REB guideline for obtaining informed consent remotely for participation in a research study

GUIDELINE STATEMENT

Under certain circumstances, it may be necessary to conduct informed consent procedures for participation in a research study remotely. All resulting alterations to the informed consent procedure shall comply with the current version of the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans – TCPS(2), and where applicable ICH-GCP and the Canadian Food and Drug Regulations (FDR) for Health Canada regulated clinical trials.

The process to obtain informed consent through alternate methods must also be clearly outlined in the protocol. All such informed consent procedures must be submitted to the REB of record for review and approval prior to implementation. Research site personnel, those delegated responsibility for the consenting process by the study investigator, must be trained on the new consent process and have appropriate documentation of this.

The Sunnybrook REB recognizes the following solutions for conducting the informed consent process:

<u>Electronic Consent</u>

- Utilization of an electronic consent system may be considered if the technology is available.
- The system must be validated in accordance with the International Council for Harmonization (ICH) E6 5.5.3.
- All required elements outlined in FDR C.05.010(h) and ICH E6, 4.8.10 must reflected in the informed consent form.

<u>Consent Obtained Verbally by Phone or Video Conference Application (Interventional Research)</u>

- The call in which consent will be obtained must include the research team member obtaining consent, the participant/substitute decision-maker (SDM), and an impartial witness (can be a family member). If desired and feasible, the participant/SDM may invite others to join the call (e.g. next of kin).
- Comprehensive documentation of the consent process is required to be kept on file.
- For Health Canada regulated studies, the impartial witness must sign an attestation:
    - The attestation must confirm that the witness was present during the consent process irrespective of method of communication.
    - A scanned copy or picture of the signed attestation must be forwarded to the study investigator or delegate (by email or text; ensure this meets privacy requirements).

- When it is not possible for an impartial witness to be present, the conversation should be recorded:
  - Parties must verbally agree to recording the conversation.
  - The recording will become part of the trial records and must be archived for the entire study record retention period.
  - Consult with the Privacy Office for appropriate recording options.
- Check with the REB of Record regarding specific attestation requirements.

Consent Obtained Verbally by Phone or Video Conference Application (Observational Research)

- The call in which consent will be obtained will include the research team member obtaining consent and the participant/substitute decision-maker (SDM). If desired and feasible, the participant/SDM may invite others to join the call (e.g. next of kin).
- Once the consent discussion is complete and the participant/SDM verbally confirms their consent to participate in the research study, the person conducting the consent discussion will complete the signature pages of the informed consent form by writing the participant/SDM name, the date of the consent discussion, and their own name, signature, and date of signature.
- Comprehensive documentation of the consent process is required to be kept on file.

Consent Obtained via Email

- Consent documents are to be sent to participants/SDMs via email for their review.
- The email should include an explanation of the consent process and contact information for any questions tha arise prior to signing the documents.
- Conduct informed consent discussion.
- Comprehensive documentation of the consent process is required to be kept on file. Participant/SDM returns a signed copy of the informed consent form to the research team. See above section to determine if an impartial witness is required.
- The research team member signs the consent form and sends the participant/SDM a copy for their records.

References

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 2018. https://ethics.gc.ca/eng/documents/tcps2-2018-en-interactive-final.pdf

Government of Canada, *Food and Drug Regulations: Part C, Division 5, Drugs for Clinical Trials Involving Human Subjects,* August 2022. https://laws-lois.justice.gc.ca/PDF/C.R.C., c. 870.pdf

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International Council for Harmonisation, *Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice E6 (R2)*, November 2016. https://database.ich.org/sites/default/files/E6_R2_Addendum.pdf

Network of Networks (N2). *Standard Operating Procedure 701.003 – Informed Consent Form Requirements and Documentation,* October 2019. https://sunnybrook.ca/uploads/1/hrpp/n2-careb---v003/sop701_003.pdf

Revision History	
Version Date	**Summary of Changes**
August 19, 2022	Original version