

Obtaining and Documenting Consent Electronically

Under TCPS2, evidence of consent should be reflected by a signed consent form or by the researcher's documentation of another appropriate means of consent (Article 3.12). For some studies, signed consent may be mandatory. For example, studies seeking consent to use health information under the *Alberta Health Information Act* for research purposes may seek consent that is either written or electronic. This guidance describes electronic methods of informed consent documentation.

Electronic documentation of consent may be used when researchers conduct the consent process with participants in person, as well as when potential participants are not physically present with the researcher during the consent process. In either situation, the consent process itself should be designed to ensure that participants are adequately informed about the research, can easily ask and get answers to questions, and recognize that participation is voluntary.

When the CHREB reviews a study, it considers how the electronic signature is being created, whether the signature can be shown to be legitimate, and how the research team plans to provide a version of the consent form to the potential participant for their review and retention.

Types of Electronic Signatures

When providing consent online, there are a number of ways in which an e-signature might be documented. Some examples include:

- Signing with a stylus in an electronic document
- Attaching a scanned handwritten signature or using an e-signature service such as Adobe's EchoSign;
- 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")

All of the above constitute "signatures."

Capturing Signatures Electronically

The CHREB permits consent forms to be executed and stored using electronic devices (e.g., tablet or iPad). In the case where this type of electronic consent is used, the person obtaining consent must witness the study participant as s/he provides her or his electronic signature and must then provide her or his 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 should be stored, accessed and transmitted according to the University of Calgary Information Security Classification Standard. Access to the consent form should be at least as closely guarded as access to paper consent forms. Both

the electronic version of the consent and paper versions subsequently generated by the researchers are to be considered originals.

Signatures Transmitted Electronically

Faxing Copies of Signed Consent Forms

It is permissible for participants to fax a signed copy of the consent form to the research team. If there are questions and/or check boxes embedded throughout 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 to be addressed include how the fax machine is monitored/who has access 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 would reveal 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, and require participants to perform some action, such as clicking "I agree," before proceeding with any research activities (e.g., answering survey questions on a website). This is an acceptable approach for low-risk research conducted online and is considered an implied consent.

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 be able to evaluate a participant's understanding of the procedures and risks related to their participation, particularly where the research involves more than minimal risk. Contact information for a member of the study team must be provided so that potential participants can have questions or concerns addressed. A brief quiz to assess the potential participant's understanding of the study, including their role, the risks and benefits and confidentiality provisions might also 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.

Confirming Identities in Online Research

A study's data 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.

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.

Health Information Act (HIA) consent requirements

If you will require information about study participants to be disclosed by Alberta Health Services for the purpose of your research (HIA s.54), and informed consent is required by the REB, the HIA mandates that such informed consent must be provided in writing or electronically (HIA S. 34 (2)). Exceptions to the requirement for written or electronic documentation of consent may be granted in exceptional circumstances and when appropriately justified by researchers.

Health Canada consent requirements

Health Canada's guidance (GUI-0100; C.05.010(h)) allows electronic signatures if the electronic system is fully validated. Proper controlled should be in place to assure the signature belongs to the user who provided it. Password-protection and limited access should be used accordingly. The participant in a clinical trial must also understand that any electronic signature is equivalent to a handwritten signature on paper.

Additional resources and web links:

1. TCPS (see Chapter 3): https://ethics.gc.ca/eng/tcps2-eptc2_2022_chapter3-chapitre3.html
2. Health Information Act of Alberta (See Section 34): <https://www.alberta.ca/health-information-act.aspx>
3. Health Canada ("Drugs for Clinical Trials Involving Human Subjects" (GUI-0100)): <https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/good-clinical-practices/guidance-documents/guidance-drugs-clinical-trials-human-subjects-gui-0100/document.html>

4. FDA (Use of Electronic Informed Consent in Clinical Investigations):
<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>
5. University of Calgary Information Security
Classification Standard:
<https://www.ucalgary.ca/legal-services/sites/default/files/teams/1/Standards-Legal-Information-Security-Classification-Standard.pdf> \
6. 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>
7. The development of this guidance document informed by the that of the University of Wisconsin-Madison: <https://kb.wisc.edu/page.php?id=76726>