Holland Bloorview
Kids Rehabilitation Hospital

	REB REVIEW OF RESEARCH		
POLICY: REB-701	**INFORMED CONSENT 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:	March 2018	**Supersedes documents dated:**	V3: January 2017
Approved:	Chair of the REB Research, Teaching & Learning Advisory Committee		

1. PURPOSE

REFERENCES

The purpose of this SOP is to describe the necessary elements for disclosure of information to make an informed decision to participate in a research study as set forth in:

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

2. POLICY STATEMENT

TCPS2 Article 3.2

ICH GCP 4.8

Researchers must provide prospective participants – or authorized third parties – full disclosure of all information necessary for making a free and informed decision to participate in a research project.

The Local Principal Investigator (LPI) and the REB are jointly responsible for ensuring that all necessary information is included so prospective participants can make an informed decision about participation and ongoing participation in a research study.

The REB must approve the Informed Consent Form (ICF) and/or other means to document informed consent before a researcher conducts any study procedures involving participants.

The LPI is responsible for ensuring and documenting that the ICF and/or other approved means is provided to prospective participants so they may make a free and informed decision according to current applicable regulations.

3. SPECIFIC POLICIES

The following policies provide general and specific ICF documentation requirements for all studies including clinical trials.

3.1 General ICF Documentation Requirements for All Studies

a. Use language in the ICF that is as nontechnical as practical and understandable to the participant or the participant's substitute decision maker (SDM) (normally the parent) as ranked in the Health Care Consent Act – and the impartial witness where applicable.
b. Use a signature page that has a statement indicating that the participant discussed the information contained in the ICF with the researcher, had all questions answered, and agrees to participate in the study. The page must allow the participant (or SDM) to print his/her name, sign, and date beneath this statement;
c. Use a signature page that has a statement beneath the participant's signature that the researcher discussed the ICF with the participant or the legally acceptable representative and answered all questions. The page must allow the researcher to print his/her name, sign, and date beneath this statement;
d. If the participant or SDM is unable to read, use a signature page that also has a statement that the participant understands the information in the ICF and agrees to participate in the study. The page must allow the person assisting with the consent process (either an impartial witness or a translator) to print his/her name, sign, and date beneath this statement;
e. Unless otherwise approved by the REB, use the Bloorview Research Institute logo on both the first page of the research information letter and signature page of the ICF. Include the consent version date and page numbers in the footer of all pages of the consent form as well as the assigned REB number in the header. Use pagination in the form 'Page x of y' on each page.

TCPS2 Article 3.2

ICH GCP 4.8

45 CFR 46.117
21 CFR 50.25

Health Care Consent Act, 1996 (http://www.e-laws.gov.on.ca/html/statutes/english/elaws_statutes_96h02_e.htm

3.2 Specific ICF Documentation Requirements

For consent to be informed, prospective participants shall be given adequate time and opportunity to assimilate the information provided, pose any questions they may have, and discuss and consider whether they will participate.

TCPS2 Article 3.2

ICH GCP 4.8

45 CFR 46.117
21 CFR 50.25

The REB will ensure that the proposed time, opportunity, and ICF provide the necessary elements and conditions for free and

CAN/CGSB-191.1-2013 – (4.4.4.2.9)

informed consent. Below is a list of commonly required ICF elements.

Although not all listed elements will be required for all research studies, the REB may ask the researcher to explain why omitted elements are not included for a particular project.

a. information that the individual is being invited to participate in a research project;
b. a statement of the research purpose, the identity of the researcher, the identity of the funder or sponsor, the expected duration and nature of participation, the number of participants involved at Holland Bloorview and all sites, a description of research procedures and an explanation of the responsibilities of the participant;
c. all reasonable foreseeable risks and potential benefits, both to the participants and in general, that may arise from research participation; when there is no intended clinical benefit to the participant, the participant should be made aware of this;
d. an assurance that prospective participants:
    i. are under no obligation to participate; are free to withdraw at any time without prejudice to pre-existing entitlements;
    ii. will be given, in a timely manner throughout the course of the research project, information that is relevant to their decision to continue or withdraw from participation and a description of the process for this to occur as well as for obtaining their ongoing consent;
    iii. will be given information on their rights and the process to request the withdrawal of data or human biological materials, including any limitations on the feasibility of withdrawals;

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e. information concerning the possibility of commercialization of research findings, and the presence of any real, potential or perceived conflicts of interest on the part of the researchers, their institutions or the research sponsors;
f. a statement concerning any personal benefits that may accrue to the qualified investigator;
g. the measures to be undertaken for the dissemination of research results and whether participants will be identified directly or indirectly;
h. the identity and contact information of a qualified designated representative who can explain scientific aspects of the research to participants;
i. the identity and contact information of the appropriate individual outside of the research team whom participants may contact regarding possible ethical issues in the research;
j. an indication of what information will be collected about

participants and for what purpose; an indication of who will have access to information collected about the identity of participants, a description of how confidentiality will be protected, a description of the anticipated uses of data; and information indicating who may have a duty to disclose information collected, and to whom such a disclosure could be made; information about any proposed data linkages and the likelihood that identifiable data will be created through the linkage;

CAN/CGSB-191.1-2013 – (4.4.4.2.16)

TCPS2 Article 5.7

k. a statement that Holland Bloorview representatives, the Holland Bloorview REB, and monitors/auditors/ regulatory authorities (where relevant) will be granted direct access to the participant's research records for verification of research procedures and/or data and compliance with relevant policies, without violating the confidentiality of the participant, to the extent permitted by the applicable laws and regulations;
l. information about payments, including incentives for participants, reimbursement for participation-related expenses and compensation for injury;
m. a statement to the effect that, by consenting, participants have not waived any rights to legal recourse in the event of research-related harm.
n. a statement that outlines the process involved for termination of participation.

TCPS2 Article 3.4

o. a statement that describes the plan for disclosing any material incidental findings to the participant or the participant's SDM

3.3 Specific Documentation Requirements for Clinical Trials

TCPS2 Article 11.2
International Committee of Medical Journal Editors (http://www.icmje.org/publishing_10register.html)

A clinical trial is any investigation involving participants that evaluates the effects of one or more health-related interventions on health outcomes. The LPI must register a clinical trial in a public trials registry if the study prospectively assigns participants to intervention and comparison groups to study the cause-and-effect relationship between a medical intervention and a health outcome.

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

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.

The ICF for a clinical trial must include the elements required for all studies (Section 3.2 above) and, in addition, the following elements:

a. the trial treatment(s) and the probability for random assignments to each treatment;
b. a description of those procedures that are investigational and those that are standard of care;
c. information on stopping rules and when the researchers may remove participants from the trial;
d. details on access to the new drug upon trial completion;
e. the alternative procedure(s) or course(s) of treatment that may be available to the participant, and their important potential benefits and risks;
f. the particular treatment or procedure may involve risk to the research participant or to an embryo or fetus, should the participant be or become pregnant, that are currently unforeseeable;
g. for research involving more than minimal risk, an explanation as to whether compensation and/or medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;
h. a statement that monitors, auditors, Holland Bloorview Representatives, the Holland Bloorview REB, and the regulatory authorities (where relevant) will be granted direct access to the participant's health records and/or research records for verification of clinical trial procedures and/or data and compliance with relevant policies, without violating the confidentiality of the participant, to the extent permitted by the applicable laws and regulations;
i. a statement indicating where applicable clinical trials will be registered and publicly accessible on the Web including the name of the registry and the unique identifying code assigned by the clinical trial registry. For *applicable* clinical (drug) trials subject to FDA regulations, the following statement must be included on the ICF: "A description of this clinical trial will be available on *http://www.ClinicalTrials.gov*, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time."

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)

CAN/CGSB-191.1-2013 – (4.4.3.3), (4.4.4.2.11)

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

CAN/CGSB-191.1-2013 – (4.4.3.2)

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

TCPS2 Article 13.2
TCPS2 Article 13.7

The ICF for a research study that seeks consent 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:

a. the type and amount of biological materials to be taken;
b. the manner in which the biological material will be taken, and the safety and invasiveness of the procedures for acquisition;
c. the intended uses of the biological materials including any commercial use;
d. the measures employed to protect the privacy and minimize risks to participants;
e. the length of time the biological materials will be kept, how they will be preserved, location of storage (i.e. Company/Institution Name, City, Country) and processes for security, access and disposal, if applicable;
f. any anticipated linkage of biological materials with information about the participants;
g. the researcher's plan for handling results and findings, including clinically actionable information and incidental findings.

3.5 Revisions to the Informed Consent Form

The ICF must be amended whenever important new information becomes available that may be relevant to the participant's consent and willingness to continue to participate. Any revisions made to the approved ICF 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
Policy REB-409

Revision History

V2/July 2014 : CAN/CGSB-191.1-2013 references incorporated to reflect compliance. Changed Research Advisory Committee to Research, Teaching & Learning Advisory Committee. Revised section 3.2: added the following required elements for ICFs: a process for disclosing new information and for obtaining ongoing consent; a statement concerning any personal benefits that may accrue to the qualified investigator; information about any possible data linkages; a statement that outlines the process involved for termination of participation; a statement that describes the plan for disclosing any material incidental findings to the participant or the participant's SDM. Revised section 3.3: added the following required elements for clinical trial ICFs: the particular treatment or procedure may involve risk to the research participant or to an embryo or fetus that are currently unforeseeable; the name of the registry and the unique identifying code assigned by the clinical trial registry. Clarified that if the clinical trial involves optional genetic testing, a description of the separate processes used for obtaining and documenting informed consent and assent is required.

V3/ January 2017: Revised to describe access to research records by Holland Bloorview representatives, Holland Bloorview REB, monitors/auditors/regulatory authorities for verification of research procedures and compliance.

V4/January 2018: Revised section 3.2 to include the requirement that participants be informed if there is no intended clinical benefit for their participation in a research study as per GCP 4.8.10(h).