

Guidance Document	Ethical considerations for remote consent and assent
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Please note that this version of the document has had specific institutional details added for Western University. Details may be different depending on the institution. However, this document represents an overall consensus on the approach to remote consent.

Background and Scope:

Research teams may require flexible informed consent processes when the researcher and participant cannot meet in person. This document provides a broad framework for different remote consent options and informed consent documentation. **The REB will determine on a case-by-case basis whether the requested adaptations are appropriate for any given study.**

Consent procedures must adhere to ethical principles and privacy protections. Research teams must be aware of and comply with any additional requirements of their sponsors, funders, and institutions.

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. 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, informed consent will be completed and documented in-person

Ethical Considerations

Informed consent is a cornerstone of ethical principles including the Tri-Council Policy Statement (TCPS 2 (2018))¹. While logistics may sometimes challenge the ability to obtain informed consent in person, the ethical principles for obtaining and documenting informed consent have not changed.

The Letter of Information and Consent (LOI/C) is a tool for enhancing communication and discussion between prospective participants/substitute decision makers (SDM)*; the LOI/C is not the sole component of obtaining informed consent. LOI/Cs can be lengthy and complex, and correspondingly require clear and open communication with prospective participants to ensure informed consent is obtained. This may be particularly challenging when consent is not obtained in person.

¹ Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council, Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, December 2018.

** Please note, for the purposes of this document, all subsequent references to 'participant' should be understood to refer to the participant as well as their substitute decision maker, in cases where such a decision-maker is required*

For some minimal risk research projects (e.g., anonymous online surveys), the REB may waive the requirement for a discussion between the prospective participant and the research team prior to informed consent being obtained; this is outside the scope of this document.

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.

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 consent process and understands the information that they are being provided with as part of the consent discussion, particularly when consent is obtained remotely. Researchers should consider that some options may be challenging to some participants – for example, that some participants may struggle with accessing or using online documentation platforms or other methods of technology. 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.

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. Clear and open communication is critical to ensure that prospective participants understand that different options are available and the research team will work with them to resolve any challenges that might occur. Research teams should consider incorporating the following into the consent discussion (these are generally applicable to all consent discussions but are particularly important for remote consent discussions):

- Confirming at the beginning of the discussion that the individual has the LOI/C with them and can follow along with the document during the discussion. If the consent discussion is conducted using videoconferencing software, consider sharing the LOI/C on the screen;
- Pausing during the consent discussion to ask for questions or ask if the prospective participant wants to further discuss or re-review any information;
- Asking questions throughout the consent discussion to gauge engagement and comprehension;
- Support participants in their use of any technological platforms, as applicable. Explain in lay terms how participants can complete the documentation process.

The REB application must clearly describe all aspects of how informed consent will be obtained and documented for a research project. This includes the context or location of consent, timeline between a participant receiving the LOI/C and being asked to document consent, how a participant will receive a fully executed copy of the LOI/C, how subsequent assent (as applicable) will be obtained, and how the informed consent discussion and/or identity verification will occur. When possible or applicable, more than one process may be used. The consent process (and any changes) must be approved by the REB prior to implementation.

Please note that if videoconferencing platforms will be used, the research team must be either at the institutional site or log in through a secure remote system. The only approved platform at Western is Western Corporate Zoom and, at Lawson-affiliated sites, WebEx. Any other platforms require review and approval at their respective institutions prior to use..

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. This is particularly of note if both research teams and prospective participant are working off-site. Consider, for example:

- 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 (when 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? Is an alternative option available for those who lack these components or who are technologically inexperienced to support equitable recruitment?
- How the research team will provide a copy of the signed informed consent form (LOI/C) to the research participant
- Institutional requirements regarding the use of email, videoconferencing/teleconferencing technology, electronic signatures, and electronic consent platforms

Prior to the Consent Discussion

Research teams must provide the prospective participant with the REB-approved LOI/C prior to the consent discussion, to assist in the consent discussion. This provides the prospective participant to review the material in advance and to follow along during the consent discussion. If there are instances for low risk studies where researchers propose that the LOI not be provided in advance, this must be appropriately justified and the expectation is that the full LOI would be read verbatim to the participant prior to seeking consent.

Based on the prospective participant's preference and prior agreement (where applicable) and as permitted by local policy, this could be achieved via secure file transfer (SFT), mail, courier, secure email, texting a link, or posting a publicly available consent form, for example.

Conducting the Consent Discussion

Remote consent does not remove the expectation for a consent discussion to occur with the prospective participant. Whether conducted in person or remotely, (video, telephone, etc.), informed consent requires a discussion to ensure prospective participants:

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

A discussion of the research project with the prospective participant occurs via telephone or teleconferencing/videoconferencing service where permitted. Videoconferencing is preferred when possible as it most closely mirrors the in-person process, but may not be feasible for all participants. Individuals should not be excluded from participation because they do not have access or otherwise do not agree to use of email and/or teleconferencing/videoconferencing, unless use of these technologies is specifically required as part of the research project (e.g., required to implement the study procedures).

As always, prospective participants should be provided with sufficient time to review the consent form, prior to providing informed consent. Research teams should address any questions raised by prospective participants prior to documenting informed consent. If the consent discussion does not include the necessary individuals to answer questions, a separate session should be arranged.

Recording of the consent discussion does not replace the need for appropriate written documentation of consent depending on the nature of the study. However, if the consent discussion will be recorded, this needs to be explained to participants in the LOI/C and this portion of the recording should be separated from any data collection.

Documenting Remote Consent

The options for documenting remote consent differ based on the type of research project and can include considerations including whether it is Health Canada regulated, US federally funded or FDA regulated (i.e., Investigational New Drug (IND), Investigational Device Exemption (IDE), or Pre-Market Approval (PMA) application).

Researchers 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.

Documentation methods and potential uses

The following table outlines potential methods for documenting remote consent based on different study requirements. Of note, different institutions and sponsors may have additional restrictions in place, particularly as it concerns Health Canada or US regulated research or sending personal health information (PHI) to participants. Additional requirements such as validation of electronic systems or tools may also apply (for Health Canada or US regulated research, for example).

<p>Observational Research (Not subject to Health Canada regulations, not US regulated)</p>	<ul style="list-style-type: none"> • Written Signature on Paper Copy by Mail, Email, or Secure File Transfer • Electronic Signatures using approved Electronic Signature Software/e-Consent platforms • Verbal Consent following corresponding process for observational research
<p>Interventional Research (Not subject to Health Canada regulations, not US regulated)</p>	<ul style="list-style-type: none"> • Written Signature on Paper Copy by Mail, Email, or Secure File Transfer • Electronic Signatures using approved Electronic Signature Software/e-Consent platforms • Verbal Consent following corresponding process for interventional research
<p>Health Canada Regulated Research</p>	<ul style="list-style-type: none"> • Written Signature on Paper Copy by Mail, Email, or Secure File Transfer • Electronic Signatures using approved Electronic Signature Software/e-Consent platforms
<p>US Federally Funded or FDA Regulated Research</p>	<ul style="list-style-type: none"> • Written Signature on Paper Copy by Mail, Email, or Secure File Transfer • Electronic Signatures using approved Electronic Signature Software/e-Consent platforms • Verbal consent can only be used if the requirements for an 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.

Written Signature on Paper Copy by Mail, Email, or Secure File Transfer (SFT)

When possible, the LOI/C(s) should be signed by the prospective participant and the person conducting the consent discussion, along with any others as applicable to the consent process. To this end, the study team may establish a process, in alignment with research regulations, whereby the paper LOI/C is mailed to the prospective participant and, following the consent discussion, the participant signs the paper LOI/C and mails it back to the institution. The person conducting the consent discussion (and any others as applicable) can then sign the LOI/C.

Alternately, the study team may send the LOI/C by SFT or email and, following the consent discussion, the participant signs the consent and mails, faxes, scans, or sends a photograph back to the study team. Email should generally be considered the last resort for the consent process due to lack of security.

The use of a wet-ink signature is generally considered the most compliant option, and may be the only option in some circumstances, but it may come with ethical challenges particularly with respect to equity, privacy, complexity and potential burden to participants. Postage should always be paid for by the study team.

Because the study team and participant will not necessarily be signing the LOI/C on the same date, the person obtaining informed consent should otherwise document (e.g. note to file) the consent discussion on the day it occurs. Then, the person obtaining informed consent should write a note on the LOI/C when they sign the document that explains the date discrepancy.

Electronic Signatures using approved Electronic signature software/electronic consent (eConsent) platforms

Another method of obtaining signatures on the LOI/C is via electronic signature software/electronic consent platforms (such as the REDCap e-consent framework or DocuSign, for example). The advantage of these systems is that they may provide a user-friendly option for individuals to personally-sign the LOI/C. However, in the research setting, additional institutional approval and validation processes may apply and there may be costs to study teams. **Currently, Western supports the use of Qualtrics and Lawson the use of REDCap for research that is not FDA or Health Canada regulated.** Please consult Lawson's *REDCap Guidance Document* and associated templates and/or the REB's *Qualtrics for Electronic Consent Guidance Document* for information on the specifics of how these platforms should be implemented.

These processes may reduce the burden on participants (by avoiding printing/scanning/photographing for example), but they may also require additional resources (email, devices such as a smart phone/tablet/computer) and be complex for less tech-savvy individuals.

Basic Requirements for an eConsent Platform

The system needs to undergo either an Authorized Technology review at Lawson or Technology Risk Assessment at Western . For a study with Lawson oversight these reviews would also engage the LHSC or SJHC Privacy Office and at Western, the Western Privacy Office. If a system has been previously reviewed, documentation of its approval needs to be provided to the REB (unless this is Lawson's REDCap or Western's Qualtrics).

- System must be equitable/accessible; backup processes are required in the event of system downtime, internet disruptions, or for participants (or substitute decision maker [SDM] if applicable) without electronic device access
- System must include version control of content, including identification of when different versions were used (i.e., Version 1 was in use between date X to date Y), and the version signed by individual participant (e.g., Participant 1 signed version A)
- Privacy – System must limit data linkage with other data within the system or other systems. Any linkage must be minimized to greatest possible degree and identified by the research team in their REB application. Additional system data collection (e.g., IP address, location) must be disabled whenever possible, or disclosed with consent obtained prior to system access when not possible to disable. First and last name of all signatories should be documented on the e-consent in most cases, unless a request not to document this information has been submitted to and approved

by Western’s REBs. Date of birth, email, and other associated information may be used to verify participant identity if justified.

- System must include an audit trail, including un-editable audit trail associated with the consent process documenting the content signed, dates/times of signatures, and user identifier associated with signature. Copies of all signed e-consents must be maintained in an un-editable format.
- System must include an acceptable electronic signature. This may be the recording of a signature by the individual (i.e., by using a mouse, stylus, or trackpad to draw their signature), signature through the use of validated user account, or another method of electronic signature currently accepted by the applicable regulations or guidelines.
- System must have capability to support electronic signatures on the Letter of Information and Consent (LOI/C) by multiple parties (participant , person conducting consent discussion (PCCD), and others as applicable).
- System or study procedures must have an accompanying process for confirming identification of participant (e.g., full name and DOB).
- **Participants must receive a copy of the completed LOI/C.** Ideally this is supported within the e-consent platform (e.g., emailing or printing/downloading of document from the platform itself). Ideally, the e-consent platform will support individuals navigating between pages/sections to review content (if applicable) and the ability to return/continue with the e-consent at a later date or time (please note that no research activities can occur prior to completion of the consent process and e-consent documentation with the participant). It is the PI’s responsibility to ensure appropriate training has been given to system users to adequately navigate the e-consent platform.

As with the paper process, all required signatures (including participant , PCCD, and any others as required by the e-consent) must be obtained through the consent process before any research participants may be enrolled or data collection from or about the participant can begin for research purposes.

The same requirements apply to e-consent documentation as to paper consent documents.

Western’s REB consent form templates should be used when building your study-specific consent in an online platform. If applying via Clinical Trials Ontario (CTO) then their templates should be used. However, changes are needed to the signature page to include, for example, a field where the participant confirms their willingness to take part.

Technical safeguards should be in place to ensure that participants are not able to modify the copy of the consent that they receive. Similarly, the e-consent platform must contain an un-editable audit trail associated with the consent process, including the documents signed dates/times of signatures, and user identifier. A copy of the completed e-consent must be retained by the system and cannot be modifiable (i.e., there must be technical safeguards in place to prevent editing/deletion of these source documents).

Reminder: e-Consent refers to the *documentation* of informed consent, and not the process of obtaining informed consent. Whenever possible and practical, the informed consent process should include a discussion between the research team and the potential participant , prior to the individual consenting to take part. There are limited circumstances in which the REB may approve a consent process that does not include such a discussion. This would depend on the nature of the study, the study population, and the logistics of the study. For example, a study of healthcare professionals that requires low-risk longitudinal surveys.

The REB must approve the consent process and any participant-facing materials, including all live (active) links to e-consents prior to use.

The e-consent (s) and any other information shown to participants must be submitted to the REB **exactly** as they will appear to the participant, including any branching logic or intro/exit messages. A standard paper LOI/C should also be submitted should the eConsent platform be unavailable or participants request a copy.

Verbal Consent

In some cases, it may not be possible for the prospective participant to sign the LOI/C. However, a signed LOI/C still serves as the preferable method of documentation. Verbal consent requirements differ based on the type of research project.

In general, this process is not ideal because the participant do not personally sign the LOI/C. However, this is a low-tech, low burden option and may be particularly appropriate for some individuals or research populations. The US federal funding agencies (e.g., National Institutes of Health, etc.) and US Food and Drug Administration (FDA) do not regard verbal consent as constituting the documentation of signed informed consent that is required by federal regulations (21 CFR 50.27; 45 CFR 46.117(a)). Verbal consent can only be used if the requirements for an REB waiver 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) and justify this relative to the study in their REB application.

Verbal Consent - Observational Research

Once the consent discussion is complete and the participant verbally confirms their consent, the person conducting the consent discussion will complete the signature pages of the LOI/C by writing/printing the participant name, the date of the consent discussion, their own name, signature, and date of signature.

Verbal Consent – Clinical Trials

When verbal consent is used for Health Canada regulated clinical trials, the consent discussion must additionally include a witness. Please note that the provision of verbal consent for clinical trials by Health Canada is also a temporary measure as of this draft. For other clinical trials, the need for a witness depends on the nature and risk of the study.

The witness should be impartial. The witness cannot be the principal investigator/project lead, an individual with a clinical relationship to the participant, or the person conducting the consent discussion (additional institutional requirements may also apply). The witness cannot participate in the consent discussion (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 complete and the participant verbally 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 (as above for observational research). In addition, the witness will separately sign (typically a separate page) to document that informed consent was appropriately obtained.

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 that separate tools such as verbal consent scripts and worksheets can be developed to document informed verbal consent.

Following Informed Consent

The participant should receive a fully signed, complete copy of the LOI/C as soon as possible and in a timely manner. A complete copy is all pages of the LOI/C, including the completed signature pages. The entire informed consent process including a detailed narrative of the informed consent discussion should be documented 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.

Questions

Please direct questions about this document to the Office of Human Research Ethics (OHRE).

Appendix 1: Documentation of Verbal Consent

Instructions to study team: This page must be included as part of the informed consent form submitted to the REB and paginated as part of the main LOI/C document (i.e., all pages, including the witness attestation page as applicable, are numbered sequentially as page X of Y). When a study involves different methods of informed consent (such as e-consent and verbal consent), all LOI/C versions must be submitted to the REB.

Documentation of Verbal Consent

Study Title: (insert study title)

Do you have any questions?

- Yes
- No

Do you agree to take part in this study?

- Yes
- No

[Insert other specific questions as they pertain to the research such as confirmation of audio-recording, use of direct quotes, consent to future contact etc. as applicable]

We would like to provide you with a copy of what we've talked about today, which will include your name and the study title and the other information you have provided over the phone. Can we send this to you by email or mail? **NOTE TO STUDY TEAM: the required text around use of email and how it is not secure must be contained within the consent form**

- Mail
- Email
- Secure File Transfer

Name of Participant

Date of Participant Verbal Consent

Name of Substitute Decision Maker
(SDM)

Date of SDM Verbal Consent

Name of person obtaining consent

Signature of person obtaining consent

Date

My signature means that I have explained the study to the participant named above. I have answered all questions,

For Interventional studies, include:

The completed consent form includes a witness attestation page.

Appendix 2 : Witness Attestation for Health Canada Regulated Clinical Trials

Instructions to study team: This page must be included as part of the informed consent form submitted to the REB and paginated as part of the main LOI/C document (i.e., all pages, including the witness attestation page, are numbered sequentially as page X of Y). When a study involves different methods of informed consent (such as e-consent and verbal consent), all LOI/C versions must be submitted to the REB.

Study Title: (insert study title)

Name of Participant

Date of Participant Verbal Consent

The consent form was read to the participant. The person signing below attests that the study as set out in this form was accurately explained to the participant, that any questions have been answered, and that the participant consented to participate.

Name of witness

Signature

Date