Conjoint Health Research Ethics Board (CHREB)
Research Services, University of Calgary
2500 University Drive N.W. Calgary, AB T2N 1N4
Ph: (403) 220-2297 | Email: chreb@ucalgary.ca

Obtaining and Documenting Consent Electronically

Under TCPS2, evidence of consent should be reflected by a signed consent form, either written or electronic, or by the researcher's documentation of another appropriate means of consent (Article 3.12). The definition of signature advanced by ICH E(6)R(3) is "A unique mark, symbol or entry executed, adopted or authorized by an individual, in accordance with applicable regulatory requirements and/or practice to show expression of will and allow authentication of the signatory (i.e., establish a high degree of certainty that a record was signed by the claimed signatory). A signature may be physical or electronic." This guidance describes electronic methods of informed consent documentation.

Electronic documentation of consent may be used when researchers have a consent conversation in person with prospective participants or surrogate decision makers (e.g., legally authorized representatives), as well as when prospective participants or surrogate decision makers are not physically present.

If any of the consent process takes place remotely and is not witnessed by study personnel, the electronic system must include an authentication method to ensure that the person providing an electronic signature is either the participant or their surrogate. If the person signing is the participant's legally authorized representative, the consent should indicate what the specific legal authorization is (e.g. committee, legal guardian).

Whether electronic informed consent is obtained on-site or remotely, there must be sufficient opportunity for the decision-maker to consider participation and there must be a process in place that allows the decision-maker to ask questions about the study both before signing as well as during the participant's research involvement.

When the CHREB reviews a study, it considers how the electronic signature will be created, whether the signature can be shown to be legitimate, and how the research team plans to provide a signed copy of the consent form to the participant.

Types of Electronic Signatures

When providing consent online, there are several ways that an e-signature can be documented.

Some examples of electronic signatures include:

- Signing with a stylus in an electronic document
- Attaching a scanned handwritten signature or using an e-signature service such as REDCap. REDCap is a platform that has been approved for such use by the University of Calgary. Other platforms may be acceptable but the researcher must demonstrate that they meet all privacy and security requirements for the University of Calgary. An IT threat risk assessment may be required before other programs can be used (Guidelines for the Software Acquisition Process). Please note, the use of Adobe Echo sign is not permitted due to contractual limitations.

- Typing one's name with an accompanying check box and statement noting an intent to affix a legal signature (e.g., "By checking this box and typing my name below, I am electronically signing this consent form").

Capturing Signatures Electronically

The CHREB permits consent forms to be executed and stored using electronic devices (e.g., tablets or iPads). When electronic consent is captured this way, researchers obtaining consent must witness the participant as they provide their electronic signature and must then provide their own electronic signature. The provision of consent will thus be witnessed, and both parties' signatures will be on the consent document.

The electronic version of the consent document must be stored, accessed and transmitted according to the University of Calgary Information Security Classification Standard. Both the electronic version of the consent and paper versions subsequently generated by researchers are considered original.

Signatures Transmitted Electronically

Faxing Copies of Signed Consent Forms

It is permissible for participants to fax a signed copy of a consent form to the research team. If there are questions and/or check boxes embedded in the document for the participant to complete, the research team should check to ensure that these pages are included. Some standards (e.g., ICH GCP) guidelines require that the study team receive a complete copy of the signed consent form. In cases where participants are faxing a consent form to the research team, the participant need not provide the investigator with the original signed consent document. Privacy concerns include how the fax machine is monitored, who has access to it and the nature of the information contained in the consent, recognizing this could be both sensitive and identifying.

Emailing Copies of Signed Consent Forms

Email is a convenient method of communication, and participants may request to send or receive copies of documents through email. If the consent form or information sheet reveals information about the potential participant's health (e.g., "You have been invited to participate in this study because you have [disease/condition]"), then the participant should not email it to the study team unless the email communication is encrypted.

Online Consent

Implied

For minimal risk research, such as web-based surveys or questionnaires, the consent form may be presented online. Participants must perform some action, such as clicking "I agree," before proceeding with any research activities (e.g., answering survey questions). This is an acceptable approach for low-risk research conducted online and is considered an implied consent.

Conjoint Health Research Ethics Board (CHREB)
Research Services, University of Calgary
2500 University Drive N.W. Calgary, AB T2N 1N4
Ph: (403) 220-2297 | Email: chreb@ucalgary.ca

Consent statement

For studies where the informed consent document is provided online, consent may be documented by the participant typing their name with an accompanying check box and statement noting an intent to affix a legal signature (e.g., “By checking this box and typing my name below, I am electronically signing this consent form”).

The research team should consider how they will evaluate a participant’s understanding of the procedures and risks related to the research, particularly when it involves more than minimal risk. Contact information for a member of the study team must be provided so that potential participants can ask questions or present concerns. A brief quiz to assess the potential participant’s understanding of the study, including their role, the risks and benefits and confidentiality provisions might be useful for more complex studies.

Other considerations:

Providing Participants Copies of Consent

In all cases where consent is obtained and documented electronically, participants must be provided with a version of the consent form that they can retain for their records, whether it is a hard copy or an electronic version. It does not need to be a signed copy.

Confirming Identities in Online Research

A study’s validity or reliability could be questioned if participants’ identities are not verified/verifiable. Examples include when there are critical eligibility criteria, or when there is a likelihood of repeat or fraudulent participation, whether for mischief or to collect multiple payments. When designing a research study, investigators should take into consideration the importance of establishing participant identity to their study (Guidelines and Tips - Preventing Fraudulent Participants).

Studies that pose more than minimal risk, or that involve the transmission of sensitive information, should consider implementing a process by which the study team confirms identities using authentication that relies upon multiple factors, for example a password that is delivered to participants by telephone or by postal service.

Conjoint Health Research Ethics Board (CHREB)
Research Services, University of Calgary
2500 University Drive N.W. Calgary, AB T2N 1N4
Ph: (403) 220-2297 | Email: chreb@ucalgary.ca

Additional resources and web links:

1. TCPS (see Chapter 3): TCPS2-2022-Word-dec-19-2022-en_Left alignment_without index_table of contents (clean)
2. Health Information Act of Alberta (See Section 34): https://kings-printer.alberta.ca/documents/Acts/H05.pdf
3. Health Canada (Guidance for Clinical Trail Applications): https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/guidance-documents/clinical-trials/clinical-trial-sponsors-applications.html#a271
4. ICH GCP E6 R3 Glossary https://database.ich.org/sites/default/files/ICH_E6%28R3%29_Step4_FinalGuideline_2025_0106.pdf
5. FDA (guidance on use of electronic consent): https://www.federalregister.gov/documents/2016/12/15/2016-30146/use-of-electronic-informed-consent-questions-and-answers-guidance-for-institutional-review-boards and https://www.fda.gov/downloads/drugs/guidances/ucm436811.pdf
6. University of Calgary Security Classification Standard: https://www.ucalgary.ca/legal-services/sites/default/files/teams/1/Standards-Legal-Information-Security-Classification-Standard.pdf
7. Medical Marijuana Class Action Law Suit (discussion of privacy breach case): http://www.cbc.ca/news/canada/nova-scotia/medical-marijuana-class-action-against-health-canada-certified-by-federal-court-1.3171897