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# Research Ethics Board Standard Operating Policies and Procedures

Informed Consent Process

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| **APPROVED BY** | Vice President, Research | | |

The WCH REO webpage version of this document is considered the most current.

Please ensure that you have reviewed all linked documents and other reference material within this SOP

## 1.0 POLICY STATEMENT:

This Standard Operating Procedure (SOP) describes the process for obtaining and documenting initial and ongoing informed consent as set forth by:

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)

An important mechanism for respecting participants' autonomy in research is the requirement to seek their free, informed and ongoing consent. This policy reflects the commitment that participation in research, including participation through the use of one's data or biological materials, should be a matter of choice. Choice must be informed for it to be meaningful. An informed choice 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.

## 2.0 DEFINITION(S):

See Glossary of Terms

## 3.0 RESPONSIBILITY:

This SOP applies to the REB Chair, Vice-Chair, REB Members, Research Ethics Office (REO) staff and Investigators.

The REB, Investigator and research team members are jointly responsible for ensuring that consent is: (a) given voluntarily and may be withdrawn at any time; (b) informed in that participants will receive full disclosure of all information necessary to make an informed decision whether or not to participate; and, (c) an ongoing process which is maintained throughout the research project.

The Investigator and REB are responsible for confirming that the informed consent process is in line with applicable policies and regulations prior to providing approval to proceed.

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The Investigator is responsible for ensuring that all written and oral information is provided to, and ample time is allowed for, prospective participants to make a free and informed decision concerning participation. Further, the Investigator is responsible for ensuring that the consent process is documented according to applicable policies and regulations.

### 4.0 PROCEDURES:

#### 4.1. Requirements for Informed Consent Discussion(s)

4.1.1. The REB must approve the consent process and the Informed Consent Form (ICF) before recruitment begins. The *WCH REB Informed Consent Elements SOP* describes the necessary elements for disclosure of information to make an informed decision to participate in research. The REB will consider both participant risk level and vulnerability when judging the adequacy of the time provided for participants to review the ICF before the consent discussion.

4.1.2. The informed consent discussion must 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.

4.1.3. The consent discussion must inform the prospective participant of all the essential elements described within the approved ICF.

4.1.4. The Investigator should answer the prospective participant's questions. The Investigator should also ask the participant study-related questions to assess whether he/she understands and appreciates the information provided.

4.1.5. The researcher should ask whether the prospective participant is interested in participating. If so, the prospective participant must sign and date the signature page of the ICF unless otherwise approved by the REB. The Investigator who obtains informed consent must also sign and date the ICF.

4.1.6. The participant should be offered a signed copy of the information and consent form.

4.1.7. The original signed ICF must be filed with study-related research files.

#### 4.2. Requirements for Informed Consent Discussion Involving Participants Who Do Not Have the Capacity to Consent

4.2.1. Capacity refers to the person's ability to understand and appreciate relevant information and appreciate the potential consequences of the decision on whether or not to participate in a research study. Capacity to consent is study-specific, is assumed to be present unless it can be shown otherwise, and should be considered during the consent discussion.

4.2.2. The Investigator will submit for REB approval a study-specific process to assess whether a prospective participant has the capacity to consent to participate in the study.

4.2.3. If the participant does not have the capacity to consent, then the highest available substitute decision maker as ranked in the *Health Care Consent Act* must consent on behalf of the participant.

4.2.4. The Investigator must conduct the informed consent process outlined in Section 4.1 involving the substitute decision maker and, to the extent possible, the prospective participant. The REB may ask the WCH Principal Investigator to justify a proposal to conduct a consent discussion without both the participant and substitute decision maker present.

4.2.5. The prospective participant should be informed about the study to the extent compatible with his/her understanding. Where possible, the researcher should discuss all ICF elements with the prospective participant using approaches that are developmentally appropriate.

4.2.6. Prospective participants who lack the capacity to consent may be capable of verbally or physically assenting to, or dissenting from, participation in research. The REB may request that the LPI submit a plan for the researcher to assess verbal and non-verbal indicators of assent and dissent.

4.2.7. While assent would not be sufficient to permit an incapable participant to take part in a study in the absence of consent by a substitute decision maker, the expression of dissent or signs suggesting a wish not to participate must be respected. The REB may waive this requirement in (therapeutic) studies where the participant may receive a direct benefit.

4.2.8. Where practically possible, the participant should sign and date a signature page (assent form) to indicate assent.

### 4.3. Ongoing Informed Consent

4.3.1. The research team must provide participants with all information relevant to their ongoing consent to participate in research.

4.3.2. 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.

4.3.3. Revisions made to the ICF are required whenever new important information becomes available and must be submitted to the REB for review and approval.

4.3.4. Participants that are affected by the changes made to the information and consent form related to any new and important information must be re-consented after REB approval is obtained.

4.3.5. Participants must be offered a signed copy of the revised ICF.

4.3.6. If a participant 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.

### 4.4. Informed Consent for Non-Therapeutic Trials

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4.4.1. In general, research studies in which there is no anticipated direct benefit to the participant (non-therapeutic) should only be conducted with participants who have the capacity to consent and who sign and date the information and consent form themselves.

4.4.2. The REB may approve non-therapeutic research studies with participants who lack the capacity to consent only if the following criteria are met:

1. The objectives of the research study cannot be met with participants who do have the capacity to consent;
2. The foreseeable risks to the participant are low;
3. The negative impact on the participant's well-being is minimized and low;
4. The research study is not prohibited by law;
5. The REB's approval is expressly sought on the inclusion of such participants and the written approval covers this aspect of the study.

4.4.3 Such research studies, unless an exception is justified, should be conducted with participants having a disease or condition for which the investigational product is intended. The researchers should closely monitor participants in these trials and withdraw them if they appear to be unduly distressed.

### 4.5. Documentation of Informed Consent

4.5.1 The REB requires evidence of consent. Typically, this evidence is provided by a signed ICF. However, there are other means of documenting consent that are equally ethically acceptable, including oral consent, field notes and other strategies. Consent may also be demonstrated solely by the actions of the participant (e.g., through the return of a completed questionnaire). Where there are valid reasons for not recording consent in writing, the procedures used to seek consent must be approved by the REB.

4.5.2 For regulated clinical trials, the research team member who obtained informed consent must record evidence of the informed consent discussion in the source documentation including statements of:

i. the participants comprehension/understanding of the material presented and reviewed;
ii. the participant having been given the opportunity to read the information and consent form and decide whether or not to participate;
iii. the participant being given adequate time to ask questions about the research study and that the questions were answered to the satisfaction of the participant;
iv. confirmation that informed consent and that the participant signed the information and consent form prior to initiating any study-related procedures.

### 4.6. Translation

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4.6.1. The informed consent document should be in a language understandable to the participant (or acceptable representative).

4.6.2. When a study participant is non-English speaking, documentation of informed consent can be by one of two methods:

4.6.3. Written consent: The REB approved English version of the informed consent document is translated to the participant's native language. Translated informed consent must be accompanied by an attestation from the translator certifying that the translated informed consent accurately reflects the REB approved English informed consent. For non-clinical studies with limited budgets, the REB will accept translations from a qualified person who can demonstrate that they have received certification from a professional regulatory body or association that they are fluent in the language, and further can certify accurate translation of the document.

4.6.4. Oral consent: A translator/intermediary fluent in both English and the participant's native language translates the REB approved English consent form orally to the participant. The translator/intermediary should be an impartial person. When the person obtaining consent is assisted by a translator/intermediary, the translator/intermediary must sign and date the consent form attesting that the study was accurately explained to, and appeared to be understood by the participant;

4.6.5. The REB requires that the translated materials be submitted for review and approval prior to use in enrolling non-English speaking participants. The investigator must include a certificate or statement by the translator/intermediary indicating that the translated materials are a true and accurate translation of the REB-approved English materials;

4.6.6. The REB may follow delegated review procedures to review and approve translated materials if the English language materials have already been approved and the signed translation certificate or statement is on file;

4.6.7. A translator/intermediary should be available to the study participant throughout the study;

4.6.8. The translator/intermediary must sign and date the consent form attesting that the study was accurately explained to, and appeared to be understood by the participant.

**5.0 REFERENCES:**

1. Holland Bloorview Research Ethics Board Standard Operating Procedure (REB-702), Informed Consent Process
2. Sunnybrook Health Sciences Centre Research Ethics Board Standard Operating Procedure– *Informed Consent Requirements and Documentation* (REB-SOP-VII-01.003)
3. Health Care Consent Act, 1996 (http://www.e-laws.gov.on.ca/html/statutes/english/elaws_statutes_96h02_e.htm

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4. Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans 2014 (TCPS2), Chapters 1 and 3, Articles 3.1-3.3, 3.9, 3.12,
5. The International Conference on Harmonization (ICH) Guidelines for Good Clinical Practice (GCP), 4.8.2, 4.8.11, 4.8.14,