**CHEO REB Guidance**

**Use of Electronic Written Informed Consent**

**Scope**

The informed consent process is essential to the ethical conduct of human research. In accordance with the *Tri-Council Policy Statement: Ethical conduct for research involving human* (TCPS2-2018), evidence of consent may be contained either as a signed consent form or as documentation by the researcher with another appropriate means of consent. This guidance document provides information on the use of electronic means to achieve the traditional written informed consent and outlines the requirements for electronic informed consent.

**Electronic Informed Consent**

Electronic informed consent means that the traditional written informed consent form is reproduced by electronic means. It refers to the use of electronic systems and processes to communicate information related to the study and to obtain and document informed consent. It includes traditional (written) informed consent as well as other formats and media (e.g., online forms (such as REDCap), text, graphics, audio, video, interactive websites).

Electronic **written** informed consent necessarily means that participants sign a consent form. Written consent is often understood to mean a handwritten (‘wet ink’) signature on a paper document. According to Canadian law, an electronic signature (also referred to as a digital signature) obtained and documented in compliance with the [Canada Evidence Act](https://laws-lois.justice.gc.ca/eng/regulations/SOR-2005-30/page-1.html) and the [Personal Information Protection and Electronic Documents Act (PIPEDA)](https://laws-lois.justice.gc.ca/eng/acts/P-8.6/index.html) is equal to a handwritten signature.

***Requirements for electronic written informed consent (eIC)***

1. EIC can take place in-person or remotely; when possible, potential participants should ideally be given the option to use paper IC or eIC.
2. The investigator is responsible for verifying the identity of the person giving their consent.
3. EIC forms must include all information generally required for informed consent in accordance with [TCPS2 Chapter 3](https://ethics.gc.ca/eng/tcps2-eptc2_2018_chapter3-chapitre3.html), section 3.2 (a)-(i).
4. A signature or an attestation of consent may be obtained using different methods: via an electronic system designed to verify digital signatures (e.g., REDCap,Docu-Sign); a picture of a signed and dated written statement may be sent via email or text; or participant replies by email. Other options may be considered with appropriate justification.
5. If it is impossible to obtain a signature, to ensure equity of participation, consent may be obtained verbally. (See [template for verbal consent](https://www.cheoresearch.ca/research-services/research-ethics-board/templates/)). This means that the content of the written consent form remains the same and participants provide consent verbally.

* If consent is obtained verbally, read the consent form to prospective participants.
* Consider providing a copy of the consent form in advance of the consent discussion.

1. Potential participants must always have an opportunity to ask questions before they give their consent.
2. A signed (electronic or hard) copy of the consent form must be provided to participants. The content of the original and signed forms must be identical.
3. All REB-approved versions of the eIC must be archived and retained for the auditing purposes.

***Additional requirements for regulated clinical trials: Electronic signatures (eSIG)***

1. It is mandatory to obtain an electronic signature for regulated clinical trials as prescribed by Health Canada and the Food and Drug Administration.
2. The electronic system used for obtaining a digital signature (eSIG) must be compliant with the [US Code of federal regulations Title 21, Part 11](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=11) (e.g., Docu-Sign). This includes that it must i) be secure with restricted access, ii) include a method to verify the authenticity of the participant’s signature (e.g., by using a password, verification question specific to that individual), iii) maintain confidentiality and privacy regarding the participant’s identity, study participation, and personal information after consent has been obtained, iv) encrypt the participant’s name and personal information, and v) capture and record the date that the participant or legal representative provides an eSIG.
3. A completed, authorized eSIG is defined as a “secure electronic signature” as defined in the [Canada Evidence Act, Secure Electronic signature regulations](https://laws-lois.justice.gc.ca/eng/regulations/SOR-2005-30/page-1.html) and [PIPEDA, Part 2](https://laws-lois.justice.gc.ca/eng/acts/P-8.6/page-8.html#h-417528).

**COVID-19 pandemic**

In accordance with [Health Canada guidance](https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/announcements/management-clinical-trials-during-covid-19-pandemic.html) for the management of clinical trials during the COVID-19 pandemic, when consent cannot be obtained in person, other methods for obtaining consent may be used, such as over the phone or via a virtual platform. Consider the following:

* ensure participants always have an opportunity to ask questions before they give their consent
* accepting a text or email of a picture of a signed and dated written statement for participants who enroll remotely
* this statement should indicate they are voluntarily accepting participation in the trial
* if consent is given verbally, read the consent to the prospective participant and provide an opportunity for the person to ask questions
  + consider providing the document to the person ahead of time
* ensure that in cases of verbal consent, a witness (can be a family member) is present and signs an attestation
  + it must be clear that the witness was present during the process regardless of the method of communication (for example, can be on a conference call)
  + a scanned copy of the attestation may be forwarded to the investigator by email or a picture of the signed attestation may be sent by email or text
  + the conversation should be recorded if it isn’t possible to have a witness (this recording becomes part of the trial records)
* ensure the method used meets local privacy requirements

**Study documentation**

Include the following information in the protocol (or CHEO-specific protocol addendum):

1. Specify the procedures that will be used to obtain electronic consent or assent (e.g., via email only, via email and supported by a discussion on a virtual platform or by telephone) and method to verify a participant’s identity.

If it includes an electronic signature, specify the method to verify the authenticity of the participant’s signature.

1. Describe the consent and assent process (in accordance with [TCPS2 Chapter 3](https://ethics.gc.ca/eng/tcps2-eptc2_2018_chapter3-chapitre3.html)), including the process to 1) address participants’ questions, 2) obtain an attestation of consent (electronic signature, signed statement, or replying via email), and 3) provide a signed (electronic or hard) copy of the consent form to participants.

See template below if participant replying by email (point #4b).

1. Describe the archival process.

***Additional requirements for regulated clinical trials***

1. Describe the method for documentation of consent.
   1. Documentation of consent by way of electronic signature must comply the requirements outlined in points 10-11 above.
   2. If not obtaining an electronic signature for clinical trials during the COVID-19 pandemic, describe the methods used to obtain an attestation of consent. (See Health Canada guidance above).
   3. Documentation of consent by way of email:

* Include a method to verify the identity of the participant replying (consenting) by email (e.g., using a password, verification question specific to that individual).
* The reply email from the participant must include the following information:
* Study title
* Version date of consent form
* Attestation of consent (below)

*By replying to this email, I attest that*:

* All of my questions have been answered
* I understand the information within this informed consent form
* I allow access to medical records and transfer of specimens and related personal health information as explained in this consent form
* I do not give up any legal rights by signing this consent form
* I understand that my family doctor/health care provider [will/may] be informed of study participation
* I agree, or agree to allow the person I am responsible for, to take part in this study

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Name of Participant Date

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Name of Parent/Guardian Date

*If consent provided by Parent/Guardian*

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Name of Person Conducting Date

Consent Discussion