# Instructions for Consent UPDATE Form Development

## New information must be provided to current and to past participants (if applicable) via a consent form update. For more information, please refer to the OCREB “Guidelines for Providing New Information to Study Participants” ([OCREB Guidelines, Templates and SOPs](https://oicr.on.ca/research-portfolio/ocreb/guidelines-templates-sops/)).

## 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).

**General Instructions:** **Form language**: Use lay language and explain concepts simply. Use short words and sentences. Replace complex medical terminology with common, easily understood words. Avoid repetition of information.

* Use online readability tools to assess the reading level of the informed consent form. Health Canada recommends a sixth to eighth-grade reading level, depending on the population. Information about readability assessments can be downloaded from the CTEP ICF website. If possible, ask participants or community members to review the form before submitting it to the REB. They can help identify potential comprehension challenges for participants.

<https://www.canada.ca/en/health-canada/services/science-research/science-advice-decision-making/research-ethics-board/requirements-informed-consent-documents.html#cons>

<https://ctep.cancer.gov/protocolDevelopment/docs/NCI_Informed_Consent_Template_Readability_Assessments.pdf>

* **Use of Text Examples:** 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.
* **Formatting:**

1. Use 1-inch margins for top, bottom, and sides of the page.
2. Use Calibri size 14 font and bold the main section headings, and size 12 font for minor headings.
3. Use Calibri size 11 font for the body of the form.
4. Do not use all capital letters or italics to call attention to information. Use other formatting sparingly.

* **Color-Coded Information:**
  + Brief instructions to consent authors are in *italics and highlighted in turquoise*. This text should be removed prior to REB submission, i.e. not included in the consent form for participants.
  + Sections where consent authors should enter or modify text are *(in blue italics and listed between parentheses)*. Adapt and enter the text as necessary. Remove the parentheses, and format as normal body text in the consent form for participants.
  + The provincial form should not be on local letterhead, nor include local contact information.

* + Instructions for centre-specific information are in *italics and highlighted in yellow*
  + Centres should keep the version date of the approved provincial form and add local contact information and all pre-approved administrative changes. Centre-specific pre-approved changes also may be added.

**New Study Information-Consent Update Form**

*Study Title for Participants: (Insert Lay Title here)*

Official Study Title for Internet Search on http://www.ClinicalTrials.gov: (Insert Study Number, “Insert Official Study Title”)

Trial Code: (XX.XX)

Study Doctor: Dr. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Sponsor: *sponsor name*

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

**Background**

You are a current/past participant in a clinical study called *name of study*, which is looking at type of cancer. This study is being done *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. New information must be* ***bolded****.*

## *For information that is not new but has been modified, e.g., risks that are not new but have changed in frequency or category/level of risk, please do not bold this information but add the following statement: ‘Although these risks are not new the categories have changed.’ If the entire section has changed or do the following for individual risks: Nausea (moved from “rare” to “common” category)*

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 Ontario Cancer Research Ethics Board (OCREB).

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:

|  |  |  |
| --- | --- | --- |
|  |  |  |
| 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 Office of the Chair of the Ontario Cancer Research Ethics Board at:

|  |  |  |
| --- | --- | --- |
| Telephone: 416-673-6648 |  | Toll Free: 1-866-678-6427 ext. 6648 |

*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.*

My signature agreeing to take part in the study

I have read this consent form or had it read to me. I have discussed it with the study doctor and my questions have been answered. I will be given a signed and dated copy of this form. I agree to continue to take part in this study. *(Include the following sentence if appropriate.)* I also agree to continue to/ to take part in any additional studies where I circled “yes”.

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| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| Signature of Participant |  | PRINTED NAME |  | Date |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| Signature of Person Conducting the Consent Discussion |  | PRINTED NAME |  | Date |

**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 |  | Date |

**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 |  | Date |