Consent/Assent Form Guidance

It is important that research participants provide voluntary, informed, and ongoing consent. This means that participants must understand and agree to what will happen to them as a participant before they begin participating. They must understand the risks and benefits of the research. Your consent and/or assent forms require specific information. This sample form and instructions are to help guide you in developing your consent/assent documentation. For further information, the Tri-Council Policy Statement (TCPS) discusses the consent process in Chapter 3. For considerations regarding the consent process when working with Indigenous persons and communities, please review Chapter 9.
See https://ethics.gc.ca/eng/policy-politique_tcps2-eptc2_2022.html

Key Points to Consider:

Consent forms should be in accessible language.

The consent agreement is a statement addressed to the participant, worded in the second person ("you") until the final section (Confirmation of Agreement), where the first-person perspective is used to refer to the person giving consent. It should be written at a grade 6-8 reading level, in language that participants can easily understand (e.g., no technical terms; clear and direct sentence structure; no extraneous information; expert verified translations provided for non-English-speaking participants). To assess the reading level of a study's consent form, consider using a reading level test, like Flesch-Kincaid (available in Word), prior to submitting your study.

The consent must be voluntary.

The consent form should present, in plain English, all the risks identified in the relevant sections of the application form including: 'Risk and Benefits', 'Indigenous Persons and Their Communities', and 'Scholarship of Teaching and Learning'. The information and consent letter should describe how you plan to mitigate risks and minimize any disadvantages of participation in the study.

It is important to be aware of situations where undue influence, coercion, or incentives might undermine the voluntariness of participants' consent. Take special care in circumstances where researchers and participants have relationships outside of the research study, particularly when there is a power imbalance. These types of relationships can include employees and employers, teachers and students, correctional officers and prisoners, physicians/counsellors and patients, and researchers recruiting family/friends. Such situations can present undue influence or manipulation whereby participants may feel obligated to participate or judged for not participating. If you have such a relationship with a potential participant, your protocol should demonstrate how you will ensure that there is no undue influence.

Example: An instructor may wish to recruit students from their classroom. To mitigate the risk of influence on potential participants, they may have someone with no relationship to the students conduct the recruitment and consent process.

In all cases, the consent form should clearly indicate that participation in the study is voluntary and that decisions regarding whether to participate will not affect any individual's relationship with the parties involved in the research, judgements of the individual, or any services the prospective participant receives.

To be considered "informed", the consent form must disclose all information relevant to the research project.

Certain information relevant to your study must be relayed for participants to decide whether to participate. The main procedures of the study need to be explained to the participants in writing. In cases where deception is a necessary part of the study design or if it is impractical to obtain consent, such as studies conducted in emergency situations (TCPS2 Article 3.8), researchers would be expected to provide the REB with a rationale for why this exception to the informed consent process would be necessary.
The consent is sometimes not fully informed until after the participants have completed the study/intervention (in which case affirmation of consent is often sought after a debriefing to ensure the consent is properly informed).

The consent shall come before any collection of data or access to research data obtained from participants in the current study.

An exception can be made when researchers consult prospective participants about their research design, as we often see in community-based research or research involving First Nations, Inuit, and Métis people.

Participants who lack the capacity to consent must still assent to participation.

Assent forms are used when a participant lacks full capacity to understand the research and therefore, cannot provide fully informed consent. This is sometimes done in the case of children or those with a cognitive impairment, whose ability to consent is determined by their ability to understand the research and its risks and benefits. Some factors that determine whether assent is adequate or whether the consent of a third party is required include the nature of the research, research setting, level of risk, provincial legislation, and other legal requirements.

Assent should be given after an explanation of the procedure is provided. It can be verbal or written, and should be documented.

Example: A child may assent to participate in a research study, but their parent would be required to sign a consent form. Even if a third-party consents to their participation, those

lacking capacity must be given the opportunity to express their assent or dissent to participate, to the extent they are able to, and any expression of dissent must be respected. Article 3.9 of the TCPS2 addresses research involving those who lack the capacity to consent. See also *https://ethics.gc.ca/eng/policy-politique_tcps2-eptc2_2022.html*