Electronic Informed Consent (eConsent)

Informed Consent Process Series

CARILION CLINIC

What is eConsent?

Electronic Informed Consent (eConsent) is a method for obtaining informed consent from research subjects using a computer-based consent form rather than traditional paper documentation.

- Process of obtaining informed consent does not change regardless of the media used to obtain consent
- Electronic informed consent (eConsent) must contain all elements of informed consent required by HHS regulations (45 CFR 46.116)
  - Navigation in document must be easy:
    - proceed forward or backward within the system
    - change responses within the eConsent form before submitting
    - Permits stopping and continuing later

Signing an eConsent

- Subjects must sign electronically by:
  1. Typing their name AND date
  2. Using ‘Signature’ field with stylus/mouse/finger
- Must be requested in IRB application and approved by IRB
  – Approval determined by type of study conducted

Considerations

eConsents may be used to either supplement or replace paper-based informed consent processes to best address the subject's needs throughout the course of the study.

- Consider the population under study, and whether eConsent is a good option (technology savvy, physical impairments, etc.)
- Prepare for technical difficulties with the platform or internet connection, paper-based consent processes may be needed as a back-up
- Subjects must have option to use paper-based or electronic informed consent methods completely or partially throughout informed consent process

Obtaining eConsent

Carilion uses REDCap to acquire and store subject consent forms through an e-consent Framework and PDF Auto-Archiver. REDCap eConsent module is 21 CFR Part 11 ready and may be utilized for FDA regulated studies at Carilion.

- Allows consent remotely and in clinic
- Accessible via computer, mobile phone, and tablet
- Person obtaining consent will be required to initiate eConsent process from within REDCap for their name and timestamp to appear on the study subjects signed consent form

Document how consent was obtained and the process of obtaining consent in the research record to ensure an accurate representation of the consent process used to obtain consent with each subject.

Project Eligibility

IRB must ensure that the consent process and documentation is appropriate for the risk level of proposed research

- Face-to-face consent may be required in some cases

➢ IRB must approve **before** it is implemented in RedCap

– HART Team must assist in setting up the consent form on a per project basis

– REDCap is the only approved method of obtaining an electronic signature

eConsent Materials to submit to IRB

- Required documents:
  - Word document of each consent document uploaded into the study submission
  - All informational materials
    - Videos (link provided in PRIS3M)
    - Web-based presentation participants will receive to consent

- Protocol must explain:
  - Consent process
    1. How eConsent will be used (e.g., Carilion or the participant's personal computer, electronic tablet, smart phone)
    2. Signature method (stylus, mouse, or finger)
    3. Methods to gauge subject comprehension of key study elements
    4. Plan for verification of the identity of the participant if occurring in a remote fashion

eConsent Form Requirements

Must include:

- Signature section for person obtaining consent
  - Person obtaining consent will be required to initiate eConsent process from within REDCap for their name and timestamp to appear on the study subjects signed consent form
- Easy navigation features
- Forward/backward movement
- Ability to change responses before submitting
- Stop/continue capability

Should be:

- Broken into pages to promote understanding
- Easy to read
- Include comprehension questions requirement at the end of each page or at the end of the consent to document their understanding before signing
- Allow responses changes before submission

Location

- Location options:
  - Study site (in-person)
  - Remote (subject's home or another convenient venue)
  - Both—study site and remote access
- Approved remote platforms:
  - Phone
  - Microsoft Teams

Authentication

IRB application or protocol must include a plan for verification of the identity of the participant if occurring in a remote fashion

- **Authentication methods:**

Established passcode	Known information verification
• Study team and subject agree on passcode during initial contact • Passcode saved as part of subject's record • Subject enters passcode at time of accessing eConsent and with their signature • Research staff manually enters passcode in REDCap prior to accessing the consent form	• Study team informs subject that a combination of their demographic data will be used as their passcode • Study coordinator uses a combination of demographic variables to represent passcode • Subjects would be prompted to answer when accessing the eConsent and signing the consent • Research staff manually enters passcode in REDCap prior to accessing the consent form

- **Must document:**
  - Verification process
  - Authentication steps

Documenting eConsent Process

Document obtaining consent in the research record. The process note should include statements about:

- Method used to discuss study with potential subject (discussion happened over the phone, Microsoft Teams, etc.)
- Questions potential subject asked
- Time the potential subject was given to make their decision
- How long conversation lasted
- Process of verifying the individual's identity over the phone and then with the eConsent signature

Consent Form Access and HIPAA

Subject access

HHS regulations require that the subject be provided a copy of the consent form.

- IRB application or protocol should include a plan for providing copies of the consent to participants

Remote:

- REDCap should be set up to display a button for the subject to download the signed consent form

In-person:

- REDCap can be set up to send the subject an email with a PDF attachment of the signed consent form or signed paper copy

HIPAA

HIPAA authorizations may be obtained electronically, provided that the signature of the subject is valid electronic signature under applicable laws and regulations.

- ➢ Must provide the subject with a copy of signed HIPAA authorization

OHRP requirements

During inspections of clinical investigation sites, OHRP regulations require that OHRP be granted access to the following:

- Records and reports by investigator
  - Site-specific versions of eConsents
  - Materials submitted to IRBs for review and approval
  - All amendments to the site-specific eConsents
  - All subject-specific signed eConsents

These should be available at the site either in electronic or paper form.

Consent Form Revisions

Process:

1. Submit a Change/Update Form in PRISM with the revised Word document
2. Must be reviewed and approved by IRB, before HART will implement a change to eConsent in REDCap
3. Investigator must obtain IRB approval for any subsequent modifications to the study-related information

Questions or need help?

Contact IRB office:

IRB@carilionclinic.org

Reference

Carilion Clinic Institutional Review Board. (2023). Investigator Guidance: Electronic Informed Consent (HRP-804). https://www.carilionclinic.org/econsentguidance