

Assent, Consent & Decision Making Capacity in Minors

In the past, researchers and regulatory bodies assumed that the age of consent for research was the age of majority. People who are not adults because they are under 18 years of age are known as “minors”. When researchers seek the participation of minors in their research, they have sought *consent* from the adult parents or guardians; from the minors, themselves, they have sought *assent*.

The most recent version the Tri-Council Policy Statement² (TCPS2 2014) has taken a new direction suggesting that, for some minors, it is appropriate for the researcher to ask for consent. The TCPS2 states that researchers should adopt a decision-making capacity approach when determining whether they should seek assent or consent from minors (see Article 3.3).

The following guidelines developed by the Conjoint Health Research Ethics Board aim to assist researchers in determining when they should seek consent from minors, and when seeking assent is more appropriate.

Please note that for studies falling under the US FDA or receiving US Federal Funds, parental consent for the participation of minors must still be sought.

Research decision-making capacity assessment

As a general rule, when proposed participants are minors under 14 years of age, the investigator should seek assent from the child and consent from the parent(s) or legal guardian.

When the proposed participants are minors 14 years and older, researchers must assess the child’s capacity to make a decision about his or her research participation. To have research decision-making capacity requires that:

1. The minor is competent in the sense that he or she has the ability to reason, and can understand and appreciate the risks and benefits of participating and of not participating;
2. The minor has the benefit of full information about the risks and potential benefits of participating and of not participation; and
3. The minor feels no compulsion, and fears no reprisal, for accepting or refusing to participate

To assess the minor regarding the first criterion, the researcher must generally consider these factors:

- a) the intelligence of the minor;
- b) the minor's ability to appreciate the reasonably foreseeable consequences of his or her actions;
- c) the stage of the minor's physical, emotional and mental development;
- d) the degree of responsibility the minor has assumed in his/her life; and
- e) the inherent risk level of the research protocol.

Alberta Health Services has drafted a document to guide the assessment of mature minor status in the clinical setting. This additional information might be useful to guide such assessment in the research setting.

Please see <http://www.albertahealthservices.ca/assets/about/policies/ahs-clp-consent-summary-sheet-minors-mature-minors.pdf>

When researchers have found that minors have research decision-making capacity, then the minors' consent for study participation should be obtained using the CHREB standard consent template. Please note that the reading level of a consent form should be appropriate for Grades 6-8 regardless of the age of the intended participant. Even when minors provide consent for themselves, it is good for the parents/guardians to understand and support their child's decision to participate. With the minor's permission to do so, it may be useful to provide parents/guardians with an Information Sheet that explains the study and the minor's role therein.

Assent forms – minors without research decision-making capacity

Researchers typically use assent forms with minors who lack capacity. The language level needs to be understandable to the group. The concepts need to be explained clearly and simply. Use of pictures might be helpful. The CHREB has two assent templates, one intended for use with children 7-10 years of age (reading level of grade 2 appropriate) and one for children 11 and older (reading level of grade 4 appropriate). Researchers will need to read the assent form to some very young children.

Confidentiality

Sexuality and use of illegal substances are two areas in which adolescents may struggle to be truthful if they believe information will be shared with their parents; nevertheless, such information can be essential to the treating physician/physician investigator.

Under the Health Information Act of Alberta (section 104 - <http://www.qp.alberta.ca/documents/Acts/H05.pdf>), adolescents with capacity are entitled to control the release of their health information.

It can be difficult for parents to understand or accept that they will not be privy to information that their child gives to another adult. One approach described later in this document, is to discuss the study with the teen first, informing him or her of any limits to confidentiality. If a teen declines to participate in the study, then the researcher should not approach the parent(s) with the information. If investigators are concerned about the challenges of keeping a minor's health information private, then the investigators should seek guidance/assistance from the Chair of the CHREB or a delegate.

Elements of the Assent Form

There are no formal requirements for the elements that must be present in an assent form, (though this is not true for consent forms). This means that the investigator can propose assent content that he/she believes will best inform the minor participants about the study. The length of the assent form should be proportionate to the complexity of the study and the age of the participants.

The signature block needs lines only for the child to write his/her name and for the person obtaining assent to sign his/her name. The person who seeks assent from the minor must be the Principal Investigator or someone delegated by the Principal Investigator.

If the child is not able to read the assent form, and oral assent is obtained using the content in the assent form, then the person who received assent should place in the chart or research record a statement with the following content:

I have discussed this research study with [name of child] using language that is understandable and appropriate for the participant. I believe that I have fully informed him/her of the nature of the study and its possible risks and benefits. I believe the participant understood this explanation and appreciates the risks and benefits of agreeing or refusing to agree to participate. I do not believe that the child feels obligated to participate or fears any negative consequences for refusing to participate.

Please see the CHREB Website under the tab "Forms and Templates" for two Assent Form templates that researchers may use as a basis of developing an age appropriate assent.

Link: [Assent for Younger Child \(7-10 years old\)](#)

Link: [Assent for Older Child \(11 years or older, or female of reproductive potential\).](#)

Note: the researcher should use this assent form for those girls who are approaching sexual maturity.