**INSTRUCTIONS FOR COMPLETING THE SAMPLE CONSENT/ASSENT FORM**

To assist your research process, a sample consent/assent form has been created. Instructions are identified by blue text in [square brackets].

The template also contains suggested wording identified by black text.

References are provided for each section throughout the template to the relevant articles in the Tri-Council Policy Statement, identified in green text in square brackets (e.g., “[TCPS2 Article 3.2(a)]). See [www.pre.ethics.gc.ca](http://www.pre.ethics.gc.ca) for a specific discussion of each article.

Ensure that your consent/assent form is carefully edited, and includes *version number* and *page numbers* in the footer of all pages.

Please proofread your consent/assentform and **remove this page and all blue and green instructional text before submitting it for REB approval.** **The REB should receive the final draft of the consent form that has been read and approved by the key members of the research team, including the research supervisor/advisor.**



**[Study Title]:[Participant Group if applicable]**

**Consent Agreement**

You are invited to participate in a research study. Before you agree to participate, please read this form carefully and ask any questions you may have to be sure that you understand what your participation will involve. [TCPS2 Article 3.2(a)]

[**INSERT TITLE OF THE STUDY**] [If the study involves using different consent forms for different populations, identify the population group as the subtitle of the study.]

**INVESTIGATORS:** This research study is being conducted by [insert names of all investigators - faculty, student, and other. Students must include the name of their supervisor], from [insert department affiliation] at Trent University.

This study is funded by [insert sponsoring agency/organization or delete if not applicable].

[If there is a possibility of **commercialization of the research findings** and the presence of any real or perceived **conflict of interest** on the part of the researchers, institutions or sponsors, this shall be clearly stated.] [TCPS2 Article 3.2(e)]

**PURPOSE OF THE STUDY:**[Please state **what** the study is designed to assess, explore, or establish in lay terms, avoiding technical terms or jargon. Explain how the results of data analysis will be disseminated (i.e., thesis, conference presentation, research paper) and if/how the deidentified data will be made available to other researchers. The language used should be at a **grade 6 to 8 comprehension level**. State the **eligibility and ineligibility criteria** used to identify prospective participants. *The information in this section of the consent form should match answers to the relevant questions in the ROMEO Application Form*.] [TCPS2 Article 3.2(b)]

**What you Will Be Asked to Do [or] What Participation MeanS:** If you agree to participate in this study, you will be asked to do the following:

[Describe the **procedures chronologically** using simple language, short sentences and short paragraphs, or bullet points. Use subheadings to help organize this section and increase readability. Medical and scientific terms should be defined and explained. Indicate the **location** where the research will be conducted and the **expected duration** of the participant’s involvement. Please be specific regarding the amount of time required for participation. For example, if participants are expected to attend a lab for six visits, inform them of this as well as the amount of time each visit will require. If the participant will be asked to complete a questionnaire or interview, describe the general types of questions they will be asked to answer and approximately how long it will take. For example, if you were doing a study on self-efficacy, you would explain that you would be asking participants questions about how confident they feel when they perform daily tasks. If applicable, describe other means of recording data including observers, note-takers, tape recorders, video cameras, etc. If participant data will continue to be collected after their interaction with the study staff ends, clear timelines and the nature of the data must be explained. Provide clear information about any demographic data that will be collected.

Include a statement of whether/how/where the research findings will be available to participants.]

**Potential Benefits:** [TCPS2 Article 3.2(c)] [Describe potential benefits participants may expect from the research, and state the potential benefits to science or society expected from the research. Please ensure you do not overstate the benefits (i.e., change of policy, particularly with small sample size research and no broad dissemination plans). If you cannot guarantee benefits to the participant, please include the following statement:]

I cannot guarantee, however, that you will receive any benefits from participating in this study.

**What are the Potential Risks to you as a Participant:** [Do NOT state that there are no potential risks or harms involved in your study. If potential risks are minimal, you may simply state that the risks are no greater than what you would experience in [insert daily activity here]. Provide a brief description of any risks or discomforts the participant might encounter because of participation. A description of provisions you have made to address these risks or discomforts is required. For example, because of the personal nature of the questions asked, a participant may reflect on unpleasant memories while responding to a questionnaire or interview. The participants should be informed of the potential for discomfort and told that if they feel too uncomfortable to answer, they may skip answering a question or stop participation, either temporarily or permanently. *The information in this section of the consent form should match the Section ‘Risk and Benefits’ of the Application*.]

If there are any potential rare but possibly catastrophic effects that the participant may experience, these should be stated. Additionally, if there are significant physical or psychological risks to participants that might cause the researcher to terminate the study, or remove the participant from the study, please describe them.][TCPS2 Article 3.2(c)]

The greater the level of risk for participants, the greater the expectation that researchers will have an effective risk management plan in place to mitigate possible harm. As an example, a project which may pose some psychological/emotional risk may require the researcher to provide mental health resources or counselling services for participants.

**Confidentiality:** [Describe the extent, if any, to which confidentiality of records identifying participants will be maintained and the measures adopted to maintain that confidentiality. State whether identification numbers or pseudonyms will be assigned and if/how participants can indicate their preference of whether their real name is used in published material. If the latter is an option, please include a checkbox on the signatory page for participants to opt in or out.

Provide information on the length of retention and security of identified data, either legislatively or institutionally required. If information is released to any other party for any reason, state the agency/person to which the information will be handed, the nature of the information, and the purpose of the disclosure. If there is the potential that participants will disclose information that would require you to report to legal authorities, this must be clearly stated (i.e., a duty to report child abuse, professional duties to report, etc.).

If participants are to be audio- or video-recorded, describe the participant’s right to review/edit the recordings or transcripts. Describe how the recording will be stored; who will have access to the raw and transcribed recordings; if the recordings will be used for educational purposes; and when they will be destroyed. **If participants are to be audio- or video-recorded, the consent process must include a checkbox or extra signature line on the consent agreement or be included on a separate consent statement**.]

**Incentives AND/OR Compensation for Participation:** Incentives are monetary or other benefits that encourage participation. If an incentive is offered to participants, describe what is being offered. If there are pro-rated amounts based on different phases or tasks of the research, this must be clearly stated. **Do not offer an hourly rate for the incentive.** If payment is in the form of a lottery or draw, state the probability of winning and how winners will be notified. **If the participant chooses to stop participation (described below under Voluntary Participation and Withdrawal), the full lump sum or pro-rated amount must be given to the participant whether they complete the research.** If an incentive is not offered, state that the participant will not be paid to participate in this study.][TCPS2 Article 3.2]

**Costs to Participation:** [If there are costs associated with participation (e.g., tests, office visits, parking, childcare, etc.), specify, in detail, the extent of these costs. If there are costs to the participant, you are encouraged to offer reimbursement. If you are providing reimbursement of these costs, please note reimbursements in this section. Reimbursements are not incentives; reimbursements are for costs related to participation. This does not necessarily include reimbursement for someone’s time but, it could be combined with compensation.][TCPS2 Article 3.2(j)]

**Compensation for Injury:** [TCPS2 Article 3.2(k)], by consenting to research, participants have not waived any rights to legal recourse in the event of research-related harm. If your research involves greater than minimal risk, please outline the compensation for injury. Refer to the information regarding Clinical Trials Template for an injury covered and not covered by the study. **If this does not apply to your research, simply remove this section or include the following sentence:]**

By agreeing to participate in this research, you are not waiving any legal right in the event that you are harmed during the research.

**Voluntary Participation and Withdrawal:** [Participants must be informed that their participation is voluntary. They must be told that they do not have to answer every question or complete all aspects of the research. If a participant wishes to withdraw from the study prior to the end date, describe how any collected data will be managed. If your research involves an online survey or task, there must be an option for complete withdrawal whereby the data entered by the participant up to that point is NOT included in the analysis. If this is not possible (for example, because submissions are anonymous), it must be clearly stated in the consent form. Can a participant’s data be removed from the study after the fact? If so, please provide a cut-off date for data not to be used. Participants must be told they can stop participating at any time and that if they choose to stop, they will still receive the full incentive (if pro-rated based on phases, participants are entitled to that pro-rated amount) and reimbursements. Participants must be told that withdrawal from the study will not influence future relations with the researchers, Trent University, and any other institutions/partners. A sample text follows. Please note the text may not be applicable to all types of research (e.g., studies not involving questions).] [TCPS2 Article 3.2(d)]

Participation in this study is completely voluntary. You can choose whether to participate or not. If any question makes you uncomfortable, you can skip that question. You may stop participating at any time and you will still be given the incentives and reimbursements described above. If you choose to stop participating, you may also choose not to have your data included in the study. Your choice of whether to participate will not influence your future relations with Trent University [and/or other institutions/partners/programs of the research]or the investigators[please include names] involved in the research.

[If appropriate, describe the anticipated circumstances under which the participant’s involvement may be terminated by the investigator without regard to the participant’s consent.]

**Questions about the Study:** If you have any questions or concerns about the research now, please ask. If you have questions later about the research, you may contact:

[Insert contact name of primary investigator and/or other investigators, title, address, Trent University phone number and email address. Do not provide personal/home numbers or addresses. Students should include their research supervisors as contacts.]

This study has been reviewed by the Trent University Research Ethics Board, the study number is [ROMEO Protocol Number]. If you have questions or concerns that you don’t wish to share with the researchers, please contact:

Anna Kisiala

Coordinator, Research Conduct and Reporting

c/o Office of the Vice President, Research and Innovation

Trent University

1600 West Bank Dr

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705-748-1011 ext. 7866

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**CONFIRMATION OF AGREEMENT:** [Consent needs to be documented either in a signed consent form or in documentation by the researcher of another appropriate means of consent. Signed consent is also mandatory in some cases (e.g., Health Canada regulations and Civil Code of Quebec).] [TCPS2 Article 3.12]

[ ]  I have read, or have had read to me, the information in this agreement;

[ ]  I have asked any questions I have about the study;

[ ]  By signing, I agree to participate in the study;

[ ]  I am aware I can change my mind and withdraw consent to participate at any time;

[ ]  I have been given a copy of this agreement; and

[ ] I am not giving up any legal rights by signing this consent agreement.

Optional

[ ]  I am aware that the researcher will use [my name or a pseudonym] when discussing my contributions in their report;

[ ]  I agree to be [audio, video, or both] recorded for the purposes of this study. I understand how these recordings will be used, stored and destroyed.

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Name of Participant (please print)

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Signature of Participant Date

[NOTE: If this consent agreement is being developed to obtain parental or third-party permission, the signature line should be labelled “Parent/Guardian of Participant - Third Party or Legal Representative.” In addition, include a line that would be used by the parent/guardian to indicate the name of the Dependant for whom they are giving permission. **Remove this signature line if not applicable to your study.]**

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Signature of Participant or Parent/Guardian Date

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Name of Dependant (print) if applicable