

## **Addendum: Consent Form to Participate in a Research Study**

**Title of Research Study:**

**Name of Principal Investigator (PI):**

**PI's contact number(s)/email(s):** Use an Ontario Tech phone number and email address, never a personal number or email address. Only study specific cell numbers may be included.

**Names(s) of Co-Investigator(s), Faculty Supervisor, Student Lead(s), etc., and contact number(s)/email(s):**

**Departmental and institutional affiliation(s):**

**External Funder/Sponsor: (if applicable)**

You are participating in the above-named research study. When you agreed to participate in this study, the researchers told you that they would tell you about any new information that might affect your health, welfare, or willingness to stay in the study.

The study now involves new *[procedures and/or risk information]* that are described below. The researchers will explain the new *[procedures and/or risk information]* and then ask for your consent *[to participate in the new procedures as well as]* to continue participating in the study. With the exception of the information provided below, **all other information presented in the consent form you signed still remains relevant to this study.**

Continuing to take part in this study is voluntary. Please request a copy of the original signed consent form if you need to review it. Take your time, read this form and re-read the original signed consent form carefully. Please make sure all your questions have been answered to your satisfaction before signing this document.

### **New Information**

*(Please note that **only new information** that may affect a participant's decision to continue to take part in the study should be included here).*

### **New risks/discomforts associated with study participation**

*(Please note that **only new risks/discomfort information** that may affect a participant's decision to continue to take part in the study should be included here).*

**Alternatives to study participation:**

*Describe any appropriate alternative procedures that should be considered before the participants decide whether or not to continue in the study.*

**Participant Rights and Concerns:**

The standard information and statements are required:

- Include the statement, “Please read this consent form carefully and feel free to ask the researcher any questions that you might have about the study. If you have any questions about your rights as a participant in this study, complaints, or adverse events, please contact the Research Ethics Office at (905) 721-8668 ext. 3693 or at [researchethics@uoit.ca](mailto:researchethics@uoit.ca).”
- Include the statement, “If you have any questions concerning the research study or experience any discomfort related to the study, please contact the researcher [your name] at [your phone number] or [your email address].” Use an Ontario Tech phone number and email address, never a personal number or email address. If cell number is specific to the study, please include it.
- Include the statement, “By signing this form 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.”

**Consent to Participate:**

Consent to study participation may be obtained in various ways such as: written, oral, use of a substitute decision maker, or online. For the section below, chose the wording that applies to the method in which consent was obtained.

**a. Written Consent**

Include the following statements:

1. I have read the consent form and understand the study being described;
2. I have had an opportunity to ask questions and those questions have been answered. I am free to ask questions about the study in the future;
3. I freely consent to participate in the research study, understanding that I may discontinue participation at any time without penalty. A copy of this consent form has been made available to me.

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Print Study Participant's Name

Signature

Date

My signature means that I have explained the study to the participant named above. I have answered all questions.

\_\_\_\_\_  
Print Name of Person Obtaining

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date

**b. If the use of third party authorization, or substitute decision maker (SDM), include the following section:**

If the use of a substitute decision maker (SDM) is required and justified to aid a participant, include the following paragraph:

“This consent form is addressed to the participant. However, in the occasion that the participant is unable to or does not have the capacity to provide consent for themselves, this form is to be carefully read and signed by you acting as their substitute decision maker (SDM) from whom informed consent will be obtained for participating in the study.

After considering the wishes, values, and goals of the study participant, they would permit the study team to perform study procedures and data collection. I can reverse this decision at any time.”

\_\_\_\_\_  
Name of Substitute Decision Maker

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Relationship to Participant

My signature means that I have explained the study to the participant and SDM named above. I have answered all questions.

\_\_\_\_\_  
Print Name of Person Obtaining

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date

**c. Oral Consent**

If the consent has been obtained orally, the consent form must be dated and signed by the researcher(s) indicating that the participant had the capacity to consent to the study.

1. I have read the consent form to the participant and they have indicated that they understand the study being described.
2. The participant has had an opportunity to ask questions and these questions have been answered. The participant is free to ask questions about the study in the future.

3. The participant freely consents to participate in the research study, understanding that they may discontinue participation at any time without penalty. A physical/digital consent form has been made available to them.

\_\_\_\_\_  
Print Name of Witness

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Relationship to Participant

**d. Online Consent**

Include the following statements:

1. I have read the consent form and understand the study being described.
2. [If applicable] I have had an opportunity to ask questions and my questions have been answered. I am free to ask questions about the study in the future.
3. I freely consent to participate in the research study, understanding that I may discontinue participation at any time without penalty. A copy of this Consent Form has been made available to me.

I agree