**Unity Health Toronto Research Ethics Board (REB)**

**Consent Form Summary Template and Guideline**

**01 March 2021**

General Guidelines

* A Consent Summary is required for any study that receives US Federal funds. It can also be used in other studies if the researchers feel that it will be helpful to their participants.
* The revised common rule, which went into effect in January 2019, includes a provision that informed consent “begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research. This part of the informed consent must be organized and presented in a way that facilitates comprehension.” [45 CFR 46.116(a)(5)(i)].
* The information provided in this summary should be as concise as possible – ideally the whole summary will be less than two pages. It can be a standalone document or it can be included at the beginning of the main consent form.

Template and Guideline Legend (each text type is differentiated by both a colour and a format style)

**Mandatory Text** – Must appear in the consent form (this text has no special formatting)

**Placeholder Text** – Replace or adapt the text with the indicated information as it applies to your study (this text is dashed underlined)

***Information/Guidance*** – *Advice on how to complete a section and some example wording (this text is in italics)*

**Conditional Text** – Mandatory and placeholder text to be used if it applies to your study (this text is shaded)

***Conditional Text Instructions – describes when to include the conditional text that follows (this text is in bold italics)***

How to Use this Template and Guideline

1. Review the document and un-highlight any shaded conditional text that is applicable to your study, using the ***conditional text instructions*** as guidance to help determine what needs to be included.
2. Delete any remaining shaded conditional text and all ***conditional text instructions***.
3. Replace the placeholder text with the indicated information as it relates to your study, using the *information/guidance text* as guidance.
4. Delete all *information/guidance text*.
5. Change all remaining text to black.

**[Site Logo]**

**Informed Consent Summary Information**

We are asking you to consider taking part in a research study. Participation in research is **completely voluntary**.

This section has the information that we think will most likely help you decide if you want to take part in this study. It includes information about the study such as the purpose, what will happen to you, the risks and benefits, and what you can do instead of participating.

Full information about this study can be found in the other sections of the consent form/the main consent form.

Study Title: Study Title

Study Purpose:

* 1-3 points explaining why this study is being done; should be written in plain language

Duration of Participation:

* State the duration of participation for an individual participant in this study.

Study Procedures:

* Concise and plain language overview of the research procedures

Potential Risks:

* Give a concise and plain language overview of the risks and discomforts that are most likely to influence the person’s decision to participate.

This section should not be an exhaustive list of all of the potential risks of participation in the study, but “should identify the most important risks, similar to the information that a doctor might deliver in the clinical context [for example] in telling a patient how sick the chemotherapy drugs will make them, but with a particular emphasis on how those risks are changed by participating in the study.”

These would likely be the risks with the greatest frequency or severity.

Discomforts or inconveniences that may influence a person’s quality of life or lifestyle restrictions that are likely to impact their decision to participate should also be described in this section.

Potential Benefits:

If there is no benefit to the participant:

* There is no anticipated benefit to you for participating in this study.

If the participant may benefit from participation in the study:

* Give a concise overview of the benefits to the participant, or to others, that may be reasonably expected from this study

Alternatives to Participation:

* You do not have to participate in this research study to receive treatment for your disease/condition.
* Your doctor can talk to you about alternatives to participation in this study, such as:
* Short description of appropriate alternative therapies, written in lay language

If there are any other components to your study that are not covered above and may reasonably influence a person’s willingness to participate:

**Section Title**

* Concise information

Please keep in mind that this summary section of the ICF is meant to be a high-level overview of the most important considerations for study participation.

Study Contact:

* PI name and telephone number
* MD Co-I name and telephone number
* Main research coordinator name and telephone number