Holland Bloorview
Kids Rehabilitation Hospital

POLICY: SOP-705	**INFORMED ASSENT PROCESS**		
This policy pertains to:	The activities of researchers and 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:	October 23, 2020	**Supersedes documents dated:**	June 2016
Approved:	Chair, Holland Bloorview REB Research, Teaching & Learning Committee		

1. PURPOSE

REFERENCES

The purpose of this SOP is to describe the process for obtaining and documenting initial and ongoing assent as set forth by:

- The Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS2 2018)
- 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)

and informed by best practices and a synthesis of research evidence in:

- Centre for Genomics and Policy & Maternal Infant and Youth Research Network. *Best Practices for Health Research Involving Children and Adolescents.* 2012. *('Best Practices')*
- Constand M, Tanel N, Ryan SE. PAeDS-MoRe: A framework for the development and review of research assent protocols involving children and adolescents. *Research Ethics.*2015;11:15-38. *('PAeDS-MoRe Framework')*

2. POLICY STATEMENT

An important mechanism for respecting autonomy in research is the requirement to seek free, informed and ongoing consent from research participants. Children and youth ('children'), however, may have developing, impaired, or diminished ability to understand and appreciate factors that may influence decisions about research participation. While parents most often assume the role as substitute decision makers, researchers must also determine the wishes of children who have some capacity for decision making by seeking

TCPS2 Article 1.1

TCPS2 Articles 4.4
Best Practices, Article 3.2

CFR 46 Subpart D 46.402
Best Practices, Article 3.1

their assent before study enrolment. Assent may be defined as 'a child's affirmative agreement to participate in research.'

Respect for Persons requires researchers to involve children in the decision-making process to the greatest extent possible and offer them an opportunity to express their wishes meaningfully. While a child's assent is insufficient without parental consent, researchers must respect expressions of dissent and signs suggesting a child does not wish to participate must be respected – except if this requirement is waived by the REB (e.g., studies involving infants/toddlers).

TCPS2 Articles 3.10
ICH GCP Article 4.8.12
Best Practices Section 3.2

The Local Principal Investigator (LPI) and REB are responsible for ensuring that the informed assent process used to determine and document the wishes of children is in line with applicable policies, regulations, and best practices, and has received REB approval. The researcher must provide the child ample time, an opportunity to ask questions, and discuss possible participation freely with parents and others before making or contributing to a decision about participation in a research study.

Best Practices Section 4.1.1

Best Practices Section 3.2

3. SPECIFIC POLICIES

3.1 Informed Assent Process Requirements

The REB must approve the research assent process and the assent information form/script ('assent disclosure') before recruitment begins. The PAeDS-MoRe process below is a framework for research assent processes involving children who do not have the capacity to consent.. SOP-704 describes the assent elements required and generally required for assent disclosures. Researchers should also refer to SOP-701 which details supplementary requirements for informed consent discussions involving participants who do not have the capacity to consent.

TCPS2 Article 3.2
45 CFR 46 Subpart D 46.408
PAeDS-MoRe Framework

Policy SOP-704

Policy SOP-701
TCPS2 Article 3.2

a. Prepare for Assent

Researchers should include a process to understand the needs of prospective participants and familiarize children and their parent, caregiver, or substitute decision maker ('parent') with the purpose of research and the meaning of free, informed, and ongoing consent and assent. Protocols should include ways to inform the child about how research is different from clinical services especially when familiar healthcare providers participate in research, and research activities are conducted within a hospital or other clinical setting.

TCPS2 Article 3.1

TCPS2 Chapter 11

b. Assess Readiness Protocols should include assessment of a child's cognitive, emotional, and physical readiness to take part in the assent discussion. This may include consulting with the parent to identify and ready appropriate accommodations to support the discussion with the child and the ensuing decision-

making process. The researcher must be able to share study information in a suitable way and assist the child to make and contribute to a decision about participation.

TCPS2 Article 3.9

c. Discuss the Study It is generally required that written information disclosures be provided before the consent/assent discussion to allow time for the child and parent to discuss the research opportunity. Unless justified otherwise, the researcher should discuss key elements of informed consent/assent with both the parent and child present so the parent can help communicate complex aspects of the study to the greatest extent possible. The researcher should present and discuss the research opportunity in a developmentally-appropriate manner and where possible in a familiar environment to promote optimal understanding and appreciation. Refer to SOP-704 for the required elements of informed assent.

TCPS 2 Article 3.9
Best Practices Section 3.1

Policy SOP-704

d. Seek Decision The researcher should be confident in the child's general understanding of the purpose of the research being conducted, role as a research participant, associated risks and benefits, as well as the voluntary nature of participation and alternatives to participation before seeking a decision about participation. The researcher should decide how dissent will be assessed including possible verbal and non-verbal dissent indicators. Documenting assent via the signature of the child is generally recommended, where possible, but may be replaced by documenting the child's verbal/non-verbal indication of assent (see SOP-704). Participants should be offered a copy of the assent disclosure and a signed copy of the signature page.

TCPS 2 Article 3.9

ICH GCP Article 4.8.12
TCPS2 Articles 3.1
Best Practices Section 4.1.2
Policy SOP-704

e. Monitor Decision Researchers should include in their protocol that they will monitor a child's assent to participate and capacity to consent during the research study, and reconfirm the child's desire to continue participation throughout the study. In unique studies and with acceptable justification, the REB may waive the requirement for researchers to seek and monitor a child's decision regarding participation where there is no reasonable alternative other than what is offered in research and the child may receive a direct benefit.

Best Practices Section 3.2

TCPS 2 Article 3.3
Best Practices Section 8.1
45 CRF 46 Subpart D 46.408
21 CFR 50 Subpart D 50.55

f. Respect Role Researchers must include in their protocol how they will respect a child's role as a research participant and contribution to scientific advancement. This could take the form of an end-of-study meeting with the child and/or a letter of thanks that includes a study summary written at a developmentally-appropriate level.

3.2 Ongoing Informed Assent

a. Researchers must provide parents who consent and their child who assents with information relevant to ongoing participation.
b. Important new information shall be communicated in a timely manner. In particular, researchers must disclose changes to the risks or potential benefits of the research. The communication should be documented in the participant's study-related research files. — TCPS 2 Articles 1.1 and 11.12; Best Practices Section 3.1, 3.2
c. Revisions made to the assent processes and disclosures are required whenever new important information becomes available. These revisions must be submitted to the REB for review and approval.
d. Participants affected by the changes made to the informed consent form and assent disclosures related to any new and important information must be re-consented and re-assented after the REB approves this plan. — TCPS2 Article 3.3; ICH GCP Article 4.8.12)
e. Participants must be offered a signed copy of the revised assent disclosure. — ICH GCP 4.8.2; ICH GCP Article 4.8.14; TCPS2 Article 3.9
f. In the case of children who are unable to assent at the start of their research involvement, the researcher must seek their assent to continue participation once they are able to understand the purpose of the research as well as its risks and benefits. — TCPS2 Article 3.3
g. If a child acquires or regains capacity during the course of the research, the researcher shall promptly seek the participant's consent as a condition of continuing participation. — TCPS2 Article 3.3

3.3 Assent for Non-Therapeutic Trials

a. The REB may approve non-therapeutic trials with children who assent only if the following criteria are met:
    i. The objectives of the research study cannot be met with participants who have the capacity to consent;
    ii. The foreseeable risks to the participant are minimal;
    iii. The negative impact on the participant's well-being is minimized and low; — ICH GCP Article 4.8.14
    iv. The research study is not prohibited by law;
    v. The REB's approval is expressly sought on the inclusion of such participants and written approval covers this aspect of the study.

    Such research studies, unless an exception is justified, should be conducted in assenting participants having a disability or condition for which the study intervention is intended. — ICH GCP 4.8.14; TCPS2 Article 3.12; Best Practices, Article 3.2
    Researchers must closely monitor participants in these trials and withdraw them if they are unduly distressed. — TCPS2 Article 3.12; ICH GCP 4.8.2

3.4 Documentation of Assent

a. The REB generally requires evidence of assent. Typically, this evidence is provided by a signed and dated assent form. However, there are other means of documenting assent that are equally ethically acceptable, including verbal or non-verbal assent, field notes, and other strategies. Refer to SOP-704 for further guidance. Where valid reasons for not recording assent in writing exist, the REB must approve alternative procedures used to document a communicated willingness to participate in a research study.

ICH GCP 4.8.2
21 CFR 50 Subpart D 50.55

b. For regulated clinical trials, the research team member who obtained assent must record evidence of the assent discussion in the source documentation including statements of:
   i. the child's basic understanding of the material presented to the greatest extent possible;
   ii. the child having been given the opportunity to decide whether or not to participate;
   iii. the child being given adequate time to ask questions about the research study and that the questions were answered to the satisfaction of the participant; and,
   iv. confirmation that the parent consents and the child assents before initiating any study-related procedures.

Revision History
V3/September 2020 : Removed the requirement for the LPI to justify not including some of the assent process elements . Revised the SOP reference numbers to correspond to N2/CAREB SOPs. Removed the reference to CAN/CGSB as these standards were withdrawn and are no longer applicable. Revised the SOP numbering to correspond with the N2/CAREB SOP nomenclature.
V2/June 2016 : Corrected name of Research, Teaching and Learning Committee.