OHRS Information Sheet
Use of Remote and Electronic Consent Procedures in Human Subjects Research

There are two components to the consent process as described in DF/HCC Policy CON-100. First is the consent discussion held between the person obtaining consent and the potential participant, second is how the consent process is documented.

Remote consent is a method of approaching a research subject and obtaining informed consent using a paper or electronic consent form where the study team and participant are not in the same physical location during the consent process.

Remote consent using a paper consent form describes the process whereby a copy of the written informed consent form is provided to the participant via email, fax, mail, or during a prior in-person visit. The informed consent discussion may be conducted via telemedicine visit over the phone, or via video conference (e.g., Zoom). The participant signs and dates a hard copy of the consent form and returns it to the study team via email, fax, mail, or at a subsequent study visit.

Electronic consent is a method of signing a consent document using an electronic system instead of a paper consent form, e.g., in Adobe Sign or REDCap.

Remote Informed Consent

1. When the consent discussion is conducted remotely, it is expected that the consent procedures will still follow CON-100. The following guidance was adapted from the NCI CIRB Standard Operating Procedure. The research team must provide the participant or Legally Authorized Representative (heretofore referred to as the participant) with the informed consent form (ICF) in advance of the consent discussion (e.g., via mail, fax, email, or in person). The research team should provide the participant with two copies of the consent form, so the participant is able to retain a copy for reference when their signed document is returned to the research team. The research team should then provide a copy of the fully executed consent form back to the study participant.
2. Once the participant has the consent form in front of them, the investigator or qualified member of the research team will then discuss the research study via telemedicine visit with the potential participant either via telephone or video conferencing (e.g., Zoom). Please note that the consent discussion should be the same whether in person or remote.
    a. When the conversation is done over the phone, the research team should have a means of verifying the identity of the participant (e.g., use of personal questions or verification of ID).
    b. When the conversation is done over videoconference identity may be confirmed via visual methods.
    c. If the consent discussion is recorded, please note that Massachusetts law requires disclosure of audio recording.
    d. If assent is required, the research staff must have a discussion with both parent/legal guardians and the child participant.
3. If the potential participant agrees to participate, and written documentation of consent is required, the participant may sign the consent during the remote process and return it to the research team (i.e., via

mail, fax or email). If the research team anticipates the use of postal mail, the participant should be provided with a pre-paid, self-addressed envelope.

4. If the consent process requires an interpreter and/or witness, the research record must document the additional party's name(s) and that they were present for the informed consent process. The research team may fill out the DF/HCC Checklist for Documenting the Use of Remote Interpreters for the Informed Consent Process.
5. Once the research team receives the signed informed consent document from the participant, the investigator/designee who conducted the consent process must sign and date the document using the current date. The consent ***should not*** be backdated to match the date signed by the participant.
6. For treatment trials, teams should document in the medical record that remote consent took place. For non-treatment trials, this can be documented on the consent itself, by indicating under the signature line that consent was obtained over telephone or video conferencing, the date of the telephone or video conference, and the date the signed consent was received. For example, "Discussed with [participant or LAR name] via [telephone or videoconferencing] on [insert date] and received signed consent form on [insert date]."
7. The date the document is fully executed, not the date the participant signed the consent, is the official date of informed consent for the participant on the research study.
8. The final informed consent document must be filed in the participant's records. A copy of the final informed consent document, signed by the participant and investigator must be sent back to the participant via email/scan, fax, or postal mail.
9. Whenever possible, the signed consent/assent should be returned to the researcher before a research procedure takes place.

Electronic Informed Consent

Electronic Informed Consent 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. The Electronic Informed Consent process is the means by which this information is provided to the participant, and as part of this process can use systems such as Adobe Sign or RedCap to obtain documentation of informed consent.

When designing the electronic consent process and documents, research teams 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.

[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 research, the platform used for electronic consent must be 21 CFR Part 11 compliant. Part 11 compliant systems have a means of verifying the identity of the signee, an audit trail, and a legally binding electronic signature. Each DF/HCC institution may have access to different Part 11 compliant platforms, such as Adobe Sign or RedCap. The IRB will consider the platform being used as part of their review process.
- The Consent form may be combined with HIPAA authorization when both are presented in electronic format, and for FDA regulated research, presented in a Part 11 compliant platform.

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.
- 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. The 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.
- The New Protocol Application must be updated to include the use of electronic consent.

Additionally, it is the research team'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 ohrs@dfci.harvard.edu .

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

- NCI CIRB Standard Operating Procedures
  https://ncicirb.org/system/files/CIRB_SOPs_01AUG2023_Final.pdf