maker fully understands what is involved in being in the study, any potential risks of the study and that he or she has freely chosen to be in the study.

Signature of Researcher	Name Printed	Day Month Year

Signature Page for Parent/Guardian

My signature on this consent form means:

- I have had enough time to think about the information provided and ask for advice if needed.
- All of my questions have been answered and I understand the information within this consent form.
- I understand that my participation in this study is voluntary.
- I understand that I am completely free at any time to refuse for my child/ward to participate or to withdraw from this study at any time, without having to give a reason, and that this will not change the quality of care that my child/ward receives.
- I understand that it is my choice for my child/ward to be in the study and there is no guarantee that this study will provide any benefits to me.
- I am aware of the risks of my child/ward participating in this study.
- I do not give up any of my my child/ward's legal rights by signing this consent form.
- I understand that all of the information collected will be kept confidential and that the results will only be used for the purposes described in this consent form.
- I allow access to my child/ward's health records and transfer of specimens and related personal health information as explained in this consent form [include as applicable].
- I understand that my child/ward's family doctor will/may be informed of my study participation [include as applicable].
- [Insert any other research specific clauses that may be important to reiterate.]

I consent for my child/ward _____to take part in this study.

_____		_____
Signature of parent/guardian	Name printed	Day Month Year
_____		_____
Signature of person conducting the consent discussion	Name printed	Day Month Year
_____		
Signature of witness **[If applicable]**	Name printed	Day Month Year

To be signed by the investigator:

I have explained this study to the best of my ability. I invited questions and gave answers. I believe that the parent/guardian fully understands what is involved in being in the study, any potential risks of the study and that he or she has freely chosen for the child/ward to be in the study.

_____	_____	
Signature of Investigator	Printed Name	Day Month Year

To be signed by the minor participant [if appropriate]
Assent of minor participant:

I understand the purpose of this research
I understand that it is my decision to take part in this study. I can stop taking part if I chose.
I understand that taking part in this research may not help me.
I understand that there may be risks to participating in this study.

I agree that I will take part in this study

_____

Signature of minor participant Day Month Year

_____

Name printed Age

Participant Assistance

Complete the following declaration only if the participant is unable to read:

- The informed consent form was accurately explained to, and apparently understood by, the participant, and
- Informed consent was freely given by the participant

_____	_____	_____
Signature of Impartial Witness	Printed Name	Day Month Year

Complete the following declaration only if the participant has limited proficiency in the language in which the consent form is written and interpretation was provided as follows:

- The informed consent discussion was interpreted by an interpreter and
- A sight translation of this document was provided by the interpreter as directed by the research staff conducting the consent.

Interpreter Declaration and Signature:
By signing the consent form I attest that I provided a faithful interpretation for any discussion that took place in my presence, and provided a sight translation of this document as directed by the research staff conducting the consent.

_____	_____	_____
Signature of Interpreter	Printed Name	Day Month Year