Conjoint Health Research Ethics Board (CHREB)
Research Services, University of Calgary
2500 University Drive N.W. Calgary, AB T2N 1N4
Ph: (403) 220-2297 | Email: chreb@ucalgary.ca

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 sought the participation of minors in their research, they sought *consent* from the adult parents or guardians; from the minors, themselves, they sought *assent*.

However, the Tri-Council Policy Statement2 (TCPS2 2022) suggests that, for some minors, it is appropriate for researchers 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 3.9).

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, researchers should seek *assent* from the child and *consent* from the parent(s) or legal guardian.

When the proposed participants are minors between the ages of 14 and 17 years old, they might be considered *mature minors*, depending on their decision-making capacity. Mature minors have the capacity to give full consent. Researchers must assess minors' capacity to make decisions about their 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:

1. the intelligence of the minor;
2. the minor's ability to appreciate the reasonably foreseeable consequences of his or her actions;
3. the stage of the minor's 's physical, emotional and mental development;
4. the degree of responsibility the minor has assumed in his/her life; and
5. 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: https://www.albertahealthservices.ca/assets/info/hpsp/if-hpsp-phys-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 (adult) consent template. Please note that the reading level of the consent form should be appropriate for Grades 8-10 regardless of the age of the intended participant.

Even when minors provide consent for themselves, it is good practice for the parent(s) or legal guardian to understand and support the minor'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.

Confidentiality

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 parent(s) or legal guardians to understand or accept that they will not be privy to information that their child gives to another adult. The preferred approach 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) or legal guardian with the information.

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 parent(s) or

legal guardian; nevertheless, such information can be essential to the treating physician/physician investigator.

Regarding pregnancy and contraception

Researchers must first discuss pregnancy testing and contraception needs with the minor in private *before* the study is mentioned to the parents. If the minor does not want their parent(s) or legal guardian to know about their sexual activity, then the study should not be introduced or discussed with the parent(s) or legal guardian.

If researchers are concerned about the challenges of keeping a minor's health information private, the researchers should seek guidance/assistance from the Chair of the CHREB or a delegate.

Assent forms – minors without research decision-making capacity

Under the TCPS2, minors without decision-making capacity should be given the opportunity to provide assent, however parental or guardian consent must still be obtained.

Researchers may need to read the assent form to some very young children.

Assent Form Considerations:

1. The language level needs to be understandable to the targeted age group.

   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).

   Note: Researchers should use the Assent for Older Child (11 years or older, or female of reproductive potential) for minors who are approaching sexual maturity.

2. The concepts need to be explained clearly and simply.

3. Use of pictures might be helpful.

4. Length of the assent form should be proportionate to the complexity of the study and the age of participants.

The signature block needs lines only for the child to write his/her name (if able) 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 clinic 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 “Forms and Templates” section for two Assent Form templates that researchers may use as a basis of developing an age appropriate assent.