	Obtaining Remote Informed Consent for a Health Canada Clinical Trial.	Effective Date: March 5 2021
Clinical Trials Standard Operating Procedures		Version: Version 1.0
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SOP Owner: Research Quality		

1. **Purpose:**
   This Standard Operating Procedure (SOP) describes the process of conducting remote consent discussion and obtaining informed consent, for research participation when it is not possible for the research team member and potential study participant (or substitute decision maker/SDM) to be in the same room due to a pandemic environment.

2. **Ethical Considerations:**
   Obtaining informed consent from prospective study participants is embedded in all ethical principles, statements and guidelines of research involving human subjects. Examples include**:**

   - Tri-Council Policy Statement (TCPS2)
   - ICH-GCP E6(R2)
   - Declaration of Helsinki
   - The Belmont Report

   The method of obtaining informed consent must be fully approved by the Nova Scotia Health Research Ethics Board prior to obtaining consent from any study participant, regardless of the modality to be used.

3. **Definitions:**

   Capacity: The ability of prospective or actual participants to understand relevant information presented (e.g. purpose of the research, foreseeable risks, and potential benefits), and to appreciate the potential consequences of any decision they make based upon this information.

   Good Clinical Practice (commonly referred to ICH-GCP): an international ethical and scientific quality standard for designing, conducting, recording, and reporting trials that involve the participation of human subjects in drug, natural health products, or medical device trials.

Informed Consent: A process by which a subject voluntarily confirms his or her willingness to participate in a particular trial, after having been informed of all aspects of the trial that are relevant to the subject's decision to participate.

Principal Investigator: The person responsible for the conduct of the trial and for the actions of any member of the research team at the site. Health Canada uses the term Qualified Investigator.

Regulated Health Canada Clinical Trial: research to discover or verify the use of drugs, natural health products, or investigational testing of medical devices. Regulated clinical trials comply with Good Clinical Practice guidelines and TCPS2

Research Ethics Board: a body of researchers, community members, and others with specific expertise established by an institution to review the ethical acceptability of all research involving humans conducted within the institution's jurisdiction or under its auspices.

Substitute Decision Maker (SDM): The legally appointed substitute decision maker able to make treatment decisions when the patient is incapable.

Tri-Council Policy Statement: Statement document that is the foundation of ethical conduct of all research involving humans in Canada.

4. Procedure for first contact of potential study participant consent:

4.1
Ensure the potential study participant has provided permission to contact by signing an "Access to Personal Health Information Consent Form" (http://www.cdha.nshealth.ca/system/files/sites/391/documents/access-personal-health-information-consent-form.doc) or other REB approved method of permission to contact if first contact for a clinical trial.

4.2
Verify the potential study participant or the SDM is still interested in the research.

4.3
Confirm identity of the potential study participant (examples: full name, date of birth, Health Card Number, current address, Primary Health Provider, Specialist Health Care Provided, health condition for which research is being conducted, awareness of signing contact permission form) from the potential study participant or the SDM.

4.4
If required, schedule a mutual appointment time for consent discussion if initial contact time is not convenient for potential study participant or SDM.

4.5
Provide overview of study and step by step process of the consent discussion, and

obtaining the informed consent

- Role of person providing consent discussion and obtaining consent.
- Estimated time for review
- Time for questions
- Answers to questions will be provided by the consenting personnel. If all questions cannot be answered during or at the end of the consent discussion, obtaining consent will be delayed until answered.
- Ability to decline to continue consent discussion at any time
- Participation is voluntary
- Confirmation of questions that coordinator will ask at end of consent discussion (Do you understand you participation is voluntary? what is being studied? what are the risks? what are the benefits?) to confirm understanding of the study and, if applicable, for PI assessment of capacity.
- A witness is required to confirm consent was given and if possible, to be present during the entire consent discussion.

4.6

Send the consent form by mail and/or email, or other appropriate platform and confirm how follow up will happen. Encourage potential study participant to contact site with questions or concerns when receives the consent form.

4.6

Review the entire contents of the REB and Sponsor approved informed consent form to the study participant or SDM, and if possible, a witness, allowing time for questions during the process.

- Allow and encourage questions or clarifications during reading of consent.

4.7

Allow time at end of reading consent for discussion of questions, clarifications, and/or concern.

4.8

Ask the four questions to verify study participant is informed and document the responses.

- Do you understand your participation is voluntary?
- What is being studied?
- What are the risks?
- What are the benefits?

4.9

If the study participant or SDM wishes to participate in the study, ask the participant or SDM and witness to sign and date the consent form on the appropriate lines.

4.10

Confirm a witness observed signature and provided their signature and date on the appropriate line of the consent signature page.

4.11
Arrange for study participant to return signed informed consent. If returning my mail, ensure envelope and stamp have been provided

4.12
Documentation of the entire process:

- How and when did you obtain their name
- How/when/where were you introduced
- Document details of discussion including date and time of first contact
- When and how was the ICF offered to the potential study participant
- What consent version was provided
- What instructions were provided
- Follow up details after ICF was provided
- Date, time, and location of informed consent discussion.
- Who was present and their role.
- List any questions asked and answers provided (and by whom).
- Answers to 4 questions to confirm study participant is informed
- Details of conversation including their participation is voluntary, did they have an opportunity to speak to the PI if required before signing the consent.
- Date and time of informed consent
- Follow up
    - Send copy of signed consent (study participant, witness, and person conducting consent discussion)
    - Plan for review and re-confirmation if will be seeing in person at a future date.

4.13
When signed informed consent is received, the person conducting the consent discussion will sign on the appropriate consent form line on the signature page along with the date informed consent received. Write a note to file as to why the dates of consent signature and conduction of consent dates are not harmonious.

4.14
Provide a copy of the signed consent form to the study participant or SDM and document. The consent does not have to have been signed by the PI or Sub-I at this time.

4.15
Consent will be signed the PI within 2 weeks of study participant signature as per REB requirements. There is no requirement to provide the fully executed signature consent to the study participant.
Document reason if there is a delay of more than 2 weeks between study participant signature and PI/Sub-I signature.

4.16
When feasible, written re-confirmation of informed consent from study participant or SDM and document discussion.

Version History

Version:	Effective:	Approved by:	What's changed:
Original	March 5, 2021	A. Dean M. Chappell	N/A
[Revised / Reaffirmed]	YYYY-MM-DD	[Sponsor or Issuing Authority	[Brief description]