Consent Process Examples

REDCap eConsent Process (FDA Part 11 Compliant)

Description

The Clinical and Translational Science Institute (CTSI) in conjunction with the University of Utah Institutional Review Board (IRB) and in partnership with the Utah Data Coordinating Center, have built and validated electronic informed consent processes and templates to be used for all REDCap based projects. This also includes 21 CFR Part 11 requirements for FDA regulated studies.

This consent process example illustrates the steps a study team should take in preparing to obtain consent using REDCap eConsent that requires FDA 21 CFR Part 11 compliance. This includes your preparation to use REDCap eConsent as well as the procedure a study team may take in obtaining and documenting consent. ***The IRB must approve a consent procedure including eConsent.*** *The details of the procedure to obtain consent can be provided on the Consent Process page of the New Study Application in ERICA. See "Preparing to Use eConsent" below for specific points that should be included in your IRB application.*

Introduction to eConsent in REDCap

What is eConsent? eConsent is an electronic format used to supplement or replace paper-based informed consent forms to provide information to a potential research participant. It can also be used to obtain documentation of informed consent. It is important to note that the consent process and investigator responsibilities remain the same regardless of the format used to obtain consent.

What is REDCap? REDCap is an easy to use, self-service application subsidized for University of Utah research needs by the Clinical Translational Science Institute (CTSI).

Preparing to Use eConsent

While preparing your application for the IRB, you may complete training and preparation to obtain and document consent using REDCap eConsent. The following steps will help you in preparing to use eConsent for your project. Training and preparation to use eConsent can take place before or while your study is being reviewed by the IRB but the IRB must approve a consent procedure including eConsent prior to finalization of the REDCap eConsent.

1. **Take REDCap FDA 21 CFR Part 11 Compliance Training** In preparation of creating eConsent using REDCap, you must take the University of Utah CTSI REDCap FDA 21 CFR Part 11 Compliance training found in Canvas. Additional training materials found on the Electronic Consent Process and Guidance page should be reviewed.

2. **Plan the use of eConsent for your study.** Determine what methods will be used to obtain and document consent. The following questions will help you prepare your application to submit to the IRB and to create your project in REDCap.

    a. How will the consent process be executed (e.g., in person, live contact remote, fully remote (self-guided), combination)?

b. How will consent be documented (e.g., uploaded wet signature, electronic signature, combination of the above, waiver of documentation)
c. What is the format for the information (e.g., traditional paper, electronic (PDF), digital content, combination)
d. What documents are needed (e.g., consent, parental permission, and/or assent)
e. Are multiple languages needed?

3. **Plan for the REDCap components of eConsent that will be used for your study.** Watch the eConsent presentation here.

    a. You may begin to create your REDCap project at any time. You won't be able to complete the eConsent in REDCap until you have final approval, but you may begin building. The eConsent REDCap template has components and instruments (e.g., assent, parental permission, etc.) prepared to help study teams obtain consent. Based on your study, you will be able to customize the template to enable eConsent and ensure it is obtained and documented properly.

4. **Ensure your IRB application includes specific information that accurately reflects your eConsent process.**

    a. **Consent Process Page, Question 2**: This question asks for a description of the location(s) where consent will be obtained. Provide a description of where consent may be obtained in person (e.g., clinic, office, ER, etc.). If applicable, provide a description of any remote aspects of consent (e.g., telephone or video conferencing).
    b. **Consent Process Page, Question 3**:
        - Provide a clear description of the consent process, including a statement confirming the investigator is using REDCap FDA Part 11 compliant eConsent.
        - Your answer should also describe whether there is a waiting period between the consent process and signing the consent.
        - State how the participant will receive a copy of the eConsent. For example, you may send a hard copy or email a copy of the consent form before using the eConsent to document the consent procedure. Other projects may deliver the eConsent via email at the time of initial contact and will view the eConsent on a tablet or phone.
        - Describe how you will provide a copy of the signed eConsent to the participant.
    c. **Consent Process Page, Question 4 and 5**: Clearly describe the measures taken to minimize coercion or undue influence and describe the provisions made to allow adequate time for questions and to exchange information.
    d. **Consent Process Page, Question 8**: Remember that if you are collecting a signature via eConsent, you **will not** request that documentation of informed consent be waived.
    e. **Documents and Attachments**: Remember that the consent document submitted to the IRB should have a signature block that reflects the signatures that need to be obtained even though using eConsent. The typical signature

block includes both the participant and the person obtaining consent. Your REDCap project created from the eConsent template will require an attestation from the person obtaining consent which also serves as their signature although captured separately from the participant's signature.

- Whether a PDF consent will be used, or the text of the consent will be entered in REDCap fields as components, the copy of the consent submitted to the IRB should have the watermark in the footer to enable the IRB approval stamp. Find the Blank Watermark Document on the Forms page of the IRB website.

Consent Process using eConsent

1. **Provide the participant with all the required information about the study in a language the participant understands.**

    a. Use the consent document checklist on the IRB website to ensure all required consent elements are included.
    b. Provide a copy of the eConsent for the participant to review. Depending upon your project, you may have different methods to send or provide a copy of the consent to the participant.
    c. Recognize the digital divide and barriers to access by planning for those who may not have access to, understanding, or capability to use the technology needed for the eConsent process. Be prepared to offer a standard consent process to accommodate, as needed.

2. **Give the participant an opportunity to ask questions before providing consent.** Be prepared to have an appropriate individual available to answer any questions.

3. **Give the participant enough time to consider being in the study.** Ensure that the process includes sufficient opportunity for the potential participant to consider being in the study.

4. **Enable participant to sign eConsent.**
    a. If using a digital signature, only a single signature can be obtained per instrument to be FDA-compliant. Therefore, the signature of the person obtaining consent will be recorded using the attestation form (see step 5).
    b. If manually uploading a wet-signature document into REDCap, the system will make a PDF and lock the document. This method allows for multiple signatures. Attestation will still need to be recorded (see step 5).
    c. As needed, there is a separate instrument for legally authorized representatives (LAR), witnesses, and interpreters. These instruments contain all the necessary questions and data entry components for the signature blocks.

5. **Before beginning any study procedures, complete attestation to finish documenting the participant's consent.** REDCap eConsent templates conform to the requirements of consent documentation.

    a. Attestation in REDCap is a data collection tool and should be completed by the person obtaining consent/conducting the consent process.

- The attestation may serve as the signature of the person obtaining consent although captured separately from the participant's signature.
- Study teams must be prepared to facilitate the completion of attestations. It may require additional time for the person obtaining consent to complete the attestation.

6. **Give a copy of the signed eConsent to the participant or instruct them how the signed eConsent is accessible for download in REDCap.** Depending on your project, different methods may be used to provide a signed copy of the eConsent to the participant. You may use REDCap to automatically email the participant a PDF of the completed eConsent. You may also instruct study participants that they may download the signed consent form.