OHRS Information Sheet
Use of Electronic Consent Process in Human Subjects Research

Electronic Informed Consent (eIC) refers to the use of electronic systems and processes that may employ multiple electronic media[1] to convey information related to the study, facilitate the informed consent process conducted by the study team, and to document the agreement of the research subject.

This document will assist Investigators in designing an eIC process that satisfies regulatory requirements and institutional policies.

When designing the eIC process and documents, Investigators should ensure that the following requirements are met:

- All required elements of informed consent[2] must be included, unless the study team requests a waiver or alteration of consent and provides appropriate justification.
- The consent process should be suitable to the study population and paper-based consent should remain an option for participants who may exhibit a lack of familiarity with electronic systems, poor eyesight, or impaired motor skills.
- Forms and related materials should be easy to navigate in order to facilitate comprehension by allowing the user to proceed forward or backward within the system, as well as the ability to stop and continue the process later.
- Subjects must have access to all consent related materials, including when the electronic process includes hyperlinks or other external documents.
- When approved by the IRB, the use of electronic and paper-based forms of consent is interchangeable through the lifespan of a study. For example, electronic informed consent may be used to re-consent subjects who initially underwent the consent process using paper-based documents and vice-versa.
- For remote consent not witnessed by the study personnel, the electronic system must include a method to ensure that the person electronically signing the informed consent is the subject who will be participating in the research study or their Legally Authorized Representative (LAR). Examples of various methods that could be used include verification of a state-issued identification or other identifying documents or use of personal questions, biometric methods, or visual methods – all based on the level of precaution warranted by the research itself (minimal risk vs greater than minimal risk).
- May be combined with HIPAA authorization when both are presented in electronic format.

Additionally, documentation of consent must comply by additional local and federal regulatory requirements specific to the validity of electronic signatures:

- The Massachusetts Uniform Electronic Transactions Act (MUETA) requires four elements to create a valid electronic signature and fulfills both OHRP and FDA requirements: (1) authentication, (2) capturing the user's intent, (3) binding of the signature to the document and (4) maintaining the integrity of the document.
- The electronic method of consent documentation must also capture and record the date that the subject or subject's LAR provides consent.

[1] Electronic media includes text, audio, video, podcasts, passive and interactive websites, biological recognition devices, card readers, etc.

[2] OHRP details the general requirements for informed consent documents: 45 CFR 46.116 https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/#46.116

- For FDA-Regulated Clinical Trials including children as research subjects, documentation necessary to verify their identity for electronic informed consent (e.g. state issued identification) may be lacking. Therefore, the IRB may find it reasonable for the parent to initially document the child's assent, which the investigator verifies when first seeing the child. This use of this process is at the discretion of the IRB.

For both initial review and subsequent modifications, the IRB must approve all electronic media that the subject will receive or view during the consent process. Therefore, when preparing to submit for IRB review Investigators should ensure the following:

- The IRB submission should include all relevant documents, informational materials, videos, web-based information, subsequent materials, etc. in the same format the study team plans to present it to the subject.
- Prior to implementation, the IRB must approve all electronic media that the subject will receive or view during the consent process. This applies to both initial review and subsequent modifications.
- The description of the informed consent procedure must include any optional questions or methods used to gauge subject comprehension and how any consent related media will be used during the consent process.

Additionally, it is the Investigator's responsibility to ensure the following:

- The person who signed the consent must receive a copy. Paper or electronic copies are acceptable.
- If a paper copy of the informed consent is provided to the person who signed, any information provided via hyperlinks, websites, or other digital media should be included in print form, as well.
- Hyperlinks to information on the Internet included in consent forms should be maintained and remain accessible through study completion.

For further guidance, please contact OHRS at (617) 632-3029.

Resources:

- OHRP and FDA Joint Guidance: Use of Electronic Informed Consent https://www.fda.gov/downloads/drugs/guidances/ucm436811.pdf
- Massachusetts Uniform Electronic Transactions Act (MUETA) https://malegislature.gov/Laws/GeneralLaws/PartI/TitleXV/Chapter110Ghttps://malegislature.gov/Laws/GeneralLaws/PartI/TitleXV/Chapter110G