# Instructions for OHSN-REB Informed Consent Form Update Template

## This consent form can only be used if the participant already consented into the study and re-consent is required. This must be be submitted with an updated/re-consent amendment form. Please see the updated/re-consent amendment form found on the OHSN-REB website.

## New information must be provided to current and to past participants (if applicable) via a consent form update. Only new information should be included; please use approved template language when including the new information.

## For new information for both an optional and a main consent form, if applicable, the information may be combined in one form – with clear headings denoting for whom the information is relevant, e.g., new information for all study participants: new information only for participants in the optional study)

**Tips for Writing and implementing the consent**

* Delete this instructional page
* Only use the logos that are applicable to your study; for TOH and OHRI logos, only use one or the other.
* Use plain (lay) language that is easy for a non-medical person to understand:
	+ Use short sentences and sections and simple words; avoid scientific or technical explanations;
	+ Ensure that the final form is properly formatted and free of spelling or grammar errors;
	+ Aim for grade 8 reading level, ideally no more than grade 10;
	+ Spelling, grammar and formatting should be reviewed prior to submission
	+ Eliminate repetition of information, the study drug should be named
* Define all acronyms and abbreviations when they first appear
* Use the term ‘study doctor’ when referring to physicians involved in the clinical trial/study, to ensure there is no confusion with the treating or primary care doctors
* If assistance is provided during the consent process, or if consent is obtained from substitute decision maker, more information, including the role or relationship of the impartial witness/interpreter/substitute decision maker, should be noted in the medical record and/or study record.

**HOW TO USE THIS TEMPLATE**

* *Turquoise italicized highlighting* indicates instructions to consent form authors; DELETE from final draft.
* *Blue italics* within sentences indicate that protocol-specific detailsneed to be inserted, such as drug/intervention name, descriptions, options for protocol details; REPLACE italics with regular font.
* Suggested text/examples are provided throughout ICF; they should be omitted if they are not relevant to the specific protocol.

**REMINDER:**

The informed consent form is only a component of the informed consent process. Researchers still need to have an informed discussion with, and respond to any questions raised by, participants.

**Informed Consent Form Update**

***Lay Title for Study Participants:*** *(maximum 20 words, ONLY applicable for Oncology studies)*

***STUDY TITLE:****insert study title as written on the protocol*

**OHSN-REB Number:** *insert number*

**Sponsor Study ID:** *Insert sponsor’s study ID if applicable*

**Study Doctor:** *insert name, department and telephone or pager number*

**Sponsor/Funder(s):** *Insert the name of the Sponsor or, if applicable, the funder(s) of the research*

[Note: A 24-hour, 7-day a week phone number is required for all studies that include greater than minimal risk research procedures or interventions.]

**Emergency Contact Number** (24 hours / 7 days a week): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Non-Emergency contact numbers are at the end of this document under Contacts.

*Le formulaire de consentement est disponible en français sur demande.*

**Background**

You are a current/past participant in a clinical study called *name of study*, which is looking at type of cancer/illness/disease. The purpose of the study is *describe briefly - consistent with information in the original ICF*.

This update provides you with new information about the study and the changes to the information in the consent form that you originally signed. You should keep all consent form updates together with the original consent form.

**What is the new information?**

*Note: modify the text to accommodate current and/or past participants as applicable****.***  *If the study is open to enrolment, the new information should be identical to the information in the revised ICF.*

As a *current/past participant* in this study, any new information *that might affect your willingness to continue to participate in this study or, that is relevant to your previous participation* must be provided to you.

*Describe new/ information briefly*

The new information includes *describe/summarize: changes to the risks of participating in the study/where the data will be sent/the number of study participants/the study procedures/etc.*

*Provide details of the new information*

The following changes have been made to the consent form that you signed prior to your participation in this study. The new information is **bolded**:

**How does the new information affect your participation in the study?**

*Describe how the new information affects current/past participation in the study - examples*:

*The extra test may increase the time of visit x. The study otherwise will continue as planned.*

 *No new patients will be enrolled into arm x of the study. Additional side effects are being provided which may ….(e.g.,.risk benefit change). The long term effects of the experimental treatment may result in….. The study will continue as planned.*

**What does the new information mean for you?**

*If applicable for current participants include* You should review the new information and determine whether it affects your willingness to continue to participate in the study. *If applicable, include*: You will be asked to sign this consent update form.

*Or if applicable for past participants, indicate the significance of the information and potential outcomes. Examples: However, because you have completed (your study treatment or your participation in the study) it is not expected that the changes will affect you. Or: You should review the new information and decide whether to follow-up with your regular doctor for additional testing.*

**Is there anything else you should know?**

*[If applicable for current participants include:* Taking part in this study is voluntary. You may choose to leave the study at any time without giving a reason. If you decide to stop participating in the study, your doctor will discuss other options with you and continue to treat you with the best means available.

*Or, if applicable for past participants:* If you have any questions about this new information, you should talk to the study team.

**What are your rights as a participant?**

By providing your consent *to participate and/or,* as a former participantin this study you do not give up any of your legal rights against the investigators, sponsor or involved institutions for compensation, nor does this form relieve the investigators, sponsor or involved institutions of their legal and professional responsibilities.

**What are your protections as a participant?**

The new information in this consent update has been reviewed by the Ottawa Health Science Network Research Ethics Board (OHSN-REB).

You will be told, in a timely manner, about all further new information that may affect your health, welfare, or willingness to stay in this study.

**Whom do you call if you have questions or problems?**

If you have questions about taking part in this study, or if you suffer a research-related injury, you should talk to your study doctor. Or, you can meet with the doctor who is in charge of the study at this institution. That person is:

|  |  |  |
| --- | --- | --- |
|  |  |  |
| Principal Investigator Name |  | Telephone |

If you have questions about your rights as a participant or about ethical issues related to this study, you can talk to someone who is not involved in the study at all. Please contact The Ottawa Health Science Network Research Ethics Board, Chairperson at 613-798-5555 extension 16719.

*NOTE: include the signature page only when the new information requires signed consent (see the consent form update guidelines for criteria). If a signature is not required, delete the signature page.*

**Study Title**: *insert study title as written on the protocol*

SIGNATURES

* The new study information has been explained to me, I have been given the chance to discuss it and to ask questions. All of my questions have been answered to my satisfaction
* I understand the information within this informed consent form update,
* I have read, or someone has read to me, each page of this participant informed consent form update.
* I allow access to my medical records and specimens as explained in this consent form update,
* I am aware of the risks to me or participating in this study,
* I do not give up any of my legal rights by signing this consent form update,
* I agree, or agree to allow the person I am responsible for, to continue to take part in this study.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Signature of Participant  |  | Printed Name |  | Date |

**Investigator or Delegate Statement**

I have carefully explained the study to the study participant. To the best of my knowledge, the participant understands the nature, demands, risks and benefits involved in continuing to take part in this study.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Signature of Person Conducting the Consent Discussion |  | Printed Name and Role |  | Date |

**Study Title**: *insert study title as written on the protocol*

**Participant Assistance**

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

* The informed consent form update 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 |  | Date |

**Complete the following declaration only if the participant has limited proficiency in the language in which the consent form update 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 |  | Date |

*Please note: More information regarding the assistance provided during the consent process should be noted in the medical record for the participant if applicable, noting the role or relationship of the impartial witness.*