**Informed Consent Form (ICF) Template Notes/Instructions**

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| --- |
| **Legend*** *Yellow highlighted text* indicates instructions for consent form authors to follow when creating their local ICF. Delete these instructions from the final draft, inserting required information in their place where applicable.
* *Blue text* describes details that should be included by the consent form authors for each section of the ICF. Replace with the details specified.
* *Red text* indicates wordings/information for consent form authors to avoid. Delete from final draft.
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* Consent forms should be written at an 8th-grade reading level
	+ Use Flesch-Kincaid calculator (for example) to check this
* Use lay language; consider that patients do not all have the same background/technical knowledge that you do, and that English is not everyone’s primary language.
* Define all acronyms when they first appear and limit their use.
* Use a size and font that is consistent and easy to read (e.g. Calibri, 11pt)

**Please check the form carefully for correct spelling, grammar, and punctuation before submitting.**

*Must be on hospital/site letterhead – include all involved sites*

**Informed Consent Form for Participation in a [type of study]**

**[Lay Title for Study Participants]**

[Full Study Title (include title and acronym/abbreviated title if applicable)]

*Include all of the following that are applicable*

**Local Responsible Investigator:**

**Co-Investigators:**

**Study Sponsor:**

**Emergency Contact:**

**Introduction/Background**

This study is being conducted for research purposes. You are being asked to consider participating in this research study because *[an explanation of why the individual is being asked to participate]*. Whether you choose to participate or not, the usual medical care you receive will not be affected.

If applicable, and for placebo controlled trials, delete the previous sentence and provide an explanation that the patient may not receive the usual treatment if they participate in the research study, and the anticipated consequences of withdrawing or withholding treatment.

For clinical trials, include a statement that [investigational agent] has not been approved for this indication by Health Canada (for Division 5 CTA trials) although it has been allowed for use in this research study.

It is important that you understand the information in the Informed Consent Form before making your decision. Please read, or have someone read to you, the rest of this document. If there is anything you don’t understand, be sure to ask your study doctor.

**Taking part in this study is your choice.**

**Why is the study being done?**

The purpose of this study is *[describe the primary purpose of the study, aiming for about 2-3 sentences]*.

**Treatment**

There are approximately *[approximate number of participants involved in study]* participants involved in the research study. The study should take *[expected duration of study]* to complete. Your participation is expected to last *[expected duration of participant’s participation in study]*.

If there is more than one study group, describe how participants are placed into study groups. See the suggestions below. If these suggestions are not applicable, provide a lay description appropriate to the specific protocol.

* RANDOMIZED STUDY: If you decide to participate then you will be “randomized” into one of the groups described below *[provide description of groups in bullet points below this paragraph]*. Randomization means that you are put into a group by chance (like flipping a coin). There is no way to predict which group you will be assigned to. You will have *[describe probability of randomization (e.g. equal, 50/50, 1 in 3)]* chance of being placed in either/any group. Neither you, the study staff, nor the study doctors can choose what group you will be in.

Explain whether participants or others will know which group the participant will be in. See suggestions below:

* + Open label, randomized studies: You will be told which group you are in.
	+ Single-blind studies: You will not know which group you are in, but the study doctor and study staff will.
	+ Double blind studies: This is a double-blind study, which means that neither you, the study doctors, the study staff, nor your usual health care providers will know which group you are in. Your group assignment can be identified if medically necessary. Requests to reveal your assignment for your information or participation in other clinical trials will not be considered until this study has been completed and the results are known.
* EXTENSION STUDY: You are near completion of the main study in which you received *[insert drug/device/procedure/placebo]* over *[list time period - e.g. ## weeks]*. In this extension study, all participants will receive the study drug for *[list time period - e.g. ## weeks]*. *[List relevant additional information such as:]* If you were on placebo, you will now receive the active study drug. If you were on the active study drug, you will continue on your previous dose.
* TRIALS WITH INTERVENTION ASSIGNED BASED ON PROTOCOL-SPECIFIC CRITERIA: If you decide to participate then you will be assigned into one of the groups described below *[provide description of groups in bullet points below this paragraph]*. The group you are assigned to will be determined by specify assignment criteria *[describe criteria (e.g. the treatment you have previously received)]*. You will be told which group you are in.

The study treatment, tests and procedures to be followed are as follows:

* *Study procedures (by treatment group if applicable) in bullet format. Include an explanation of the responsibilities of the research participant for each procedure.* Note: ensure that standard of care procedures are clearly differentiated from research-related procedures, focusing on the research-related procedures and discussing standard of care where necessary

IF SEEKING TO COLLECT HUMAN BIOLOGICAL SAMPLES FOR RESEARCH (required or optional, and related to the current study): As a part of this study, human samples *[“will” or “may”, depending on whether required or optional]* be taken from you for research purposes. See below for important information about the collection of samples in this study:

*Answer the questions in the table below, aiming for no more than 2-3 sentences.*

|  |  |
| --- | --- |
| **What samples, and how much of them, will be taken?** |  |
| **How will the samples be collected, and how safe is it?**  |  |
| **How will the samples be used?** *(include any commercial uses)* |  |
| **How will my privacy and safety be protected?** |  |
| **How long will the samples be kept, and where/how will they be stored?** *(include process for disposal if applicable)* |  |
| **How will the samples be linked with information about me?** |  |
| **How will researchers handle the results and findings?** *(including clinically relevant information and incidental findings)* |  |

IF GENETIC RESEARCH: *Provide the plan for managing information revealed through the research.*

IF PHASE II CLINICAL TRIAL: *Provide details on access to the new drug upon trial completion; and make reasonable efforts to secure continued access to the drug for those who the drug appears to be efficacious.*

**Risks and Potential Harms**

By participating in this study, you may experience certain risks/harms from the procedure or treatment. See the table below for information on the most relevant risks/harms:

*Edit table below as needed to include all reasonably foreseeable harms/risks or inconveniences to the participant that may arise from research participation from the Investigator’s Brochure or Product Monograph. Be sure to provide a comprehensible description of each and, where necessary, the long-term impact (i.e. temporary or permanent).*

|  |  |  |
| --- | --- | --- |
| **Likelihood** | **Description of Risk/Harm** | **Severity (mild, moderate, severe)** |
| Expected (30-100%) |  |  |
|  |  |
| Likely (10-30%) |  |  |
|  |  |
| Less Likely (1-10%) |  |  |
|  |  |
| Rare (0-1%) |  |  |
|  |  |

 (IF APPLICABLE) For individuals who are pregnant or breastfeeding, there may be risks/harms to your child’s health from the procedure or treatment. Some possible risks/harms include:

* *Comprehensible description of reasonably foreseeable risks to an embryo, fetus or nursing infant. Where there is a stated risk to an embryo, fetus or nursing infant, describe the need for birth control during and after the study is described as applicable.*

You may also be subject to some unexpected risks not mentioned above. In the event of a research-related injury, contact *[name, position, contact information]* immediately.

**Potential Benefits**

Note: monetary compensation is NOT a benefit.

IF BENEFITS EXPECTED: You may or may not receive direct benefit by participating in this study. Some potential benefits of taking part in this research include:

* *Bullet list with comprehensible descriptions of reasonably foreseeable benefits that may arise from research participation.*

IF NO BENEFITS EXPECTED: There are no known benefits to you associated with your participation in this research study.

**Voluntary Participation and Withdrawal**

Your participation is voluntary. You are free to refuse participation or withdraw from the study at any time, with no penalty and no influence on future treatment.

*Provide any further information on the participant’s right to request the withdrawal of data or human biological materials, including any limitations on the feasibility of that withdrawal.* Note: do not include any Sponsor contact information. The participant should never contact the Sponsor directly to withdraw. The participant’s identifiable information should remain with the study doctor. The participant should only contact their study doctor to withdraw.

**Can participation in this study end early?**

Researchers may choose to withdraw you from the study for any of the following reasons: *[Identify reasons why participants may be taken off the study. Examples are outlined below; include or modify the bullets as applicable.]*

* The study intervention does not work for you
* You are unable to tolerate the study intervention
* You are unable to complete all required study procedures
* New information shows that the study intervention is no longer in your best interest
* The study doctor no longer feels this is the best option for you
* The Sponsor decides to stop the study
* The Regulatory Authority/ies (for example, Health Canada) or research ethics board withdraw permission for this study to continue
* Your group assignment becomes known to you or others (like the study doctor or study staff)
* If you plan to or become pregnant

If this happens, it may mean that you would not receive the study intervention for the full period described in this consent form. If you are removed from this study, the study doctor will discuss the reasons with you and plans will be made for your continued care outside of the study.

**What other choices are there?**

IF ALTERNATIVES EXIST: If you decide not to participate or if you withdraw from the study before it is completed, the alternative procedure(s) or course(s) of treatment will be as seen in the table below.

*Edit table below as needed to list and describe alternatives and their important benefits and risks.*

|  |  |  |
| --- | --- | --- |
| **Alternative** | **Benefits** | **Risks** |
|  |  |  |
|  |  |  |

IF NO ALTERNATIVES EXIST: An alternative to the procedures in this study is to not participate in the study and continue on as you do now.

**Collection of Information and Confidentiality**

Note: Use of data includes secondary uses. Be sure the participant is aware of these uses as well. Also, be sure to explain that that follow up information about their health and medical condition may also be collected from other physicians contributing to their care. Please clarify why you would do this, and provide examples of the physicians who may be asked to do this (at GRH and CMH? Family physicians?)

*This section should not contain any language that may be construed as requiring the participant to consent to unrestricted access to his or her medical records by third parties.*

If you choose to participate in the study, the information listed below will be collected about you *[add bullet list of specific information being collected and for what purpose below this paragraph]*. The people who will have access to this information are *[people with access to information collected]*.

(If applicable) As well as new information being collected, researchers will access your original medical records for *[information being collected from records and for what purpose (e.g. verification of clinical trial procedures and/or data)]*. This data would be collected from your records by *[people with access to records]* on a *[how often data will be collected]* basis.

Any data collected will be stored *[location where data will be stored]* for *[duration of data storage]*. Confidentiality will be protected by *[describe measures to protect confidentiality]*.

If necessary, researchers may have a duty to disclose information collected. This information could be disclosed to *[applicable individuals]*.

**Costs**

*Provide information on any costs or payments. The anticipated expenses, if any, to the participant for participating in the research study.*

**Compensation**

Note: payments should be prorated and not contingent on completion of the trial.

*Provide information on any compensation, reimbursement, and/or incentives. Describe how payments will be pro-rated if participants withdraw early from the study.*

**Rights as a Participant**

Note: this section should not have any suggestive language that a patient's rights to care could potentially be compromised in the event of study-related injury.

You do not waive any legal rights or liability by signing the consent form. As a participant, you are guaranteed the following: *[Standard participant rights are outlined below; add any other bullets as applicable]*:

* A copy of the signed and dated written informed consent form and any other written information provided to the participants.
* Continuing and meaningful opportunities for deciding whether or not to continue to participate in the study.
* No improper restrictions on compensation and/or treatment in the event of research-related injury.
* That new information will be provided to you whenever it is important to your decision to participate in the study.
* That records identifying you will be kept confidential and, to the extent permitted by the applicable laws and/or regulations, will not be made publicly available. If the results of the research study are published, your identity will remain confidential.

**What if researchers discover new information about me?**

During the study, the researchers may learn something about you that they didn’t expect. For example, the researchers may [insert anticipated incidental findings (e.g. find out that you have another medical condition)].

If this happens, then *[describe anticipated management plan in the event of an incidental finding].*

**Questions about the Study**

If you have any questions about the study, please contact *[study doctor name, position, contact information].*

If you have any questions or concerns about your rights as a research participant or the conduct of this study, you may contact the Waterloo Wellington Research Ethics Board (WWREB) Chair.

For clinical trials, include the following statement of online registry: A description of this clinical trial will be available on http://www.ClinicalTrials.gov , as required by US Law. This website will not include information that can identify you. At most the website will include a summary of the results. You can search for this website at any time.

**Conflict of Interest**

Describe the presence of any apparent, actual, or possible conflict of interest. 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. See examples below:

[Individual (e.g., study doctor)] is receiving personal financial payment from [source of funds (e.g., the study Sponsor)] for [reason for payment (e.g., providing advice on the design of the study)]. You may request any details about this payment.

OR

There are no conflicts of interest to declare related to this study.

OR

The [recipient of funding (e.g. hospitals)] is receiving financial payment from [Sponsor/Funder] to help offset the costs of conducting this research. The doctor treating you also may be the doctor in charge of the study**.**

**Consent**

1. **Participant/Substitute decision-maker**

By signing this form, I confirm that:

* This research study has been fully explained to me and all of my questions answered to my satisfaction
* I understand the requirements of participating in this research study
* I have been informed of the risks and benefits, if any, of participating in this research study
* I have been informed of any alternatives to participating in this research study
* I have been informed of the rights of research participants
* I have read each page of this form
* I authorize access to my personal health information, medical record, and research study data as explained in this form
* I have agreed to participate in this study or agree to allow the person I am responsible for to participate in this study
* (If applicable) I understand that my family doctor will be informed of my participation in this research study
* (If applicable) This informed consent document will be placed in my medical records

|  |  |  |
| --- | --- | --- |
| Participant/substitute decision-maker name | Participant/substitute decision-maker signature | Date |

1. **Person obtaining consent (required for clinical trials)**

By signing this form, I confirm that:

* This study and its purpose has been explained to the participant named above
* All questions asked by the participant have been answered
* I will give a copy of this signed and dated document to the participant

|  |  |  |
| --- | --- | --- |
| Person obtaining consent name | Person obtaining consent signature | Date |

1. **Statement of the Investigator (required for clinical trials)**

I acknowledge my responsibility for the care and well being of the above participant, to respect the rights and wishes of the participant as described in this informed consent document, and to conduct this study according to all applicable laws, regulations and guidelines relating to the ethical and legal conduct of research.

|  |  |  |
| --- | --- | --- |
| Investigator name | Investigator signature | Date |

|  |  |  |
| --- | --- | --- |
| Person assisting**\*** name | Person assisting signature | Date |

*\**e.g. translator/ or if participant unable to read

Note: Collection of samples/tissues for future unknown research and/or banking (i.e. where the research purpose is not yet known) must have a separate informed consent form.

If banking of genetic material, indicate how they plan to address the associated ethical issues, including confidentiality, privacy, storage, use of the data and results, possibility of commercialization of research findings and withdrawal by participants as well as future contact of participants, families, communities and groups.