# Guidance for Applications for Ethics Review:

# Informed Consent and Assent

In general, researchers submitting an Application for Review to the Aurora College Research Ethics Committee (REC) must include a written consent form with their application and explain the consent process that will be used during their research. If the study employs a verbal consent process, the principal investigator must submit a consent script that will be communicated to the participant and a protocol for recording consent. The information in this guidance document is designed to describe the principle elements required for an informed consent process.

**General Principles[[1]](#footnote-1)**

The consent process starts with the researcher’s first contact with the potential research participant and continues until the study is completed or the withdrawal/refusal of the research participant. Individuals (or an authorized third party legally representing an individual who is unable to consent) must give their consent before they can participate to a research project[[2]](#footnote-2).

The consent and assent must be voluntary[[3]](#footnote-3), informed, and free of coercion or undue influence. Before consenting, a potential research participant should reasonably understand the purpose of the research, its risks, and its potential benefits. Researchers must take steps to ensure that prospective and enrolled research participants have sufficient time to fully consider their options, do not feel pressured to join or continue their participations in the study, and understand that they are free to withdraw from the study at any time without any explanation, disadvantage, or reprisal[[4]](#footnote-4).

Consent to participate in research is a continuous process: it has to be maintained throughout the research project[[5]](#footnote-5). As well, researchers have to provide each participant with all the information pertinent to giving their consent to participate[[6]](#footnote-6). This would include, for example, disclosing any findings discovered during the research that could affect the research participant’s willingness to participate in the study[[7]](#footnote-7). Researchers also have to document the consent process in written form and/or any other appropriate means[[8]](#footnote-8). A research project may not proceed with a person that has refused to participate or has withdrawn. It should be noted that, even though consent has been given by an authorized third party before beginning research, the consent of a research participant should still be sought from the research participant whenever appropriate (ie. if there is a change in capacity to consent.)

**Legal Requirements and Authorizations**

Researchers are responsible for ensuring that the REC approved consent process is followed and that all legal requirements, depending on the nature of their research and the jurisdiction(s) in which this research will be conducted, are always met. Legal requirements may include provincial, territorial, national and, if applicable, international requirements.

When potential research participants are minors or adults unable to consent, researchers should be aware of possible provincial/territorial legal and other requirements concerning specifically these research participants and refer to it if need be. Assent should be sought from minors or adults unable to consent, if appropriate, alongside consent from a legal representative or an authorized third party (not a research team member)[[9]](#footnote-9). The assent and the consent processes should be documented by the researcher in his or her application and during research. Dissent from a research participant must be respected[[10]](#footnote-10).

1. For more information on informed consent and assent, please consult:

   *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS-2)* (2018) Chapter 3 [↑](#footnote-ref-1)
2. TCPS-2, art. 3.5. [↑](#footnote-ref-2)
3. TCPS-2, art. 3.1. [↑](#footnote-ref-3)
4. TCPS-2, art. 3.1. [↑](#footnote-ref-4)
5. TCPS-2, art. 3.3. [↑](#footnote-ref-5)
6. TCPS-2, art. 3.2. [↑](#footnote-ref-6)
7. TCPS-2, art. 3.4. [↑](#footnote-ref-7)
8. TCPS-2, art. 3.12. [↑](#footnote-ref-8)
9. TCPS-2, art. 3.9 et 3.10. [↑](#footnote-ref-9)
10. TCPS-2, art. 3.10. [↑](#footnote-ref-10)