	Obtaining Verbal 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 verbal 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:**

   Attestation: act as a witness and confirms by written or verbal oath

   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.

Verbal consent (non-written consent)
The study participant states their consent to participate, but does not sign any written form.

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

Verbal 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 new to the clinical trial.

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

4.3
Verify identity of the potential study participant (examples: 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 step by step overview 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
Read 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
Receive the study participant or SDM consent, with a witness present, to participate in the clinical trial.

4.10
Receive attestation by the witness that consent was given and document response.

4.11
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
- Attestation of witness.
- Follow up
    - Send copy of blank consent
    - Plan to review and re-confirm participate if will be seen in person at a future date.

❖ If it is not possible to have a witness for the entire consent discussion and/or to confirm consent, document why this could not be done. Include documentation of awareness and approval from Sponsor if no witness possible.

4.12
When feasible, re-confirmation of participation and written signature and date or appropriate means of confirmation of informed consent from study participant or SDM.

4.13
Re-confirmation of person conduction informed consent discussion by signature and date on appropriate line on signature page of consent form.

4.14
Provide copy of signed consent to study participant.

4.15
Document re-confirmation discussion.

4.15
Obtain PI or Sub-I signature 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.

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]