Title	Standard Operating Procedure for Remote Consent
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Revised:	
Approved By:	REB Chair

1.0 Purpose:

This Standard Operating Procedure (SOP) describes the process for conducting a remote consent discussion and obtaining informed consent from a potential research participant (or substitute decision maker/ SDM). This document supersedes the previous Guidelines for Remote Consent Document.

2.0 Scope:

This SOP pertains to local Osler research studies that meet the criteria for remote consenting process. The process begins when a participant is identified as a potential candidate for a research study. For OCREB studies, please refer to the Oncology SOP for Remote Consent. For other CTO studies, please confirm that the Board of Record will allow for remote consent.

Criteria:
For the purpose of this document, “remote consent” refers to the process of conducting the consent discussion and obtaining informed consent when the research team and the prospective participant/ Substitute Decision Maker (SDM) are not physically in the same room, and it is unlikely that the participant/SDM will be seen in-person for some time. This procedure can be used to obtain consent from a participant/SDM so that the team can begin conducting study-specific screening procedures. While there may be instances where in-person study activities will appropriately follow remote consent, the expectation remains that if participants/SDM are seen in- person, written re-confirmation of informed consent will be completed and documented in-person, if possible, Verbal consent cannot be used for remote consent at this time.

3.0 Responsibilities:

The research team is responsible for ensuring that the requirements of this SOP and all the applicable regulatory, International Conference on Harmonisation (ICH) Good Clinical Practice (GCP), sponsor, and local requirements are met. The Researcher is also responsible for providing the REB with a detailed description of the of the consent process.

4.0 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.

Food and Drug Administration (FDA): The Food and Drug Administration is a consumer protection agency of the government of the United States of America. The United States regulatory authority charged with, among other responsibilities, granting Investigational New Drug (IND) and New Drug Application (NDA) approvals.
Health Canada (HC/SC): Federal government agency that oversees health and food products.

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.

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.

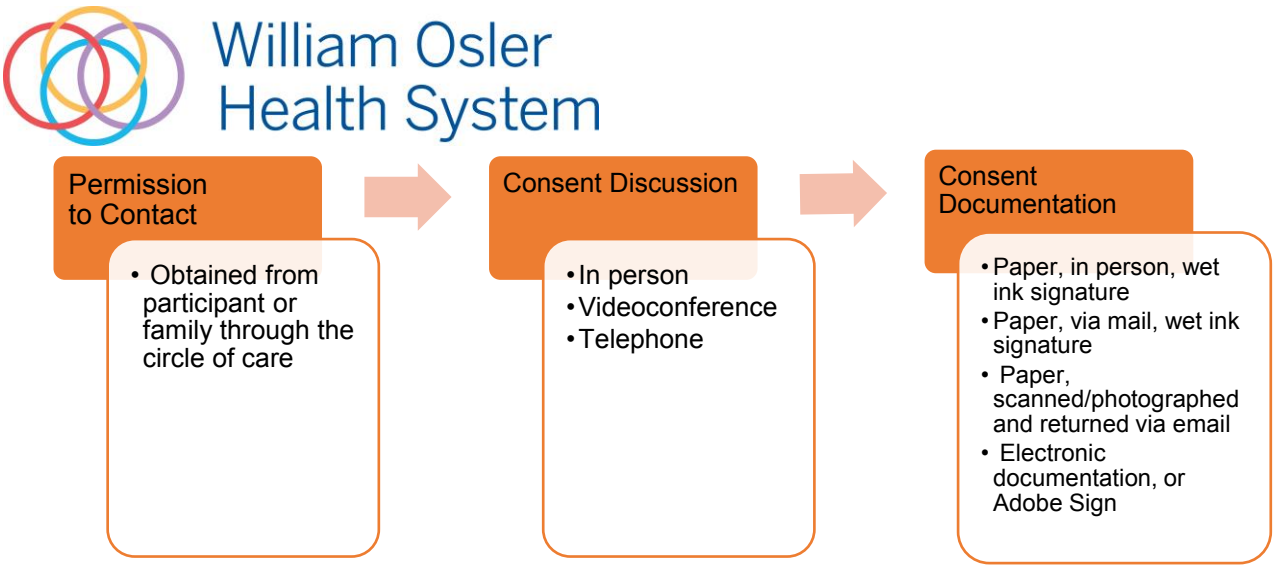
Tri-Council Policy Statement: Statement document that is the foundation of ethical conduct of all research involving humans in Canada.

5.0 Introduction:

The standard REB requirements outlined in REB SOP(s) regarding informed consent, also apply to remote consent. Regardless of the mechanism by which informed consent is obtained, researchers must be certain that voluntary informed consent (or assent as appropriate) has been provided by all research participants (or their SDM, where appropriate) prior to participation in the research project.

Whether conducted in person or remotely, (video, telephone, etc.), informed consent requires a discussion to ensure:

1. participants understand the procedures, risks and benefits of the study,
2. participants can easily ask and get answers to questions, and
3. participants understand that participation is voluntary. The default expectation is for research teams to use videoconference for remote consent discussions.



Study-Specific Considerations:

For each research project where remote consent is proposed, the research team must consider the logistical aspects that may interfere with feasibility for both the participant and researcher who are working offsite.

Please consider the following:

- Is this an US Federally Funded or FDA or Health Canada Regulated study? Regulated studies have different requirements that must be in place in order to conduct remote consent.
- The level of risk of the study
- Sponsors documentation requirements
- How informed consent and the consent process will be documented
- How capacity to consent will be assessed and documented (as applicable)
- When and how the consent process will be explained to the prospective participant so that they are aware of what will happen and what the expectations are
- Do the proposed procedures require prospective participants to have computers / tablets / printers / scanners / internet or other technical components?
- How likely is it that they will have these components?
- Are these otherwise required for study participation?
- To support equitable recruitment, is an alternative option available for those who lack these components or who are technologically inexperienced?
- How will the research team provide a copy of the final signed informed consent form to the research participant?
- Institutional requirements regarding use of email, videoconferencing/teleconferencing technology, electronic signature, and electronic consent platforms
- How will interpretation/ translation be used? If required, please follow N2 CAREB SOP 701.003 and develop a specific addendum for your study

6.0 Process:

Prior to the Remote Consent Discussion:

Research teams should provide the prospective participant with the REB approved informed consent form (ICF) and any other study consent related documents or materials in advance of the remote consent discussion. This can be sent via mail or secure file transfer. Whenever possible, consent forms should be sent by encrypted email. Another option is to send a password protected consent document and to send the password in a different email in order to improve privacy. Teams may also ask the study participants for their preference on if they wish to receive the consent document without encryption or a password.

Options for conducting a remote consent discussion:

1. Videoconferencing: Zoom Health care, MS Teams or Telemedicine
    - Virtual video discussion is preferred because the person obtaining consent can assess the participant's visual cues and ensure the participant understands the research study and the commitment required.
2. Telephone:
    - An option if the participant cannot or will not use videoconferencing, but care must be taken to confirm identity and comprehension
    - Confirm that you are speaking with the right individual
    - Confirm that they did agree to be contacted about the study

Remote Consent Process:

The following is an example of a remote consenting process:

1. Consent for a research team member to contact a participant must first be obtained by someone in their circle of care.

2. Consent to participate in the study is obtained by a member of the research team, NOT someone from the circle of care. This is to minimize the potential of undue influence.

3. The research team contacts the potential participant, briefly explains the study and asks if they are interested in learning more about it, if affirmative they proceed to schedule a remote research appointment.

4. Research staff will send a copy of the REB-approved consent form to the participant using one of the methods listed above.

5. Research staff will include the following disclaimers in all email communication:

    - *"This e-mail message (and any attachments) may contain confidential and/or privileged information for the sole use of the intended recipient. Any review or distribution by anyone other than the person for whom it was originally intended is strictly prohibited. If you have received this e-mail in error, please contact the sender and delete all copies. Opinions, conclusions or other information contained in this e-mail may not be that of the organization."*
    - *"Email is generally not a secure way to communicate sensitive or health-related information as there are many ways for unauthorized users to access email. Emailing back consent forms is not a secure practice."*

6. Participant capacity to consent will be assessed by a regulated healthcare professional. This person may be a member of the research or care team. Research team may also reach out to the clinical team to confirm capacity.

7. Those without capacity to consent for themselves should have a parent/guardian/Substitute Decision Maker (SDM) to consent on their behalf, and assent obtained where possible.

    If assent is required, the research team must have a discussion with both parent/legal guardian/SDM and child participant. If there is a separate assent form, ensure the child participant signs, dates and returns the assent form to the research team, when possible. Otherwise, research team should document assent on the assent form that would accompany the SDM consent.

8. Prior to starting the consent discussion with participant /SDM, verify their identity.
    a. Ask the participant to show their government-issued photo ID and confirm their first and last name.
    b. Consider the additional following statements to confirm identity:
        - "Your contact information was obtained from [describe where/from whom contact information was obtained]."
        - "You are being contacted because you had previously indicated [describe when (e.g., when you participated in study X)] that you were interested in being contacted about future research."
        - "You were sent an information letter about this study [state time frame (e.g., a month ago)].
        - If using telephone consent, ask the participant to confirm that they agreed to be contacted about the study. You can also ask them to confirm their first and last name.

9. Informed consent requires two things: a) a discussion about the research study, and b) documentation of consent.
    a. Consent Discussion: Review all of the material contained in the REB-approved consent form. Ensure the participant/SDM is given time to consider the information and ask any questions they may have.
    b. Consent Documentation: Document the date (time) and identity of the person obtaining and giving consent for the research study.

10. The participant/ SDM sends back the signed and dated consent form. The signed and returned consent form should include all pages, not just the signature page. Return document may be scanned, mailed, faxed or photographed, whatever works best for the participant. Please check with your sponsor if the original 'wet ink' signature is required from the participant. If returning by mail, ensure envelope and stamp have been provided.

11. Upon return receipt of the consent form, it must be signed-off by the research team member who conducted the consent discussion.
    a. Use the date of receipt of the signed consent document, not the date of the consent discussion with patient/SDM.

12. The participant should receive a fully signed, complete copy of the consent form as soon as possible. A complete copy is all pages of the consent form, including the completed signature pages.

13. All required signatures must be obtained prior to enrolling study participants into the research study or conducting any study-related procedures.

14. Document in a separate note, that consent discussion took place remotely.
    a. Example: "Consent discussion was conducted remotely [using video Zoom Healthcare or MS Teams or Telemedicine] on [insert full date]. Electronic documentation of the consent was obtained using [Adobe Sign, etc.] and received from the participant on [insert full date] and signed by the research team member who conducted the consent discussion on [insert full date]."

7.0 Documenting Remote Consent:

The options for documenting remote consent differ based on the type of research project and include considerations including whether it is Health Canada regulated, US federally funded or FDA Regulated.

Research teams must be aware of and are expected to comply with additional requirements from funders, sponsors, and their institution and obtain any additional approvals as applicable. This should occur prior to REB submission.

Type of Research	Acceptable Documentation Method
Observational Research (Not subject to Health Canada regulations, not US regulated)	• Written Signature on Paper Copy by Mail, Email, or Secure File Transfer • Electronic Signatures using approved Electronic Signature Software/e-Consent platforms (Adobe Sign)
Interventional Research (Not subject to Health Canada regulations, not US regulated)	• Written Signature on Paper Copy by Mail, Email, or Secure File Transfer • Electronic Signatures using approved Electronic Signature Software/e-Consent platforms (Adobe Sign)

Health Canada Regulated Research	• The Health Canada regulations note that the process for obtaining informed consent via electronic means should also be detailed in an SOP, including how the form will be explained and discussed with the clinical trial participant (will the participant have the option to sign a paper copy, bring a copy home or have access to an electronic signed copy, etc.) [C.05.012(4)]. • Electronic signatures are considered acceptable, only if the electronic system is fully validated. The proper controls should be in place to ensure that the signature belongs to the user who applied it. • Written Signature on Paper Copy by Mail,
US Federally Funded or FDA Regulated Research	• Written Signature on Paper Copy by Mail • Electronic signature must use 21 CFR Part 11 Compliant Approved Electronic Signature Software/e-Consent platforms

8.0 REB Submission Requirements:

The remote consenting process must be described in either the REB application or a separate addendum. It should include how informed consent will be obtained and documented for a research project. This includes what remote consent option will be used, timeline between a participant receiving the consent form and being asked to document consent (will wet-ink signatures be required etc.), how a participant will receive a fully executed copy of the consent form, how assent (if applicable) will be obtained, and how the informed consent discussion and/or identity verification will occur. If applicable, how other forms of informed consent may be used. The consent process (and any changes) must be approved by the REB prior to implementation.

9.0 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 2022. https://ethics.gc.ca/eng/documents/tcps2-2022-en.pdf

FDA Guidance on Conduct of Clinical Trials of Medical Products During the COVID-19 Public Health Emergency, August 2021. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/fda-guidance-conduct-clinical-trials-medical-products-during-covid-19-public-health-emergency

Government of Canada, Food and Drug Regulations: Part C, Division 5, Drugs for Clinical Trials Involving Human Subjects, August 2022. https://lawslois.justice.gc.ca/PDF/C.R.C., _c._870.pdf

OHRI Virtual Guidelines for Studies Requiring Written Consent: More than Minimal Risk (Regulated and Non-Regulated) & Minimal Risk Studies, July 15, 2021