

IRB SUBMISSION GUIDANCE – REDCAP ECONSENT

REMINDER

This tipsheet from the VUMC HRPP provides the regulatory aspects of using REDCap eConsent in research. Please reach out to the VICTR REDCap team for any technical support questions while setting up eConsent in REDCap.

- REDCap Technical Support: REDCap Team at redcap@vumc.org
- REDCap FDA / 21CFR Part 11 Compliance Support: REDCap Central Team at redcapcentral@vumc.org
- General Research Support: VICTR Research Support Services at research.support.services@vumc.org
- IRB Submission Support: VHRPP website <https://www.vumc.org/irb/> or phone (615) 322-2918

IMPORTANT NOTE: If a study is FDA regulated and records data or consent electronically, the study must use a 21 CFR Part 11 compliant platform for electronic records and/or electronic signatures. It is the investigator’s responsibility to ensure that the chosen platform is set up and validated to meet [21 CFR Part 11 regulations](#). Available platforms that have part 11 compliant features include but not limited to the following: REDCap Central, Veeva, Florence, OnCore, AdobeSign, DocuSign, etc.

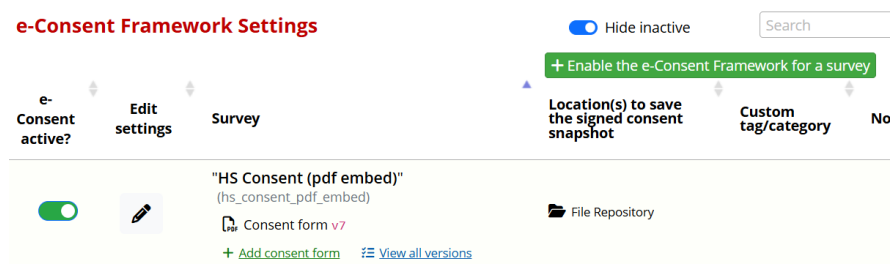
GENERAL GUIDANCE

Researchers using eConsent must obtain IRB approval before implementing this method for obtaining participant consent. REDCap’s eConsent Framework offers:

- Secure electronic signatures for adult participants, parents, legal guardians, children, witnesses, and study personnel.
- Automatic archiving of signed consent documents with date and time stamps for audit purposes.
- Flexibility to accommodate optional components in research procedures (e.g., opt-in tests or procedures).
- PDF copies of the signed consent document that can be generated to give to participants.

To use eConsent in REDCap, you can create a new instrument, mark it as a survey and enable the e-Consent Framework. You can add the text from the IRB approved consent by:

- In “e-Consent Framework Settings”, uploading a PDF of the IRB approved consent document (required for [21 CFR Part 11](#) FDA regulated drug and device studies); OR



- In the Online Designer, modifying this instrument by adding new fields (e.g. Descriptive Text) with IRB approved language

Vanderbilt University Medical Center Institutional Review Board

Edit Field

You may add a new project field to this data collection instrument by completing the fields below and clicking the Save button at the bottom. When you add a new field, it will be added to the form on this page. For an overview of the different field types available, you may view the [Field Types video](#).

Field Type: Descriptive Text (with optional Image/Video/Audio/File Attachment) Codebook

Question Number (optional)
Displayed only on the survey page

Field Label Use the Rich Text Editor ?

Open Sans Paragraph 10pt **B** *I* U ~~S~~ **A**

You are being asked to take part in this research study because . . .

This consent form should start with a short paragraph that outlines key information a participant may want to know to help them decide, such as the following:
[Briefly identify what will happen during the course of the study and the duration]

Variable Name (utilized in logic, calcs, and exports)
study_purpose Enable auto naming of variable based upon its Field Label? ONLY letters, numbers, and underscores

How to use: [Smart Variables](#) [Piping](#) [Field Embedding](#)

Optional media to embed or attach:
Embed media (video, website, survey, etc.) ?
Provide media URL:
e.g. <https://youtube.com/watch?v=E1cCuWMupz0>,
<http://example.com/movie.mp4>, [survey-url[instrument_name]],
<https://redcap.myinstitution.org/surveys/75-M9-HLB8WWT>

Display format of media: Inline Inside popup

– or –

SUBMISSION TYPE

In all cases, IRB approval must be obtained before uploading and utilizing the revised eConsent document in REDCap.

New Studies:

- The application, consent documents and/or protocol, should include details about eConsent and the consenting process.

Amendments:

- If the research will be modified to add eConsent processes**, the application, consent documents and/or protocol should be updated with an Amendment submission, and the submission form should include a rationale for making these changes.
- If the research is already approved to utilize eConsent processes and requires revisions to the eConsent document**, the consent document(s) should be revised to align with the associated study updates, and both a clean copy and tracked copy showing revisions should be submitted for review.

DOCUMENTS – PDF UPLOAD

One document will be approved for use as both the standard paper consent and eConsent. To utilize the PDF upload feature with REDCap eConsent, the following statement should be included within the consent document following the signature lines:

“If electronic signature(s) are obtained, they will be signed separately.”

STATEMENT BY PERSON AGREEING TO BE IN THIS STUDY

I have read this consent form and the research study has been explained to me verbally. All my questions have been answered, and I freely and voluntarily choose to take part in this study.

Date Signature of patient/volunteer

Consent obtained by:

Date Signature

Printed Name and Title

Time: _____
[Time is an optional field. When used, this field should be completed by the person obtaining consent.]

If electronic signature(s) are obtained, they will be signed separately.

PLEASE NOTE: Following IRB approval, the approved consent document stamped with the IRB approval and expiration date should be uploaded to REDCap.

RECOMMENDED IRB APPLICATION TEMPLATE LANGUAGE

Please include language within the Consent section of the IRB Application adequately describing the specific steps for obtaining consent electronically. The below language is recommended and may be used as-is or can be modified based on your study's needs when initially completing or amending IRB applications for use of REDCap eConsent.

The patient consent process will be conducted using a REDCap-based electronic consent form. The consent form has been developed in REDCap, a secure, web-based, HIPAA-compliant, data collection platform with a user management system allowing project owners to grant and control varying levels of access to data collection instruments and data (e.g. read only, de-identified-only data views) for other users.

This study will utilize the electronic consent (eConsent) framework within the REDCap system. The eConsent forms will be presented to participants electronically, allowing them to review, complete, and sign the consent form online. The system will ensure that all signed forms are archived as PDF snapshots for compliance and future reference. Version control will be strictly maintained, and any changes to the consent form will be resubmitted to the IRB for approval prior to implementation. The information obtained from participants within the REDCap system during the eConsent process will align with the information that would have been collected during the paper consenting process.

All consent form versions will be managed using the REDCap version control system. Each version of the consent form will be automatically archived upon participant signature. If a new version of the consent form is required, the previous version will be deactivated, and the new version will be submitted to the IRB for approval before use in the study.

Potential participants will participate in the consent process by (**select method**):

- 1.) Being approached in-person at a Vanderbilt Clinic and accessing the REDCap survey via iPad or other portable electronic device and/or
- 2.) Self-initiated access of consent forms on personal portable electronic devices using posted QR codes or web-links on study posters, brochures, or websites. Self-initiated accessing of consent forms may occur in clinic or at home.

During the in-person consent process, patients will be consented by a member of the key study personnel.

For self-initiated consent, contact information will be provided (email and phone) for prospective patients to contact a member of the key study personnel with questions, prior to consent.

[If the study is not FDA regulated, the following language should be used:

Participant signatures will be obtained using a (**select method**: typed signature, PIN number, written signature – via stylus/cursor, etc.).]

[If the study is FDA regulated, the following language should be used:

Participant signatures will be collected using the REDCap 'Scribble Signature' feature, which captures handwritten electronic signatures in compliance with FDA 21 CFR Part 11 and other applicable regulatory standards.]

Multiple stakeholders (e.g., guardians, participants) will sign separate eConsent forms if required by the study protocol. Upon completion of the consent, participants will be provided with a copy of their version of the consent document by (**select method**: downloading directly from REDCap after certification, printing a PDF copy of the consent form in clinic, providing participants with a business card/brochure with the web link to the appropriate version of the consent, provide home address for mailing of a hard copy of the consent).