

Guidance Document	Western Qualtrics for electronic documentation of consent
Effective Review	HSREB/NMREB
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Prior to data collection, it is critical that researchers conduct an appropriate informed consent process with participants. An important aspect of this process is the documentation of informed consent. There are several ways to do this including electronic consent (eConsent) either in-person or remotely. This document addresses specific requirements for the use of Western Qualtrics to document consent.

For a full description of eConsent and remote consent* options and best practices, please consult the HSREB/NMREB Guidance Document: *Ethical considerations for remote consent and assent*.

Implied Consent

The most basic use of Qualtrics to document informed consent is by collecting implied consent. This is when a participant is presented with the Letter of Information and Consent (LOI/C) and then indicates their consent to participate by submitting a survey or questionnaire. TCPS2 recommends collecting data with only the identifiers necessary to answer the research question. Therefore, this form of collecting informed consent is advantageous for one-time questionnaires because participants can respond anonymously (or with minimal identifiers) to a generic Qualtrics link.

Key Considerations

- The LOI/C must be the landing page for the Qualtrics survey link. Please consult the Human Ethics website for LOI/C guidance documents and templates.
- Preferably, the LOI/C is also presented as an attachment in Qualtrics should participants wish to download a copy for their records.
- The last statement in the LOI/C should indicate that submission of the survey serves as consent.
- There is NO need for an “I do not consent” radial button, as a participant who does not consent would simply close the window.
- Participants should be able to skip all questions unless otherwise justified to the REB. A researcher’s desire for a full data set is not sufficient justification.
- It is preferable for participants to be able to navigate backwards and forwards.
- If you seek to collect identifiers such as email or name for a follow-up study, this must be done from a SEPARATE Qualtrics link that is not connected to the data. Qualtrics can be programmed to automatically navigate a participant to this separate link.
- All “live” links must be submitted to the REB for review prior to approval.

* 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 are not physically in the same room. “eConsent” refers to the documentation of explicit informed consent in a proprietary electronic platform either remotely or in-person.

Explicit consent (eConsent)

When research participation requires more than a one-time survey and implied consent is not appropriate, Qualtrics can be used to document informed consent explicitly.

Key Considerations

- Each participant should receive a unique link to the Letter of Information and Consent (LOI/C) in Qualtrics. The REB will consider instances using a generic link but this raises the standard for identity verification later in the research procedures.
- This link should hold ONLY the LOI/C. Data collection needs to be done separately (i.e. by another means or on a SEPARATE Qualtrics link)
- There must be some form of “live” identity verification. This could be:
 - o When a participant first contacts the study team prior to the participant receiving a unique link,
 - o During an informed consent discussion (in-person or remote) after the participant has had sufficient time to review the LOI/C,
 - o After the participant has received and signed the LOI/C at the time of a study procedure such as an interview.
 - Study teams may verify identity of the participant by another means appropriate to the research (e.g. Using Qualtrics functionality to password protect the link and informing the participant of the password by secure means). However, in all instances the researcher must provide the REB with logistical details.
- The landing page must include the text of the LOI (not solely a link to the LOI as an attached document).
- There must be fields for the participant AND person obtaining informed consent to enter:
 - o First and last name,
 - o Signature,
 - o Date
- Ultimately, participants must be provided with a PDF of the fully executed LOI/C. This can be done on paper, via email, or using regular mail according to participant preference.
- Collection of any optional consent (e.g. future contact, audio-recording, direct quotes etc.) must be documented on the same page as the signatures.
- The method of documenting the attestation of the person obtaining informed consent will be different depending on whether the eConsent is collected in-person or remotely:

In-Person

Both the participant and person obtaining informed consent should execute the LOI/C at the same time. Then the researcher needs to export a PDF of the fully executed LOI/C to provide to the participant.

Remote

After the participant submits their LOI/C via Qualtrics, the researcher must export a PDF with the empty fields for the person obtaining informed consent. Then, an eSignature (e.g. DocuSign) or a print-out and wet-ink signature can be added by the researcher. This should be done by the study team member who conducted informed consent, confirmed consent, and/or verified identity. Then a PDF of the fully executed document needs to be provided to the participant

Please note:

- The use of Western Qualtrics for eConsent is not available for London Health Sciences Centre (LHSC)/St. Joseph's Health Care (SJHC) affiliated studies. LHSC/SJHC researchers are directed to REDCap.
- While the Research Ethics Boards (REBs) have provided this guidance on the construction of eConsent in Qualtrics, it is the researcher's responsibility to use the "Help" features and tutorials in Qualtrics for technical assistance in implementing the guidance. Technical assistance for using Qualtrics is outside of the REB and Office of Human Research Ethics's (OHRE) scope.
- If you propose to collect identifiers in an installation of Qualtrics that is hosted by another institution, it would be subject to review by Western's Technology Review Assessment Committee (TRAC).
- Qualtrics can be used to collect data without having to also document eConsent in Qualtrics. It is entirely acceptable to collect verbal or wet-ink consent outside of Qualtrics and then implement Qualtrics for data collection.
- Your plan for the retention and destruction of identifiable data held on Qualtrics and electronic LOI/Cs needs to be compliant with institutional policy and explained in the REB application.
- When submitting to the REB in WREM (the human research ethics online submission platform), please include the live links to your Qualtrics projects, PDF exports of the projects, and an LOI/C that could still be used for wet-ink signatures if required/requested.

Appendix A. Example of eConsent in Qualtrics with optional components as required/applicable



Letter of Information and Consent

Study Title

PI

Funder

INSERT FULL LOI/C TEXT (with formatting) AS PER REB GUIDANCE DOCUMENTS AND TEMPLATES.

I consent to [insert OPTIONAL research component here]

☐ Yes

☐ No

This study has been explained to me and any questions I had have been answered.

I know that I may leave the study at any time. I agree to take part in this study.

I will be emailed a copy of this document.

Type First Name of Participant

Type Last Name of Participant

Signature of Participant

×

SIGN HERE

clear

Today's Date (mm/dd/yyyy)

Please enter [the verification code provided to you on the phone/video-conference] [date of birth].

FOR RESEARCH TEAM USE ONLY (if you are a participant, please proceed use the next arrow below to submit)

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

Type Name of Person Obtaining Informed Consent (to be completed by researcher on submission)

Signature of Person Obtaining Informed Consent (to be completed by research team on submission)

×

SIGN HERE

clear

Date Person Obtaining Informed Consent Signs (mm/dd/yyyy)