Ottawa Health Science Network Research Ethics Board (OHSN-REB) /
Conseil d'éthique de la recherche du réseau de science de la santé d'Ottawa (CÉR-RSSO)

Virtual Guidelines for Studies Requiring Written Consent: More than Minimal Risk (Regulated and Non-Regulated) & Minimal Risk Studies

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Introduction

Consent procedures must adhere to ethical principles and privacy protections, even in a remote consent process. Research teams may require flexible informed consent process when the researcher and participant cannot meet in person. This document provides guidance for remote consent options, signatures and consent documentation. It also provides suggestions for how to approach participants through virtual interactions. Different approaches can still be used, provided the privacy and security details of the approach are approved by any combination of the applicable offices, such as, REB, Clinical Research Facilitation, Privacy Office, Virtual Care Team, TOH Information Systems, Method Centre, and/or Contracts Office. The REB will determine on a case-by-case basis whether the requested adaptations are appropriate for any given study.

All remote consent documentation plans must be approved by the REB. We encourage study teams to send a meeting request to rebadministration@ohri.ca to discuss any plans beyond what this document offers. The REB Office can arrange a collaborative meeting with any of the offices listed above via a MS Teams virtual meeting. We also encourage that the meeting occurs in advance of your REB application submission to reduce delays with review.

In addition, research teams must also be aware that they must comply with any additional requirements of their sponsors, funders and other institutions; working together ensures the safety and privacy protections of our staff and study participants.

A virtual videoconference discussion is the most preferred method for a remote consenting process because the person obtaining consent can assess the participant's visual cues and ensure the participant understands the research study and the commitment required.

If you have any questions about your study plan to connect with participants virtually, please visit the following sites for further information:

- Legal, Privacy, Governance & Risk Management Services
- Virtual Care Services
- Join the MS Team User Group
- OHSN-REB Website, Guidance and REB Templates Tab

Message for Health Canada and/or US Regulated Research

- It is Health Canada's recommendation that all efforts be made to discuss and obtain informed consent in person but if that is not possible, an alternate approach can be considered (e.g., MS Teams/ OTN/ Zoom in Epic/ over telephone). OTN is available for research staff. Zoom in EPIC is only available to clinical staff, however if the clinician has a scheduled visit the patient/participant, the research team member can be invited to discuss the stud with the potential participant.
- The method used, along with a valid rationale and justification for its use, must be submitted to the REB for approval.
- The process must be approved by the REB prior to implementation.

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. The following is for consideration:

- ✓ Requirements of the applicable regulations/guidelines for the research project
- ✓ 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

Prior to the Remote Consent Discussion

Best Practices

When consent is not obtained in-person, prospective participants should be provided with information on what to expect in terms of the consent discussion in advance. Research teams must 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 virtual consent discussion.

Requirements in the REB Application:

- Must include a plan to provide the potential participant with the ICF and any other participant facing consent documents in advance of the consent discussion.

- Based on the prospective participant's preference and prior agreement (where applicable) and as permitted by institutional policy, this can be achieved via **secure file transfer (SFT)**. The methods of transfer must be included in the REB application.

- The following options are SFT methods that have been approved by TOH and UOHI Privacy Office, TOH IT and TOH Virtual Care Team:

    - ICF **mailed/couriered** to potential participant
    - ICF sent to potential participant though **EPIC – MyChart**
    - ICF emailed to potential participant via **Microsoft 365 SharePoint link**

- ICF sent to potential participant via **TOH Methods Centre Electronic Data Capture System**
- ICF emailed to potential participant via **encrypted email (UOHI only)**
- ICF emailed to potential participant via **password protected email attachment (UOHI and TOH)**
    - TOH IT and TOH Privacy Office do not consider password protected attachments a method of SFT and strongly do not recommend; therefore, should only be considered as a last resort at TOH.
- ICF **faxed** to potential participant
- ICF **posted on a publicly available website**

- For low risk studies, if a researcher proposes that an ICF not be provided to a prospective participant in advance, this must be appropriately justified, and the expectation is that the REB approved ICF will be read verbatim to the participant when consenting the participant.

- **Study teams should consider including more than one option (SFT methods A, B and C) to avoid future amendment submissions, should the main option not be feasible.**

Remote Consent Discussion

It is recommended that videoconferencing be used for remote consent discussions to better mimic in-person consent where social cues can be observed. Telephone should only be used for a remote consent discussion when videoconferencing is not possible.

Best Practices

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

- Participants understand the procedures, risks, and benefits of the study.
- Participants can easily ask and get answers to questions.
- Participants understand the participation is voluntary.

The informed consent process requirements outlined in Chapter 3 of the TCPS2 2018 still apply to a remote consent process.

Research teams must be cognizant of the challenges that exist when consent is obtained remotely. Additional care must be taken to ensure the prospective participant is engaged in the remote consent process and understands the information that they are being provided with during the consent discussion. Researchers should consider that some options may be challenging to some participants. For example, some participants may struggle with accessing or using online platforms. Research teams should ensure that the consent procedures are equitable and do not exclude prospective participants who lack access to technology that may be required.

Research Teams should:

- ✓ Confirm at the beginning of the discussion that the individual has the ICF with them and can follow along with the document during the discussion.

- ✓ Consider sharing the ICF on the screen during the videoconference consent discussion.

- ✓ Make sure to pause during the consent discussion and ask the prospective participant if he/she has any questions or would like to further discuss any of the information provided so far.

- ✓ Ask questions throughout the consent discussion to gauge engagement and comprehension.

- ✓ Support participants in their use of any technological platform, as applicable. Explain in lay terms how participants can complete the documentation process.

Approved Virtual Platforms

If videoconferencing will be used, the research team must be logged into a virtual platform through their TOH/OHRI or UOHI/OHIRC institutional account, whether onsite at the institution or working remotely.

The only platforms approved for use at TOH and UOHI are:

- *Microsoft Teams*
  - TOH Research Staff: Questions on how to use the platform and options available should be directed by opening up an incident in Service Now (servicenow@toh.ca) or posting a question in the M365 Business Analysts' MS Team User Support 'Questions' Channel.

  - UOHI Research Staff: Questions on how to use the platform and options available should be directed to the UOHI IT Help Desk.

- *Ontario Telemedicine Network (OTN)*
  - This option is available for clinical staff, but research staff can be set up with access.

- *Epic Telehealth powered by Zoom*
  - ✓ Only accessible to clinical care personnel
  - ✓ EPIC Telehealth is unfortunately only available for clinical staff and not research staff. However, it may be used if the clinician is having a remote clinic visit with the patient and invites the research staff to attend the clinic visit to discuss the study.
  - ✓ Epic Telehealth powered by Zoom

Alternative Virtual Platforms

If the above institutionally approved virtual platforms do not work for your study, you may submit a request to use an alternative virtual platform to:

- ✓ **For TOH/OHRI study teams:**
  - Request to purchase a licence for a new virtual platform must be submitted to TOH IT Audiovisual Team by completing the Request for Use of Alternative Virtual Platforms at TOH form. Please submit directly to Alain Audette, TOH Senior Technology Analyst & Audiovisual Team Lead at aaudette@toh.ca and copy Anne Lavigne, Director, TOH Privacy Office at alavigne@toh.ca and Marwan Dayfallah, TOH Information Security Officer at madayfallah@toh.ca.

- TOH IT must obtain the licence as it is their responsibility to ensure the security and protections are in place (PHIPA compliant) prior to use to protect staff, patients and other participants.

✓ **For UOHI/OHIRC study teams:**
- Requests to use other virtual platforms must be submitted directly to the UOHI IT Help Desk.

The REB will require evidence of approval from TOH Audiovisual Services or UOHI IT prior to issuing REB approval for use of any alternative platform.

Telephone

In a remote process, the option to use telephone should be considered when the participant cannot, or will not, use video conferencing; extra care must be taken to confirm identity and comprehension (i.e.: confirm that you are speaking with the right individual and that they agreed to be contacted about the study). It is unethical to exclude prospective participants who lack access to technology, unless the study is solely based upon access/use of technology.

Requirements in the REB Application

The REB application must clearly describe all aspects of how the informed consent discussion will be delivered. Study teams should consider including more than one option (plan A and B) to avoid future amendment submissions should the main option not be feasible.

This includes:

- Remote consent location for potential participants and research staff (e.g.: at home, in hospital, etc.).
- Indicate the virtual platform to be used and whether telephone will be used for potential participants without technology software or abilities.
- How the potential participant will be identified. Researchers must follow their institutional policies for identifying patients/participants when connecting remotely.
  - TOH Virtual Care Guidelines:
    - Validation of the individual's identity is required at the beginning of every virtual interaction
    - If potential participant is known: Confirm their information is up to date
    - If potential participant is not known: Request visual confirmation of health card or ID, verify using one other identifier (i.e., date of birth, medication)
- Study team will introduce themselves by showing their badge to the potential participant.
- Will REB approved documents in addition to the ICF be provided to the participant during the videoconference? If so, what documents will be provided in the platform?
- How will the information be stored, and if sending documents through MS Teams chat, confirmation that they will be deleted from the chat.
- If using a virtual platform outside of what is approved by the institution, study teams should be prepared to address additional questions that may be posed by the REB to mitigate risk. For example:
  - ✓ What type of data will be collected, used, stored, and processed by you and by the vendor?

- ✓ Does the vendor claim the right to use the information for its own secondary purposes?
- ✓ Where does the vendor operate and/or store the data and what laws govern data in that jurisdiction? Are those laws comparable to Canadian Privacy laws? (i.e., GDPR, US Regulations)
- ✓ Is access to personal information limited and restricted to authorized individuals?
- ✓ What controls does the vendor have in place for intrusion detection, perimeter security, physical security, application of security patches, and data-leak prevention, among other safety measures?
- ✓ What policies and procedures are in place to detect, prevent and mitigate identity theft?
- ✓ How are incidents and breaches reported?
- ✓ Will we receive notification if a breach to our data occurs?
- ✓ Can the data be retrieved and/or permanently deleted from the vendor's system and servers?
- ✓ Who shall be the administrator to ensure privacy and protection is in place for the platform?

Remote consent discussion plans and any changes to consent processes must be approved by the REB prior to implementation. If you wish to discuss other remote consent discussion options for your study, please contact REBAdministration@ohri.ca to schedule a meeting with the Chair, REB Manager and REB Coordinator.

Remote Consent Documentation

Obtaining and documenting written consent remotely may be permitted when in-person consent is not possible and/or affects the safety of the participants and/or research team members. "Remotely" means that written consent is obtained by remote means (e.g.: email, mail, fax, photo, or electronic signature) instead of in-person.

Options for documenting remote consent:

1. Oral remote consent + deferred in-person written consent
2. Remote collection of inked participant signature
3. Remote collection of electronic participant signature
4. Oral remote consent only with impartial witness or audio/video recording

Oral Remote Consent + Deferred In-Person Written Consent

Where the potential participant enters into an oral agreement during the virtual consent discussion and signs the written consent form onsite at the clinical or procedural visit prior to the intervention. The REB will need to review the length of time (reasonable) it takes from time of the consent discussion to the time written signature is obtained in clinic.

For regulated clinical trials where deferred in-person written consent will follow remote oral remote consent, an impartial witness does not need to be present during the remote oral consent process because it is expected that the participant has an opportunity to ask questions and have them answered prior to signing in-person.

Remote Collection of Inked Participant Signature

Most commonly used if the participant does not have a planned / schedules visit to the institution. Note, depending on which methods are used, participants may need access to a computer / tablet / printer / scanner / fax / internet /email / cell phone to send a photo by email, or other type of technology.

Options for study teams to securely send and/or receive the ICF to obtain written consent remotely:

- *EPIC – MyChart (best practice at TOH and UOHI)*
  - Fusion Tip Sheet: MyChart – Sending PDFs and Questionnaires
  - Can only be used if the patient has a MyChart account
  - At this time, documents can only be sent to participants through MyChart (not able to receive from the participant). The patient would need to return their signed consent form to the study team via one of the secure file transfer methods listed.
    - A request has been sent to EPIC/Fusion Team to include a feature to receive documents through MyChart from patients and will hopefully be implemented in fall 2021.

- *Email using Microsoft 365 SharePoint/One Drive (best practice at TOH)*
  - Instructions for Use of SharePoint and OneDrive
  - The potential participant can be provided with 2 separate links:
    - One to access and download the consent form
    - One to upload their signed consent form to return to the study team

- *Encrypted Email and/or Password Protected Attachments:*
  - TOH IT and TOH Privacy offices do not consider email a SFT method and strongly recommend that documents be sent using EPIC/MyChart or Microsoft 365 SharePoint/OneDrive.
  - At TOH, sending password protected documents via email must be used as a last resort and if used, the password must be communicated to the participant over phone.
    - ✓ Tip Sheet- How to Password Protect MS Office Documents and PDFs
  - UOHI IT and UOHI Privacy offices permit UOHI research staff to send password protected documents to participants via email by selecting the "confidential" option which encrypts the entire email using **FortiMail.**

Note, in order to use the two email options above, the institutional "Research Participant Consent to Communicate by Email" form must be used to obtain and document consent prior to communicating with patients via email:

- ✓ Guidance for Obtaining Consent from Participants to Communicate by Email
- ✓ Guidance for Use of Email in Clinical Research
- ✓ Consent Form: Research Participant Consent to Communicate by Email: English | French

- *Email Photograph of Signature Page of ICF*
  - Instructions for Use of Photograph to Document Written Consent
  - May be used by participants to return their signed ICF to the study team when they are unable to obtain a paper copy of the consent form and/or scan.

- *Microsoft Teams Meeting Chat*
  - Instructions for Use of Microsoft Teams Chat to Send/Receive Documents
  - During a virtual meeting in MS Teams, documents can be sent to the potential participant via the meeting conversation/chat. This is only considered a partial SFT method and documents shared through chat must be deleted from the chat and stored in the study team's MS Teams or SharePoint site.

- *Mail/Courier*
  - Instructions for Use of Mail or Courier
  - Standard Canada Post Mail or alternative secure mailing service (e.g., UPS)

- *Fax*
  - Instructions for Use of Fax
  - If research staff are working on site, TOH fax machines may be used to send/receive documents. Personal fax machines are not permitted to be used.

Remote Collection of Electronic Participant Signature

Electronic signatures allow for the signature to be captured electronically, preventing the need for the participant to print and/or scan. There is a cost associated with the use of e-signature systems.

Validated systems for regulated studies

✓ TOH Methods Centre through the Electronic Data Capture System

Non- validated systems for non-regulated studies

✓ OHRI DocuSign
- A Purchase Request Form must be submitted to William Read, OHRI Senior Research Program Manager.

× **REDCap cannot be used remotely to capture electronic signature**.

- REDCap e-consent is only permitted at UOHI and when research staff are working onsite and inked written signature cannot be obtained, the participant can sign an iPad device to provide their electronic signature.

Oral Remote Consent Only

Obtaining written consent prior to any study activity is best practice, but in some cases, this may not be feasible or possible for the participant. The REB may consider this option when all other remote consent options do not work for the participant; for example:

- ✓ mail/courier is not time sensitive for collection of written signature
- ✓ participants do not have the technological capability or capacity
    - It is unethical to exclude participants from a trial solely because they do not have the technological capability to provide written consent via remote means.
- ✓ Oral remote consent + deferred written consent is not feasible

While "remote consent" refers to the process of conducting the consent discussion and obtaining informed consent when the research team and the prospective participant are not physically in the same room, there may be instances where in-person study activity will follow remote consent; therefore, the expectation remains that traditional consent (i.e., written consent) will still be sought with the participant when in-person.

The options below must be well justified in your REB application. A note in the trial records should be made explaining the circumstances of why informed consent was obtained through an alternative method.

The REB would not typically approve an oral remote consent method for the entire study plan but will conduct careful review and consideration for selective individual study participants. The REB Office and/or full Board will require appropriate justification for a request for an alteration to the REB approved written consent requirement.

The US federal funding agencies (e.g., National Institutes of Health, etc.) and US Food and Drug Administration (FDA) do not regard oral consent as constituting the documentation of signed informed consent that is required by federal regulations (21 CFR 50.27; 45 CFR 46.117(a)). Oral consent can only be used if the requirements for a REB waiver of written consent as outlined in 21 CFR 56.109 (c) (for FDA regulated research) or in 45 CFR 46.117 (C)(1) (for US federally funded research) are met. The researcher must identify the criteria that apply (i.e., the section of the regulations under which they are applying for a waiver of written consent) and justify this relative to the study in their REB application.

Recommended Best Practice when Obtaining Oral Remote Consent Only

In addition to the "**oral remote consent only**" options mentioned above for regulated and non-regulated studies, if the participant is able to provide a photograph of a written consent statement on a piece of paper and send to the researcher via email, this would be considered best practice.

The participant should email a picture of a piece of paper containing the following information to the study team:

- Brief study title
- REB Protocol number
- Written statement that they voluntarily agree to participate in the study
- Participant Signature
- Date of Participant Signature

Traditional consent (i.e., written consent) and documentation will still need to be sought if the participant will be seen in-person in the future.

- ✓ Instructions for Use of Photograph to Document Written Consent

Oral Consent Only in Regulated Studies

When oral consent is used for Health Canada regulated clinical trials, the consent discussion must additionally include either an impartial witness or audio/video recording of the entire consent discussion. While audio/video recording may be considered, the REB will have discretion on whether a witness will be required depending on the nature and risk of the study.

Oral Consent Using an Impartial Witness

Where the patient enters into a verbal agreement during the virtual consent discussion and there is no plan for the patient to attend a visit onsite and no signature will be obtained from the participant.

The witness should be impartial. The witness is a person who is independent of the trial and cannot be unduly influenced by the people involved with the trial and who attends the informed consent process. It cannot be the principal investigator/project lead or study team member, or the person conducting the consent discussion (additional institutional requirements may also apply). The witness cannot participate in the consent discussion, must only observe and must be able to complete the documentation requirements outlined below. The witness must be able to hear both the person conducting the consent discussion and the prospective participant.

Once the consent discussion is completed and the participant orally confirms their consent, the person conducting the consent discussion will complete the consent form by writing the participant name, the date of the consent discussion, and their own name, signature, and date of signature. In addition, the witness will need to complete a separate attestation stating that they were present during the consent discussion regardless of the method of communication and forward to the researcher by email or photo of the signed attestation.

Please note that no one should ever sign or enter a signature on behalf of, or instead of, the person providing consent (the participant). An alternative and preferable approach is to document the oral consent discussion on a separate document (document that is created at the end of the verbal consent script tool – should provide a copy of the tool here).

Traditional consent (i.e., written consent) will still need to be sought if the participant will be seen in-person in the future.

- ✓ Instructions for Use of Impartial Witness when Obtaining Oral Consent
  *Document includes remote **impartial witness attestation template** and an **oral consent documentation tool** for the person conducting consent discussion.*

Oral Consent Using Audio/Video Recording

When the patient does not have the technological capability to provide remote written consent, an impartial witness is unable to be present and consent is time sensitive, consent can be documented via an audio and/or video recording through an institutionally approved virtual platform. The entire remote consent discussion must be recorded and saved on the SharePoint file and it becomes a part of the trial record. Traditional consent (i.e., written consent) will still need to be sought if the participant will be seen in-person in the future.

- ✓ Instructions for Use of Audio/Video Recording when Obtaining Oral Consent
- ✓ Guidelines for Use of Audio/Video Recording of Participants
- ✓ Instructions for Audio/Video Recording in Microsoft Teams
- ✓ Instructions for Transcription in Microsoft Teams

Oral Consent Only in Non-Regulated Studies

Once the consent discussion is complete and the participant provides oral consent, the person conducting the consent discussion will document using the oral consent documentation tool and attach to the ICF. Traditional consent (i.e., written consent) will still need to be sought with the participant when in-person. An impartial witness or audio/video recording is not generally required for non-regulated studies; however, the requirement is under the discretion of the REB.

Remote Consent Follow Up

The participant should receive a fully signed completed copy of the ICF as soon as possible and in a timely manner. A complete copy includes all pages of the ICF, including the completed signature pages. The entire informed consent process including a detailed narrative of the informed consent discussion should be documented in the study for each participant.

Consent is an ongoing process. It may be necessary to provide updated information to participants and obtain their ongoing informed consent. The above principles may be applied, or further alterations may be permitted depending on the nature of the changes. Above all, research teams must remain responsive to participant questions and concerns and ensuring that they remain informed throughout the course of the research project.

Additionally, researchers should consider and incorporate the logistical requirements of maintaining appropriate document and data management. Institutional policies around the secure storage and eventual destruction of identifiable data still apply. Such considerations are even more important with electronic retention on third-party platforms and with study staff potentially working remotely.

Requirements in the REB Application

- ✓ Must include method on how the fully signed ICF will be provided to the participant
- ✓ Indicate time frame of when the fully signed ICF will be provided to the participant

Additional Resources

- Health Canada - Management of clinical trials during the COVID-19 pandemic: Notice to clinical trial sponsors

- FDA Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Public Health Emergency Guidance for Industry, Investigators, and Institutional Review Boards
- OHRP Guidance on Coronavirus | HHS.gov - Research Guidance on Coronavirus