

**Holland Bloorview Research Ethics Board (REB)
Standard Operating Procedures**

	REB REVIEW OF RESEARCH		
POLICY: REB-704	INFORMED ASSENT ELEMENTS		
This policy pertains to:	The activities of the Research Ethics Board (REB) operating under the authority of Holland Bloorview Kids Rehabilitation Hospital.		
Responsibility for executing this policy:	Chair, Holland Bloorview REB (or designate)		
Effective date:	June 2016	Supersedes documents dated:	May 2016
Approved:	Chair, Holland Bloorview REB Research, Teaching & Learning Committee		

1. PURPOSE

The purpose of this SOP is to describe the necessary assent elements for disclosure of information for making or contributing to informed decisions to participate in a research study as set forth in:

- The Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS2 (2014))
- Health Canada, Food and Drugs Regulations (Division 5) including the ICH Guidance E6: Good Clinical Practice: Consolidated Guideline (ICH GCP)
- US Department of Health and Human Services, Code of Federal Regulations (45 CFR 46)
- US Food and Drug Administration, Code of Federal Regulations (21 CFR 50)
- National Standard of Canada, Research Ethics Oversight of Biomedical Clinical Trials (CAN/CGSB-191.1-2013)

and informed by best practices as described in:

- Centre for Genomics and Policy & Maternal Infant and Youth Research Network. *Best Practices for Health Research Involving Children and Adolescents*. 2012. ('Best Practices')

2. POLICY STATEMENT

Children and youth ('children') may have developing, impaired, or diminished ability to understand and appreciate information that may influence their decisions about research participation. *Respect for Persons* requires researchers to involve these children in the decision-making process to the greatest extent possible and offer them an opportunity to express their wishes.

TCPS2 Articles 1.1 and 3.10
ICH GCP 4.8

The Local Principal Investigator (LPI) and the REB are jointly responsible for ensuring that necessary study information is shared and freely discussed with children who are determined by the researcher to lack the capacity to decide on their own behalf. The

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purpose of sharing information is to allow children to contribute to informed decisions about their initial/ongoing participation in research and to support their developing autonomy.

Assent may be defined as ‘a child’s affirmative agreement to participate in research.’ The REB must approve the assent process ensuring that the elements of informed assent are discussed before a researcher conducts any study procedures. The LPI must ensure and document that assent information is provided to prospective participants in a developmentally-appropriate way and in accordance with contemporary policies, regulations, best practices, and as approved by the REB.

CAN/CGSB-191.1-2013
45 CFR 46 Subpart D 46.402
Best Practices, Article 3.1

3. SPECIFIC POLICIES

The following policies provide general and specific assent documentation requirements for all studies. Researchers must not conflate assent documentation requirements with the assent process as a whole. It is the responsibility of the LPI (or research assistant/coordinator) to assess and tailor information to the child’s capabilities during the assent process. REB-705 describes the process to obtain and document initial and ongoing assent processes involving children. Refer to REB-701 for corresponding documentation requirements for informed consent by a child who has the capacity to consent or the parent/substitute decision maker (‘parent’).

TCPS2 Article 3.2

ICH GCP 4.8
45 CFR 46.117
21 CFR 50.25
Policy REB-701/705

3.1 General Assent Documentation Requirements for All Studies

Best Practices, Article 3.3

- a. Use language in assent forms/scripts/other documents read by and discussed with children (‘disclosures’) that is non-technical, culturally appropriate, and accessible for children who are eligible to participate in a research study.
- b. Use a signature page that has a statement by the child indicating that s/he discussed the study information with the researcher, had all questions answered, and agrees to participate in the study. The page must provide space to allow the child to print his/her name, sign, and date beneath this statement. When appropriate, the researcher should offer but not require the child to confirm assent in writing. A child who indicates assent (verbally/non-verbally) may decline or not have the ability to print, sign, and/or date the signature page. In such cases, researchers must document the child’s assent indication and assent process (see REB-705) in their study file.
- c. The signature page must have a statement beneath the participant’s signature line that the researcher discussed the assent information with the (named) participant, answered all questions, and confirmed that the child communicated a willingness to participate in the study. The page must allow

TCPS2 Article 3.2
ICH GCP 4.8

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the researcher to print his/her name, sign, and date beneath this statement.

- d. Unless otherwise approved by the REB, add the approved study title and a lay alternate title, the study number assigned by the REB office, and the Bloorview Research Institute logo on both the first page of the assent disclosure and its signature page. All assent disclosures must include the version date and page numbers on all pages using the pagination format of 'Page x of y'.

3.2 Specific Assent Documentation Requirements

Researchers must give children adequate time and opportunity to consider the information provided, ask questions, and discuss with parents and others before making a decision about participation.

45 CFR 46.117
21 CFR 50.25

CAN/CGSB-191.1-2013 –
(4.4.4.2.9)

Information disclosures for assent **must** include the following elements:

Best Practices Article 3.2

- a. a statement that the child is being invited to participate in a research study;
- b. the research purpose;
- c. an explanation of what the child will be asked to do;
- d. all foreseeable risks and potential benefits;
- e. assurance that the child does not need to take part in the study;
- f. the child has the right to withdraw at any time, how to withdraw, and assurance that no one will be upset about this decision;
- g. how the research results will be shared.

TCPS2 Article 3.2
21 CFR 50 Subpart D 50.25
ICH GCP 4.8.2
Policy REB -705

The following additional elements are **commonly required** in information disclosures for assent:

- a. assurance that the child will be told about new information that may affect his/her decision to continue to do the study;
- b. a statement when it may be impossible to withdraw from a study (e.g., anonymized data/samples);
- c. information about when a researcher may need to withdraw the child from the study;
- d. information about how the child's identity of child will be protected;
- e. information about when the researcher has a duty to tell others if worried about the child's well-being;
- f. information about receiving compensation for participation as it relates to covering expenses, the value of a thank you gift, and prorated value for partial participation;

TCPS2 Article 3.2
21 CFR 50 Subpart D 50.25
ICH GCP 4.8.2
Policy REB-705

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- g. name, phone number, and email address of the researcher who can answer questions about the study; and,
- h. name, phone number, and email address of the person in the REB office who the child can contact if unsure or worried about doing the study.

The LPI must explain why these additional elements are not included for a particular project (e.g., including additional element 'x' would cause unnecessary confusion/fear in younger children during the assent discussion). However, the LPI should propose a flexible strategy to include additional elements in studies where the rationale applies only to some participants (e.g., a study that involves both younger children and mature adolescents).

In some cases, the REB may require elements that approach the requirements of informed consent per REB-701. This may be required in studies that include adolescents who have an emerging capacity to consent or may develop/regain a capacity to consent during the conduct of the study.

3.3 Specific Assent Documentation Requirements for Clinical Trials

A clinical trial is broadly defined as 'any investigation involving participants that evaluates the effects of one or more health-related interventions on health outcomes.' A regulated clinical trial is an investigation in respect of a drug for use in humans that is intended to discover or verify the clinical, pharmacological or pharmacodynamic effects of the drug, identify any adverse events in respect of the drug, study the absorption, distribution, metabolism and excretion of the drug, or ascertain the safety or efficacy of the drug.

TCPS2 Chapter 11 (p 151)

Health Canada, Food and Drug Regulations (CRC c870 (2106), Division 5, C.05.001)

The assent disclosure for a clinical trial must include the elements required for all studies (Section 3.2 above) and, in addition, the following elements are **commonly required**:

- a. the trial interventions and the chance of assignment to each intervention;
- b. a description of those procedures that are investigational and those that are standard care; and,
- c. the alternative procedures or interventions that may be available to the child and their potential benefits and risks.

TCPS2 Article 11.2

If the clinical trial involves genetic testing, a description of the separate processes used for obtaining and documenting informed assent must be included and have the necessary elements described in Section 3.4 below.

Guidance Document for Clinical Trial Sponsors: Clinical Trial Applications (Health Canada File: 13-108409-403)

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3.4 Specific Assent Documentation Requirements for Research Studies Involving of Human Biological Material

Assent disclosures for research that seeks assent from prospective participants to collect human biological materials must include the elements required for all studies (Section 3.2 above) and, in addition, the following elements are **commonly required**:

- a. the type and amount of biological materials to be taken;
- b. how the biological material will be taken, the safety steps and developmentally-appropriate contextual information about the level and duration of discomfort associated with study procedures;
- c. the measures employed to protect privacy and minimize risks to participants;
- d. how long the biological materials will be kept, how they will be stored and protected, and how the identity of the child will be protected;
- e. the plan for sharing individual results including material incidental findings.

TCPS2 Article 11.2

45 CFR 46 (Section 46.116)
21CFR 50.25

ICH GCP 4.8.10

CAN/CGSB-191.1-2013 –
(4.4.4.2.9)

TCPS2 Article 3.4

3.5 Revisions to the Assent Disclosures

The assent disclosures must be amended whenever important new information becomes available that may be relevant to the child's assent and parent's consent, and the child's willingness to continue to participate. Any revisions made to the approved assent disclosures must be submitted to the REB for review and approval prior to use. Refer to Policy REB-409 for amendment request submissions to the REB.

ICH GCP Article 4.8.2

TCPS2 Article 3.3

CAN/CGSB-191.1-2013 –
(4.4.3.3), (4.4.4.2.11)
Best Practices, Article 3.3

Policy REB-409

Revision History

V2/June 2016 : Added research purpose as a required element for assent disclosures. Changed 'generally required' to 'commonly required' elements of informed assent to be consistent with the elements of informed consent policy. Corrected name of Research, Teaching and Learning Committee.