

Guidance concerning consent and capacity when research involves children and adolescents

An important mechanism for respecting participants' autonomy in research is the requirement to seek their free, informed and ongoing consent. An informed consent is one that is based on as complete an understanding as is reasonably possible of the purpose of the research, what it entails, and its foreseeable risks and potential benefits, both to the participant and to others. For more detailed guidance concerning informed consent see *REB SOPs 701 and 702*.

When research involves children and their capacity to consent to participate is unclear, a study-specific process to assess capacity must be in place. If the prospective participant does not have the capacity to consent, then the highest available substitute decision maker must consent on behalf of the participant. Even if the child does not have the capacity to consent, he or she should be informed about the study to the extent compatible with his/her understanding in a manner that is developmentally appropriate. See, also, *REB SOP 702*.

Submitting an application to the REB

When an application is submitted to the REB that involves children as research participants, and their capacity to participate is unclear, the REB expects the researcher to provide the following information regarding the decision making process:

1. A clear procedure for assessing capacity including:
 - a. Who is doing the assessment (their experience/ background/qualifications)
 - b. The plan for assessing capacity, including any materials or tools that may be used (e.g. questions, script)
2. A description of, and justification for, the proposed involvement of the child and parent in the decision process.
3. A plan to reassess capacity throughout the study, if appropriate.
4. The appropriate decision making documentation may include:
 - a. Informed Consent Form
 - b. Assent Form
 - c. Recruitment material
 - d. Other documentation that may be used to assist children/parents to decide whether to participate in a research project.

Open Line of Communication

Before capacity can be assessed, it is important to first establish an open line of communication.

An open line of communication requires:

1. Attention – The child has the ability to focus on the information.
2. Communication – The child and person obtaining consent are able to communicate – this may include using an interpreter, a preferred communication partner, or communication system.
3. Responding – Minimally, the child has a reliable method of indicating “yes” or “no” to specific questions.

If an open line of communication cannot be established, then it will not be possible to assess capacity, and consent or refusal should be obtained from a substitute decision-maker.

The following are questions that may be used to assess a child’s capacity:

1. About the Study

Who is this study for?
What do the researchers want to learn?

2. Risks and Benefits

What are some good things that might happen in this study?
What are some bad things might happen in this study?

3. Privacy and Confidentiality

Who will know what you say during the study?

4. Voluntary

Do you have to be in this study? Why or why not?
What should you do if you are not sure about participating?

5. Questions

If you have any questions about the study, who can you ask?

Tools used for capacity assessment must be developmentally and ability appropriate. Inaccurate or unclear responses should cue the researcher to explain the information differently to help the child to understand and appreciate the elements of consent. The REB encourages researchers to engage the parent in the consent discussion to make research information more accessible for the child.

General guidelines for involving children and adolescents in the decision making process:

Developmental Level	Adolescents (Or at this cognitive developmental level)	Primary School Aged Children (Or at this cognitive developmental level)	Preschool Aged Children (Or at this cognitive developmental level)
Decision level	Independent Decision Making	Shared Decision Making	Best Interest Decision Making
Capacity skills	- Adolescent may have the decision making capacity of an adult	- Child, generally, does not have full decision making capabilities unless it pertains to a simple procedure or is one which the child has considerable prior experience	- Child does not have the capacity for meaningful participation in decision making
Level of participation	- The adolescent provides consent or refusal for him/herself if the capacity requirements are met	- The child participates in the consent/assent process with the parent	- Parent/ substitute decision-maker decides according to the best interests of the child

How to engage the in the participant in the process	<ul style="list-style-type: none"> - Provide appropriate info before the consent discussion and capacity assessment - Encourage independent decision-making - Encourage involvement of the parent in supporting shared decision making but respect the adolescent's preference 	<ul style="list-style-type: none"> - Provide appropriate information before the consent/assent discussion - Provide some appropriate choice to encourage developing capacity - Enlist support of parents to include child in consent discussion and decision making to the greatest extent possible 	<ul style="list-style-type: none"> - Share appropriate information with the parent before the assent discussion - Consider supplementing assent discussion with non-verbal techniques such as toys and drawings to encourage decision making development to the greatest extent possible
Who signs which forms?			
Child	Consent	Assent (signature optional)	If appropriate, Assent
Parent	Support Statement (optional)	Consent	Consent

For more information contact:

The Holland Bloorview Research Ethics Board

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Additional resources:

Canadian Institutes of Health Research (CIHR), Avard D, Black L, Samuël J, Griener G, Knoppers BM: Best Practices for Health Research Involving Children and Adolescents. <http://www.genomicsandpolicy.org/best-practices.html>.

Dove ES, Avard D, Black L, Knoppers BM. Emerging issues in paediatric health research consent forms in Canada: working towards best practices. *BMC Med Ethics*. 2013 Jan 30;14:5.

Gibson BE, Stasiulis E, Gutfreund S, McDonald M, Dade L. Assessment of children's capacity to consent for research: a descriptive qualitative study of researchers' practices. *J Med Ethics*. 2011 Aug;37(8):504-9.