UCLA Health | David Geffen School of Medicine

Office of Clinical Research
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Subject: Use of Electronic Processes to Obtain Informed Consent

Informed consent involves providing a potential subject with adequate information about the research to allow for an informed decision about the subject's voluntary participation in a research study. Informed consent must include a process that facilitates the subject's comprehension of the information and allows adequate opportunity for the subject to ask questions and consider whether or not to participate (45 CFR 46.116 and 21 CFR 50.20).

A variety of approaches may be used to fulfill HHS and FDA regulatory requirements for informed consent. The purpose of this memorandum is to outline the process for obtaining informed consent using a digital consent form where the study team and participant are not in the same physical location during the consent process, referred to as remote consent (also known as "teleconsent"). Our goals are to:

- **Ensure protection of the rights, safety, and welfare of human subjects**
- **Facilitate the subject's comprehension of the information presented during the remote consent process**
- **Ensure that appropriate documentation of consent is obtained when electronic systems and processes that may employ multiple electronic media are used to obtain informed consent**
- **Ensure the quality and integrity of remote consent data adheres to HHS and FDA regulatory requirements**

Protection of the rights, safety, and welfare of human subjects

- The informed consent document used to guide the consent conference should be the current one approved by the IRB for an approved study.
- The informed consent conference should be conducted by a member of the study team, authorized by the IRB to obtain consent.
- The potential subjects or subject's LAR will be provided with copies of the following documents (as applicable) for review before an informed consent interview:
    - Research Participant's Bill of Rights
    - IRB Approved Informed Consent Form
    - Permission to Use Personal Health Information for Research (HIPAA)
- Study personnel will schedule an informed consent interview with the subject or the subject's LAR, during which the authorized consenter will present the Bill of Rights (if applicable), review details of consent document, and (if consent is obtained) review the HIPAA authorization (if applicable).
    - The authorized consenter is responsible for assessing whether the potential subject/LAR understands how the research will impact the potential subject and other pieces of key information about the research.
    - The authorized consenter is responsible for ensuring that the potential subject has the opportunity to ask questions during the consent conference throughout their involvement in the research. This may be accomplished by in-person discussions with study personnel or by providing means to access the study team electronically through electronic messaging, telephone calls, video conferencing, and/or a live chat with a remotely located investigator or study personnel.
    - When live chat or video conferencing is used during the remote process, investigators and study personnel should remind subjects to conduct the remote discussion in a private location to help ensure privacy and confidentiality.
- Study personnel will verify the identity of the person electronically signing the informed consent is the subject who will be participating in the research study or is the subject's LAR (see 21 CFR 11.100(b)).
    - If the person electronically signing the informed consent is the subject, study personnel will ask the potential subject to verbally confirm their name and date of birth.

- If the person electronically signing the informed consent is the subject's LAR, study personnel will ask the individual to verbally confirm their name, relationship to the subject, subject's name, and subject's date of birth.

Ensure that appropriate documentation of consent is obtained when electronic systems and processes that may employ multiple electronic media are used to obtain informed consent

- For studies with FDA oversight:
  - regulations found at 21 CFR part 11 set forth the criteria under which FDA considers electronic records, electronic signatures, and handwritten signatures executed to electronic records to be trustworthy, reliable, and generally equivalent to a handwritten signature executed on paper (see 21 CFR 11.1(a)).
  - Signatures obtained electronically will use a 21 CFR Part 11 validated solution. UCLA Health has a Part 11 compliant version of DocuSign available for electronic consent documentation for FDA-regulated research.
- For studies not under FDA oversight:
  - Either the UCLA Health or UCLA Campus versions of DocuSign may be used
- Study personnel should ensure that all required electronic signatures are completed contemporaneously.

Ensure the quality and integrity of remote consent data included in FDA applications and made available to FDA during inspections (as applicable)

- Study personnel may submit a signed informed consent form to Health Information Management Services (HIMS) for upload to the EPIC (CareConnect) electronic health record system. Ref. How to Scan a Signed Consent Form into CareConnect on the researchConnect Training Site.
- The informed consent or permission document can be produced in hard copy for review upon request.

Reference:

- 21 CFR 11 - ELECTRONIC RECORDS; ELECTRONIC SIGNATURES
- 21 CFR 50 - PROTECTION OF HUMAN SUBJECTS
- 21 CFR 56 - INSTITUTIONAL REVIEW BOARDS
- 45 CFR 46 - PROTECTION OF HUMAN SUBJECTS
- Use of Electronic Informed Consent in Clinical Investigations – Questions and Answers Guidance for Institutional Review Boards, Investigators, and Sponsors December 2016 (Docket Number: FDA-2015-D-0390)
- UCLA OHRPP – Guidance and Procedure: Obtaining and Documenting Informed Consent