Bloorview RESEARCH INSTITUTE

Holland Bloorview Kids Rehabilitation Hospital

SOP Title:	Informed Consent/Assent Process
SOP #:	706
Version #:	1.0
Date Effective:	September 18, 2024

1.0 PURPOSE

This Standard Operating Procedure (SOP) describes the procedures for obtaining and documenting initial and ongoing assent. This SOP will address guidelines for capacity assessment and the assent process.

It does not apply to the informed consent process, this information can be found in BRI/N2 SOP 008 "Informed Consent Process."

It does not apply to exceptions to informed consent requirements for emergency situations, or departure from the general principles of consent approved by the Research Ethics Board (REB). This information can be found in REB SOP 701 "Informed Consent Form and Documentation"

2.0 SCOPE

This SOP is applicable to all research studies undertaken under the auspices of Holland Bloorview, subject under review by the Holland Bloorview REB.

This SOP is applicable to local research studies (conducted within Holland Bloorview) where capacity assessment and assent is required and to research personnel responsible for or involved in performing, documenting, reviewing and/or approving these processes. All parts of this SOP are applicable, whether the capacity assessment and assent process occur in-person or in a remote manner.

Note: Article 3.10 of the Tri-Council Policy Statement describes the following cases with respect to participants who may be capable of assent or dissent:

- *Individuals whose decision-making capacity are in the process of development (e.g. children)*
- *Individuals who were once capable of making an autonomous decision but may have diminishing or fluctuating decision-making capacity*
- *Individuals with partially developed decision-making capacity (e.g. individuals with permanent cognitive impairment.*

3.0 RESPONSIBILITIES

All REB members and REB Office Personnel are responsible for ensuring that the requirements of this SOP are met.

The Researcher is responsible for providing the REB with a detailed description of the rationale for an assent process waiver and/or the assent/capacity assessment documents and a description of the assent process.

4.0 DEFINITIONS

See Glossary of Terms

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5.0 PROCEDURE

5.1 REB Review of the Assent Process

5.1.1 The REB must approve the assent process (including the capacity assessment process), the assent form and the capacity assessment document before recruitment begins.

5.1.2 The REB expects the researcher to provide the following information regarding the decision-making process:

- A clear procedure/plan for assessing capacity including any materials or tools that may be used (e.g. questions, script)
- A clear description of the assent process
- A description of, and justification for, the proposed involvement of the child's parent/legal guardian/substitute decision maker (SDM)'s in the decision process
- A plan to reassess capacity throughout the study, if appropriate
- The associated documents which include the Informed Consent Form (ICF), assent form, and any other documentation that may be used to assess children/parent to decide whether to participate in a research project

5.1.3 The Holland Bloorview assent form template includes the necessary elements for disclosure of information to make an informed decision to participate in research:

- For Holland Bloorview investigator-initiated projects submitted through the eREB system, the Holland Bloorview template must be used
- For externally sponsored research projects, the Holland Bloorview templates are still recommended, however, they are not mandatory. Study teams are expected to review the "Informed Consent Form Elements Checklist" to ensure that all essential elements are included.

5.1.4 The REB expects the researcher to adhere to the following requirements regarding the assent process:

- The potential participant should be provided with a copy of the consent/assent documents and any other REB approved written information. The potential participant should be provided with ample time to read the ICF and/or assent form, ask questions and consult with a caregiver or other trusted individual, as may be necessary. This may include taking the ICF/Assent form home to review with a family member, or other trusted individual. The REB will consider both participant risk level and vulnerability when judging the adequacy of the time provided for participants to review consent and assent documents before the consent and assent discussion.
- Assessment of the potential participant's competence to consent/assent to research must be completed prior to obtaining participant's consent/assent.
- Discussion of study details must be conducted in language appropriate for the prospective participant's level of comprehension. REB-approved supplementary materials can be used to aid the discussion, as necessary.
- During the consent review, the qualified individuals should review the study details with the potential participant.
- Discussion must be conducted in a quiet and private location for both parties.
- The informed consent discussion should take place with a qualified and knowledgeable investigator or delegate who is not in a position of authority with prospective participants to avoid undue influence.

  ***Note**: Individuals obtaining consent and assent should not be within the research participant's circle of care. Should this be the case, the individual can introduce the study to potential participants and answer questions regarding the study, but consent and assent*

should ideally be obtained from another member of the study team who is not directly involved in the patient's clinical care. This minimizes any potential form of coercion or undue influence. Individuals who obtain consent and assent must be delegated by the study Principal Investigator (PI) to do so, and they must be trained and qualified for the consent process.

5.1.5 All assent documents and tools utilized during the assent process and the method of obtaining assent are subject to review and approval from the REB prior to implementation. Other forms of assent (i.e. non-written assent) are also subject to REB review and approval prior to implementation.

5.1.6 Any changes to the assent/capacity assessment form(s) or the assent/capacity assessment process should be submitted and approved by the REB prior to being implemented.

5.1.7 Any deviations to the REB-approved assent process should be appropriately documented and reported, when applicable, per REB Requirements for Reportable events in REB SOP 404 "Ongoing REB Review Activities."

5.2 Requirements for Capacity Assessment

5.2.1 An important tenet in upholding the ethical principle of respect for persons in clinical research is ensuring free and fully informed consent. An informed consent is based on an individual's decisional capacity (herein referred to as capacity). Capacity refers to the prospective participant's ability to meaningfully make decisions regarding participation in research. Capacity is generally understood to include the following:

- Understanding – ability to comprehend information pertaining to the purpose of the study, what it entails, foreseeable risks and potential benefits
- Appreciation – ability to appreciate the significant of such study information to oneself, within the context of their condition or situation
- Reasoning – ability to rationally enter into the decision-making process, especially regarding potential risks or benefits, if any, of research participants
- The ability to freely express their choice (whether or not to participate)

Capacity is situational and specific to a research protocol. For example, an individual may have capacity to consent to a low-risk research study but may be deemed to have reduced/impaired capacity within the context of a high-risk protocol, while they are under duress or in pain.

5.2.2 Ontario's provincial laws do not specify an age of consent. As such, establishing processes for evaluating capacity for consent in research studies, especially studies recruiting pediatric participants or participants with disability is crucial. To determine if participants have the capacity to consent on their own behalf, research personnel must consider if the prospective participant has the capacity to fully understand the risks of the research study, including risks to privacy.

When appropriate, it is highly encouraged for participants with limited capacity to be involved in the consent process for studies they may participate in. They should be informed of the essential aspects of the study in non-technical language and suited for their level of understanding.

5.2.3 Should the capacity assessment outcome indicate that the participant does not have the capacity to consent, they should be asked to provide assent to research, if possible. The Investigator must obtain REB approval for a study-specific process to assess whether a prospective participant has the capacity to consent to participate in the study.

5.2.4 The Capacity Assessment process should be appropriate to the nature, degree of risk and complexity of research study. More complex or high-risk research should have more rigorous means of assessing capacity.

5.2.5 Documentation of all capacity assessment must be retained in study records, along with documentation pertaining to the informed consent/assent process.

5.2.6 Capacity is dynamic. It may be developed with time/experience, or reduced or impaired by illness or other circumstances. There should always be a plan to assess capacity at regular intervals, especially for longitudinal research studies.

5.3 Assent Process

A. General Guidelines for the Assent Process

5.3.1 Potential participants who lack the capacity to provide consent must still be informed of the research study at a comprehension level they are able to understand. If these participants are able to meaningfully express their wishes, assent or dissent must be sought.

5.3.2 Potential participants should not be excluded from research on the basis that they lack capacity as this goes against principles of justice.

5.3.3 Assent is not merely the absence of dissent and must be expressly provided given adequate understanding of essential information pertaining to the study. Any explicit objection by persons who are incapable of giving informed consent must be respected even if the parent/legal guardian/SDM has provided their consent.

5.3.4 Non-verbal cues for assent or dissent:

- In cases where the potential participant may not have the ability to provide verbal or written assent, researchers must be mindful of the most appropriate means of communicating with the prospective participant and be aware of non-verbal cues of agreement/assent (e.g. Nodding, a 'yes' response) and dissent (e.g. crying, resistance).
- Dissent must be differentiated from expressions of discomfort or non-compliance which may or may not be related to study activities (e.g. expressions of autonomy, difficulties with self-regulation). However, researchers must also be careful not to dismiss such expressions of non-compliance or distress.
- Researchers are encouraged to communicate with the prospective participant and their parent/legal guardian/SDM, a trusted communication partner, or care-provider to effectively interpret potential expressions of dissent.

5.3.5 All reasonable effort must be made to monitor potential signs of distress in the participant, ascertain the reason behind such distress and to minimize distress throughout the process.

B. Documentation of Assent

5.3.6 A participant's assent, on its own, is not sufficient to permit participation in a study. If the individual lacks capacity, then they should be assented, when applicable, to participate in the study and their parent/legal guardian/SDM must consent to their participation.

5.3.7 Where practically possible, the participant should sign and date a signature page (assent form) to indicate assent. Document the participants' assent or dissent.

5.3.8 Additionally, a parent/legal guardian/SDM must consent on behalf of participants who fall under the category of developing, impaired or reduced capacity to consent. The preferred method is to have parent/legal guardian/SDM sign and date an ICF.

5.3.9 The researcher conducting the discussion and other individuals involved as required (i.e. interpreter/impartial witness) must also sign the assent form or documentation of other assent in keeping with Good Documentation Practice.

5.3.10 The participant and SDM must be provided a copy of the signed assent form, as applicable, and ICFs for retention.

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C. Ongoing Assent

5.3.11 In ongoing research studies, assent must be considered as a process that is attentive and responsive to changes in the participants' cognitive status or situation. In the case of children initially unable to provide assent for their research participation, researchers must seek their assent to continue participation once they are able to meaningfully express their wishes. Ensure that the participant's assent to participate in the study remains valid throughout the study by providing ongoing opportunities to ask questions about the study. Should the participant be deemed capable of providing consent, processes pertaining to the informed consent process should be followed in obtaining the participants' informed consent.

5.3.12 In accordance with ensuring the participant's consent remains valid throughout the duration of the study, Capacity must also be continually assessed within the context of the informed consent or the assent process. As such, in alignment with section 5.2.6, if a participant acquires or regains capacity during the course of the research, the researcher shall promptly seek the participant's assent or consent as a condition of continuing participation.

5.3.13 Communicate any new, important information that may be relevant to the participant's assent, in a timely manner. This communication should be documented in the participant's source documents.

5.3.14 Revise the assent form (and any other written material), and submit to the REB for approval (refer to the Assent Form template and eREB guidance for submission processes). Re-assent the participants affected by the changes, after REB approval following the same procedures above.

6.0 REFERENCES

See References.

7.0 REVISION HISTORY

Version #	Date	Action/Modifications	Date effective
1.0	September 16, 2024	Original Version	September 18, 2024