Vancouver CoastalHealth Research Institute

Standard Operating Procedure

Informed Consent Process

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Site Approval

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Document History

Version	Summary of Changes Made	Effective Date
1	Original document.	09-JUL-2010
2	This version has undergone extensive revision for administrative, educational, regulatory, and clinical changes by individual content experts and the VCHRI SOP Committee. This document has also had substantial formatting, grammatical and glossary updates. It has been classed as a rewritten document.	10-JAN-2016
3	This version has undergone revision for administrative, education, regulatory and clinical changes by individual content experts and VCHRI SOP Committee. There have been changes made to 6.1, 6.2, 6.3. References have been updated and a new definition has been added.	01-Jun-2021

1. PURPOSE

1.1. This Standard Operating Procedure (SOP) describes the procedures for obtaining and documenting initial and ongoing Informed Consent. This SOP also describes Informed Consent guidelines, and the roles of the legally authorized representative and impartial witness.

1.2. It does not apply to obtaining Informed Consent from minors or to exceptions to Informed Consent requirements for emergency situations.

2. SCOPE

2.1. This SOP is applicable to all Clinical Trials/Studies undertaken at the Institution, and to those Research Team Members responsible for performing, reviewing, and/or approving the Informed Consent process.

3. RESPONSIBILITIES

3.1. The Principal Investigator or Sponsor-Investigator is responsible for ensuring that the Informed Consent process and the Informed Consent Form (ICF) meet all of the applicable regulatory, International Conference on Harmonisation (ICH) Good Clinical Practice (GCP), Sponsor, and local requirements.

3.2. Any or all parts of this procedure may be delegated to appropriately trained Research Team Members, but remain the ultimate responsibility of the Principal Investigator or Sponsor-Investigator.

4. RELATED SOPS/DOCUMENTS

4.1. British Columbia Common Clinical Informed Consent Form Template
4.2. UBC Research Ethics Board Guidance Notes
4.3. UBC Research Ethics Board SOPs
4.4. VCHRI SOP 006: Informed Consent Forms
4.5. VCHRI SOP 007: Research Ethics Board-Ongoing Communication
4.6. VCHRI Tool: Reference for Verification of Protocol or Protocol Amendment

5. DEFINITIONS

5.1. See VCHRI Glossary of Terms.

6. PROCEDURE

6.1. Informed Consent before Clinical Trial/Study Entry

6.1.1. Ensure that the person obtaining Informed Consent (as documented on the task delegation log and training record) is qualified by training to do so, and is knowledgeable in the Clinical Trial/Study procedures, and the therapeutic area being studied.

6.1.2. Allow the potential Participant ample time to read the ICF, ask questions and consult with a caregiver or other trusted individual, as may be necessary.

6.1.3. Review the Clinical Trial/Study details with the prospective study Participant, preferably in a quiet, private location. Do not coerce or unduly influence a Participant to participate, or to continue to participate in a Clinical Trial/Study.

6.1.4. Assess the Participant's competence to consent to research, and document if the Participant is deemed not competent to consent.

6.1.5. Fully inform the Participant of all pertinent aspects of the research (i.e., all essential elements as described in the Informed Consent Form), including any additional Research Ethics Board-approved written information, in non-technical language that is easy for the Participant to understand.

6.1.6. Provide the Participant with a copy of the Informed Consent Form and any other REB-approved written information, in either paper or electronic format. Ensure that the most recent version of the REB-approved Informed Consent Form is used. Allow the Participant ample time to read the Informed Consent Form and ask questions. This may include taking the Informed Consent Form home to review with a family member, or other trusted individual.

6.1.7. Ask the Participant questions to assess their comprehension of the material reviewed. Ensure that he/she fully understands the information.

6.1.8. Ascertain the Participant's willingness to participate. Document the decision of any Participant who declines to participate (on a study screening log, or similar).

6.1.9. Inform the Participant that they may withdraw consent at any time. If applicable, as per Tri-Council Policy Statement (TCPS): Inform the Participant that this may include withdrawal of their data and human biological materials. Any circumstances that do not allow withdrawal of data or human biological materials once collected shall be clearly explained to the Participant.

6.1.10. Where applicable, as per ICH GCP, request the Participant's permission to notify his/her family physician or care provider about his/her participation in the Clinical Trial/Study. If the Participant either does not have a family physician or does not wish him or her to be notified of participation in the Clinical Trial/Study, document this accordingly (on the Informed Consent Form or separate signed/dated document). For minimal risk research, the Participant may be given the choice of their family physician NOT being notified as long as the point is clearly made that there could be consequences to this decision. Refer to the BC Common Informed Consent Template for recommended language.

6.1.11. Request that the Participant sign (and initial, if required) and date the Informed Consent Form in the indicated places, using either paper or electronic format.

6.1.12. Sign and date the Informed Consent Form as the person who conducted the Informed Consent discussion. Obtain any other signatures/dates, as indicated on the Informed Consent Form. All required signatures must be obtained prior to enrolling the Participant into the Clinical Trial/Study, or conducting any study-related procedures.

6.1.13. Provide the Participant with a photocopy (or similar if consenting electronically) of the signed and dated document, and any other REB-approved written information reviewed during the Informed Consent discussion.

6.1.14. File the original signed Informed Consent Form with the Essential Documents (and a copy with the medical record/Participant Source Document, as per site practice).

6.1.15. If using an electronic platform is approved by institutional and REB policies, ensure the electronic system being used for informed consent and/or electronic signatures are fully validated as per ICH and regulatory requirements.

6.1.16. Further information on validation of electronic systems for use in Clinical Trials/Studies can be found in Health Canada GUI-100 5.12 Records (related to C.05.012).

6.1.17. Further guidance on electronic consent can be found on the UBC CREB website.

6.2. Ongoing Informed Consent and Re-Consenting

6.2.1 Ensure that the Participant's consent to participate in the Clinical Trial/Study remains valid throughout the Clinical Trial/Study by providing ongoing opportunities for the Participant to ask questions about the Clinical Trial/Study

6.2.2 Communicate any important new information that becomes available, and that may be relevant to the study Participant's consent, in a timely manner. This communication should be documented in the Participant's source documents

6.2.3 Revise the Informed Consent Form (and any other written material), and submit to the Research Ethics Board for approval [Refer to the British Columbia Common Clinical Informed Consent Template and applicable SOPs for Informed Consent Forms and Research Ethics Board submission process].

6.2.4 Re-consent the Participants affected by the changes, after REB approval is obtained (if required) in a timely manner. This communication should be documented in the Participant's Source Documents.

6.2.5 When consenting with a revised full document or a consent form addendum, provide copies of the signed documentation to the Participant.

6.2.6 File the original signed revised document with the study-related Essential Documents (Participant chart or other).

6.2.7 Methods for re-consent/notification include:

6.2.7.1 Informed Consent with a revised full document: Some Sponsors may require that the full consent document be revised and re-signed (either electronically or on paper) by enrolled Participants. If this method is utilized, the new information should be highlighted in some fashion. The Participant will sign the new (revised) ICF.

6.2.7.2 Informed Consent Form addendum: Recommended when new information needs to be communicated to already enrolled Participants. The document consists of new findings/changes and a discussion of these changes in the context of what the Participant originally consented to. The consent form addendum is to be signed at the Participant's next visit.

6.2.7.3 Letter: The letter should contain the following elements of consent (new information, the right to withdraw, and voluntary consent). The nature of the new information dictates whether the Participant needs to sign and return a copy to the Clinical Trial/Study research team.

6.2.7.4 Telephone call: The information provided to the Participant should be documented in the research record. The documentation should include what information was provided, by whom and the date of interaction.

6.3. Participants Incompetent to Provide Informed Consent and/or Assent

6.3.1. A Legally Authorized Representative (LAR) may consent on behalf of Participants who are unconscious, or who are so severely ill or cognitively impaired that they cannot provide informed consent. See specific provincial or local regulations and policies, if required.

6.3.2. In such cases, conduct the Informed Consent procedure with the Participant's LAR. The decision to participate must be made by the LAR in the best interests of the person involved. The LAR must not be the Principal Investigator or a member of the research team.

6.3.3. Inform the Participant to the extent compatible with his or her understanding. If capable, the Participant should also sign and date the ICF.

6.3.4. Obtain signed consent from the Participant as soon as possible, if his/her ability to consent returns, e.g., regains consciousness.

6.3.5. Distribute and file documentation, as described above.

[Refer to the UBC REB Guidance Notes for further information]

6.4. Participants or Legally Authorized Representative Unable to Read (English/French)

6.4.1. If a Participant or Legally Acceptable Representative (LAR) is unable to read, an Impartial Witness must be present during the entire Informed Consent discussion.

6.4.2. Obtain verbal consent from the Participant or LAR, after the Informed Consent Form and any other written information is read and explained to the Participant.

6.4.3. Obtain dated signatures, in electronic or paper format, from both the Participant (if capable) or LAR, and the impartial witness on the Informed Consent Form, where applicable. The signature of the impartial witness attests that the information was accurately explained to, and apparently understood by, the Participant or LAR, and that Informed Consent was freely given by the Participant or LAR.

6.4.4. Distribute and file documentation, as described above.

6.5. Participants Unable to Speak English/French

6.5.1. If the Participant does not speak English or French (where applicable), the Informed Consent discussion must take place in the Participant's first/preferred language, using a qualified interpreter/translator.

6.5.2. Obtain an REB-approved translated Informed Consent Form, if possible.

6.5.3. Obtain the dated signatures of both the Participant and the Interpreter/Translator on the REB-approved Informed Consent Form. By signing the Informed Consent Form, the Interpreter attests that the information in the Informed Consent Form and any other written information was accurately explained to, and apparently understood by the Participant, and that Informed Consent was freely given by the Participant.

6.5.3.1. Please be reminded that the Research Team Members must also communicate with this Participant throughout the entire Clinical Trial/Study, so the Informed Consent process is on-going, not just when the Informed Consent Form is signed.

6.5.4. Distribute and file documentation, as described above.

[Refer to UBC SOP on Documentation of Informed Consent and UBC REB Guidance Notes for further information]

6.6. Participant Consent for Non-Therapeutic Trials

6.6.1. Additional restrictions apply to non-therapeutic research studies (i.e., research studies in which there is no anticipated direct clinical benefit to the Participant). Such studies should be conducted in Participants who personally give consent, and sign and date the Informed Consent Form.

6.6.2. Non-therapeutic research studies may be conducted with Participants, with the consent of a legal representative, provided the following conditions are fulfilled:

6.6.2.1. The objectives of the study cannot be met by means of a study with Participants who can give personal informed consent;

6.6.2.2. The foreseeable risks to the Participants are low;

6.6.2.3. The negative impact on the Participant's well-being is minimized and low;

6.6.2.4. The study is not prohibited by law; and

6.6.2.5. The approval/favorable opinion of the REB is expressly sought on the inclusion of such Participants, and the written approval/favourable opinion covers this aspect.

6.7. Documenting the Informed Consent Process

6.7.1. Record evidence of the Informed Consent process in the Source Documentation, including statements of:

6.7.1.1. The Participant's comprehension of the material reviewed;

6.7.1.2. The Participant having been given ample opportunity to read the Informed Consent Form and to decide whether or not to participate in the Clinical Trial/Study;

6.7.1.3. Adequate time having been given for all questions about the Clinical Trial/Study to be answered to the satisfaction of the Participant;

6.7.1.4. Informed Consent having been obtained prior to initiating any study-related procedures; and

6.7.1.5. Any other relevant information involving the process of Informed Consent.

[Refer to the British Columbia Common Informed Consent Template for a list of statements that should be included above the Informed Consent Form signature section.]

7. REFERENCE(S)

BC Freedom of Information and Protection of Privacy Act, [RSBC 1996, c. 165], as amended from time to time.

British Columbia Common Clinical Informed Consent Template.

Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council of Canada, *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans,* December 2014.

Department of Justice (Canada), Personal Information and Protection and Electronic Documents Act (PIPEDA), , last amended June 23, 2015, current to December 31, 2016

Government of Canada, Medical Devices Regulations, SOR/98-282, May 7, 1998; last amended February 13, 2017, current to March 20, 2017.

Government of Canada, Natural Health Products Regulations, Part 4 Clinical Trials Involving Human Subjects, SOR/2003-196, June 5, 2003; last amended June 1, 2008, current to March 20, 2017.

Health Canada, Food and Drug Regulations, Part C, Division 5, Drugs for Clinical Trials Involving Human Subjects, (Schedule 1024), June 20, 2001.

Health Canada, Guidance Document: Part C, Division 5 of the Food and Drug Regulations "Drugs for Clinical Trials Involving Human Subjects". GUI-0100. August 20, 2019.

International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), ICH Harmonised Guideline, Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice, E6(R2), November 9, 2016.

Network of Networks (N2) Informed Consent Process. SOP008_09. Effective 15 May 2021.

US Food and Drug Administration, Code of Federal Regulations, Title 21, Volume 1:

- Part 11, Electronic Records; Electronic Signatures, (21CFR11).
- Part 50, Protection of Human Subjects, (21CFR50).
- Part 54, Financial Disclosure by Clinical Investigators, (21CFR54).
- Part 56, Institutional Review Boards, (21CFR56).
- Part 312, Investigational New Drug Application (21CFR312).
- Part 314, Applications for FDA Approval to Market a New Drug (21CFR314).

US Department of Health and Human Services, Code of Federal Regulations, Title 45, Part 46, Protection of Human Subjects (45CFR46).

US Department of Health and Human Services, Guidance for Industry: Computerized Systems Used in Clinical Investigations, May 2007.

8. ATTACHMENT(S)

None.