GUIDELINES FOR OBTAINING CONSENT AND ASSENT

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1. Purpose

The purpose of this guideline is to provide researchers with information on consent and assent as it pertains to research involving human participants. Consent templates and appendices are also provided below to help researchers prepare their consent and assent documents.

2. Background

Individuals conducting research involving human participants must ensure that their participants provide voluntary, informed, and ongoing consent. In some cases, where consent from participants is not applicable (see Section 4 below) researchers must obtain assent from their participants. For more information on the importance of obtaining consent and assent, see Chapter 3 of The Tri-Council Policy Statement (TCPS 2).

3. The Three Important Components of Consent

According to the TCPS 2, consent must (i) be given voluntarily, (ii) it must be informed, and (iii) it shall be ongoing.

I. Voluntariness

Researchers have a responsibility to ensure that participants who decide to participate in their projects do so voluntarily. Part of this responsibility entails that researchers are aware of situations where undue influence, coercion, or incentives might undermine the voluntariness of participants' consent. Special care should be taken in situations where researchers and participants stand in already existing asymmetrical relationships. For example, employers and employees, teachers and students, correctional officers and prisoners, physicians/nurses/counsellors and patients, and researchers, family and friends are examples of asymmetrical relationships that may place an undue influence on participants to participate in research projects.

Researchers who stand in asymmetrical relationships must demonstrate to the Research Ethics Board (REB) that there is no undue influence on potential participants to participate in their projects. In all cases, the consent form should clearly indicate that participants' participation in the study is completely voluntary and that decisions regarding whether or not to participate in a project will have no effect on participants' relationships with any member of the research team.

II. Informed Consent

Consent must be informed. This entails that research participants have a clear understanding of the following information:

i. The type of research being performed;
ii. The name(s) of the investigator(s) conducting the study;
iii. The potential risks and benefits of the project;
iv. What their participation involves;
v. Any potential, real, or perceived conflicts of interest;
vi. Any applicable funding sources;
vii. Any incentives, reimbursements, costs, or compensation relevant to the study;
viii. How confidentiality or anonymity will be maintained;
ix. How participants may withdraw from the study; and
x. Who will have access to the data, and how the data will be managed and destroyed.

Research participants should also be given an opportunity to ask any questions they might have regarding any of the above information.

It is the duty of the researcher to convey all of the above information to participants in an accessible manner. To this end, consent forms should (i) be written at a grade 6-8 reading level, (ii) be addressed to the participant (i.e., in second person by using “you-statements”), (iii) contain no technical terms or long sentences, and (iv) contain no extraneous information. Also, in cases where potential participants do not speak or understand the language that the study is being primarily conducted in, researchers must provide adequate translations and appropriate interpreters.

III. Ongoing Consent

Researchers should obtain consent from their participants prior to their participation in research-related activities (i.e., before collecting any data from participants, or accessing data). In some cases, however, this requirement may be waived. In these types of cases, the onus is on the researcher to demonstrate to the REB why consent is not being obtained prior to participants participating in research-related activities.

Researchers have a responsibility to respect the autonomy of their participants throughout all stages of the research. This entails that researchers not only obtain initial consent from their participants, but also that participants provide ongoing consent – or at least tacit consent – throughout the duration of their participation. Where possible, researchers should incorporate various mechanisms into their research design to allow for participants to change their minds regarding their participation and withdraw from the study.

4. Assent

In some cases, potential participants may be unable to consent to participating in a research study. In cases such as this, potential participants must nonetheless agree or assent to participate in the project. Assent forms are typically used when a participant lacks the full capacity to understand the nature of the research and thus cannot provide consent. (Recall that consent, according to the TCPS 2, must be voluntary, informed, and ongoing, and if participants cannot understand the nature of the research, they cannot meet the informed component of consent.) Assent is typically sought by researchers conducting research involving children, whose ability to understand – and not simply their age – makes them incapable of consenting to participate in a project.

Some factors that determine whether child assent is adequate, or whether consent of a third party is required, include: (i) the nature of the research, (ii) the research setting, (iii) the level of risk, and (iv) any legislation or legal requirements. Even if a legitimate third party (e.g., legal guardians for young children) gives their consent, participants lacking the capacity to consent must also assent to participate in the project.

For more information on determining whether consent or assent is appropriate, see Chapter 3 of The Tri-Council Policy Statement.