

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 use 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)

Introduction

Include the required standard paragraph:

You are invited to participate in a research study entitled [*insert title of research project*]. You are being asked to take part in a research study. Please read the information about the study presented in this form. The form includes details on study procedures, risks and benefits that you should know before you decide to participate. You should take as much time as you need to make your decision. You should ask the Principal Investigator (PI) or study team to explain anything that you do not understand and make sure that all of your questions have been answered before signing this consent form. Before you make your decision, feel free to talk about this study with anyone you wish including your friends and family. Participation in this study is voluntary.

This study has been reviewed by the University of Ontario Institute of Technology (Ontario Tech University) Research Ethics Board [*insert REB assigned #*] on [*insert date*].

Purpose and Procedure:

This section must include the following required statements and information:

Purpose:

If relevant, describe any background information pertaining to the current study such as the experience to date, data from other studies that led to the development of this study.

The purpose of the study/significance of conducting the study.

Insert the statement, “You have been invited to participate in this study because [*insert the main reason(s) the individual is being asked to participate, i.e., how the participant meets the required criteria for participation*].”

Procedures:

Describe all study procedures and data collection methods, as the participants would experience the study. Indicate the number of study visits, procedures and give an estimate of the length of time entailed by participating in **each** study procedure and the overall project. For studies with multiple visits, the table below can be used to summarize the procedures:

Visit	Study procedure/tests/interventions	Duration of visit
Visit 1		
Visit 2		

Clarify all **research related** procedures, tests and/or interventions.

What is the usual standard approach/procedures in this subject area?

Note: The **consent should focus on the research related procedures** and discuss standard approaches/procedures where necessary.

Provide the number of participants taking part in the study.

Explain the study related responsibilities of the participant.

Briefly describe the type of research data that will be collected, the anticipated use(s) and how it will benefit the research.

If the research will take place in another location other than the one where the participant will read or be read the consent form, indicate where the research will take place.

Potential Benefits:

Describe any direct benefits to the participant, as well as any indirect benefits, e.g. potential for benefit to society, further research, etc. If benefits from participation do exist, indicate so without overstating.

If there are no benefits to the participant, state, “You will not directly benefit from participating in this study.”

It is important to note that compensation for study participation is not a potential benefit to the study. Study compensation must be described in the Compensation and Reimbursement section of the consent.

Potential Risk or Discomforts:

This section must include the following required statements and information:

Full description of any reasonably foreseeable risks (e.g. physical, psychological, or social) both for the participant and in general that are associated with the procedures described above.

Any steps that will be taken to minimize those risks, and the procedures that will be in place for debriefing (including, where appropriate, referrals for counseling and other services).

If there are risks that have a very low probability, state the risks and include information on the frequency or probability of occurrence for these risks.

If there are no known risks, state, “There are no known or anticipated risks to you from participating in this study.”

If your study includes a safety or emergency plan, describe it.

If the research project extends over a significant length of time, include a statement to the effect that the researcher will advise the participant of any new information that could have a bearing on their decision to participate or willingness to continue participating. Also, participants should be informed about the process by which ongoing consent will be sought.

This section must include the following required statements if research is being conducted in-person:

COVID-19: Please note, there is a risk of contracting the COVID-19 virus when participating in face to face research. There may be additional risks to participating in this research during the COVID-19 pandemic that are currently unforeseen and, therefore, not listed in this consent form.

We ask that you reschedule your study visit to participate in the research study if you a) have any new or worsening symptoms associated with COVID-19 (See list of [COVID-19 symptoms](#)), b) have COVID-19 as confirmed by a test, and/or c) have been in close-contact with someone with confirmed or suspected COVID-19.

If research is taking place on-campus, please include the required statements and information:

At this time, the university has a mask mandate in effect. This means that you will be required to wear a mask inside any building on our university campus. The researchers you will be working with will also be wearing a mask.]

If research is taking place off-campus, please include the required statements and information:

For research activities occurring outside of Ontario Tech, you are required to follow the COVID-19 protocols for the location where participation in the research occurs. At the discretion of the PI, we may require more stringent COVID-19 protocols to enhance participant safety. This is encouraged when working with higher risk populations (e.g. older age groups, immunocompromised, individuals living with others that may be susceptible to COVID-19).

At this time, you are not required to wear a mask at (*insert location*); however, we strongly encourage you to wear one to help minimize the spread of COVID-19.

OR

At this time, you are not required to wear a mask at (*insert location*); however, given the vulnerable nature of the participants in this research, we ask that you wear one.

Use and Storage of Data:

In the case where the data collected contains personal information, personal health information and/or biological materials (e.g., contact information for follow-up studies, digital records, interview recordings, etc.) the following information is required below:

Researchers shall provide details to the REB regarding their proposed measures for safeguarding information, for the full life cycle of information: its collection, use, dissemination, retention and/or disposal.

In particular, describe how the data will be stored (e.g., password-protected digital file, encrypted digital file, password-protected computer, locked cabinet, etc.).

Explain what information will be collected about the identities of participants/other personal information, personal health information, and/or biological materials and for what purpose(s) it will be collected.

Explain what demographic information will be collected, if that information can be identifying and for what purpose(s) it will be collected.

Identify who will have access to the data. Will data be shared outside of the institution? If yes, describe the format in which the data will be shared and how the information will be transmitted (e.g. anonymous or anonymized; de-identified, encrypted devices).

If audio or video data is being transcribed, describe the safeguards that are in place during the transcription process and identify if the original data will be kept or destroyed.

Define the length of storage time. If parts of the data will be destroyed and parts of it will be kept for a longer term, describe the storage time for each of the different data storage components.

If data will be anonymized, de-identified or aggregated, describe how this will be done. State whether the original data will also be kept or if it will be destroyed, state the timelines for this process.

Describe if/how data will be appropriately destroyed when the data is no longer required.

For sponsor/industry-initiated studies, indicate if the study sponsor or industry will receive any research data and a rationale for sharing the data. If yes, describe the format in which the data will be shared (e.g. anonymous, anonymized, de-identified, etc.,).

If there is the potential to use data for a secondary research purpose, inform the participants of this and that permission will be asked in an optional section at the end of the consent. In addition, the consent must indicate that the PI will submit a separate application form to the REB for the secondary use of data for future research use. **IMPORTANT NOTE:** all future secondary use of data requires a new submission to the REB once the project scope has been defined. If it is defined in the original application, it is not secondary use of data. Therefore, access to secondary use of data requires REB approval prior to the collection, access and use, except when exempt based on Article 2.5.

Include the required statement, “All information collected during this study, including your [*choose the most applicable: personal information, personal health information*], will be kept confidential and will not be shared with anyone outside the study unless required by law. You will not be named in any reports, publications, or presentations that may come from this study.”

If relevant, describe the plan for managing incidental findings.

Confidentiality:

This section must include the following statements and information:

Describe the procedures that will be used to safeguard the confidentiality and anonymity of participants, as well as any limitations on the degree to which confidentiality and anonymity can be guaranteed (e.g. focus groups, rare instances including potential harm).

Include the required statement, “Your privacy shall be respected. No information about your identity will be shared or published without your permission, unless required by law. Confidentiality will be provided to the fullest extent possible by law, professional practice, and ethical codes of conduct. Please note that confidentiality cannot be guaranteed while data is in transit over the Internet.”

Use this paragraph only when demographic data is collected:

“This research study includes the collection of demographic data which will be aggregated (not individually presented) in an effort to protect your anonymity. Despite best efforts, it is possible that your identity can be determined even when data is aggregated.”

Describe the procedures for handling aggregate demographic data when there is the possibility of participant identification.

Voluntary Participation:

This section must include the following statements and information:

Voluntary Participation:

Include the standard paragraph, “Your participation in this study is voluntary and you may partake in only those aspects of the study in which you feel comfortable. You may also decide not to be in this study, or to be in the study now, and then change your mind later. You may leave the study at any time without affecting your [*choose the most applicable: employment status, academic standing, medical care, relationship with the institution, access to services, grades in a course, payment, research credit, etc.*] You will be given information that is relevant to your decision to continue or withdraw from participation.”

If applicable, insert, “You may refuse to answer any question(s) you do not want to answer, or not answer an interview question by saying, ‘pass’.”

Right to Withdraw:

This section must include the following statements and information:

Include the statement, “If you withdraw from the research project at any time, any data or human biological materials that you have contributed will be removed from the study and you do not need to offer any reason for making this request.”

For studies with a longer duration of study participation, indicate what will happen to the study information when a participant withdraws from the study. How will their data be managed?

For studies with a defined withdrawal date or timeline, inform participants of that date or timeline.

For instances when there are practical withdrawal limits, include the statement, “In some research projects, the withdrawal of data or human biological materials may not be feasible (e.g., when personal information has been anonymized and added to a data pool).”

For studies that collect anonymous data, inform the participant that data cannot be withdrawn after they have completed the study and let participants know if the data is kept or removed if they stop answering questions or close an online browser early.

If relevant, inform participants that it may be impracticable to withdraw results once they have been published or otherwise disseminated.

For interventional/clinical trial studies, include information on stopping rules and when researchers may remove participants from the study.

Conflict of Interest:

This section must include details of any real, perceived, or potential conflicts of interest concerning this study if applicable. For instance, past consultation, past service on advisory board, financial, stocks, etc.

For internally funded or non-funded studies, insert the following statement:

“Researchers have an interest in completing this study. Their interests should not influence your decision to participate in this study.”

For sponsored/industry studies, insert the following statement:

“[Insert name of company], the sponsor of this study, will reimburse the Ontario Tech University and researcher for the costs of doing this study. All of these people have an interest in completing this study. Their interests should not influence your decision to participate in this study.”

Commercialization: (if applicable)

Indicate if there is any commercialization intent with the study intervention or data collected.

Include the statement: “[Insert company name] intend to claim sole ownership of any results that would come from this study. You will not receive any financial benefit that might come from the results of this study.”

Compensation, Reimbursement, Incentives:

This section must include the following statements and information:

Include whether participants will incur any expenses as a result of their participation in the study and compensation for injury.

Indicate if there is reimbursement for reasonable study related costs (e.g. travel, transportation).

Include any remuneration, payments, gifts in-kind, vouchers, etc., to participants and how reimbursement will be pro-rated if participants leave the study early, and compensation for injury.

The participant should not suffer any disadvantage or reprisal for withdrawing nor should any payment due prior to the point of withdrawal be withheld. If the research project used a lump-sum incentive for participation, the participant is entitled to the entire amount. If a payment schedule is used, participants shall be paid in proportion to their participation.

Debriefing and Dissemination of Results:

Indicate how the participants will be informed of the study results, if interested, and include a description of how the results will be published and how the participants will be informed of the publication. If participants are interested in learning of the results, provide them with an opportunity to contact the researcher.

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@ontariotechu.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, choose 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.

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 a third-party authorization or substitute decision maker (SDM) is used, 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) for 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 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 he/she understands 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 he/she may discontinue participation at any time without penalty. A physical/digital consent form has been made available to him/her.

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

e. Optional Secondary Use of Research for Future Research Purposes

At the end of the consent form, an optional section is required for studies that would like to obtain consent for potential secondary use of data for future research purposes. Researchers must obtain the participant's initial for this optional component of the study and the following statements must be included:

1. I understand the possible need for secondary research uses of my research data for future research use and provide consent for the use of my data to be used in future studies.
2. The research team has informed me that a separate REB application will be submitted for the secondary use of data for any future research purposes.

Participant must initial _____ Yes

_____ No



Important notifications:

- Please note that this consent template is provided as a guide to assist researchers to develop a consent form that meets the standards set out by the current guidelines, policies and regulations. This template can be refined to be tailored to the particular study and for the researcher's personal use.
- This document is a work in progress and will be revised /updated periodically to meet compliance requirements of applicable guidelines, policies and regulations. **The most recent consent form templates will be updated on the REB's website.**
- Consent forms must be written at an appropriate reading level for the target audience. For general audience members, the consent must use plain language and written at a grade 6 to 8 reading level for the general audience members. Please avoid technical words/jargon for general audience members, if technical wording must be used, include a simple definition beside the terminology in brackets. The Flesch-Kincaid Grade Level score in Microsoft Word can be used to assess the reading level. All consent forms must be organized in a fashion that ensures easy readability and flow.
- Consent forms must include the total number of pages and the version date in the footer region of the form in the format of (Day-Month-Year).
- If email communication will be used, please include the following suggested wording:

“Please note that the security of e-mail messages is not guaranteed. Messages may be forged, forwarded, kept indefinitely, or seen by others using the internet. Do not use e-mail to discuss information you think is sensitive. Do not use e-mail in an emergency since e-mail may be delayed.”

or

“Please note that communication via e-mail is not absolutely secure. Thus, please do not communicate personal sensitive information via e-mail.”
- All future secondary use of data requires a new submission to the REB once the project scope has been defined. If it is defined in the original application, it is not secondary use of data. Therefore, access to secondary use of data requires REB approval prior to the collection, access and use, except when exempt based on Article 2.5.