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.

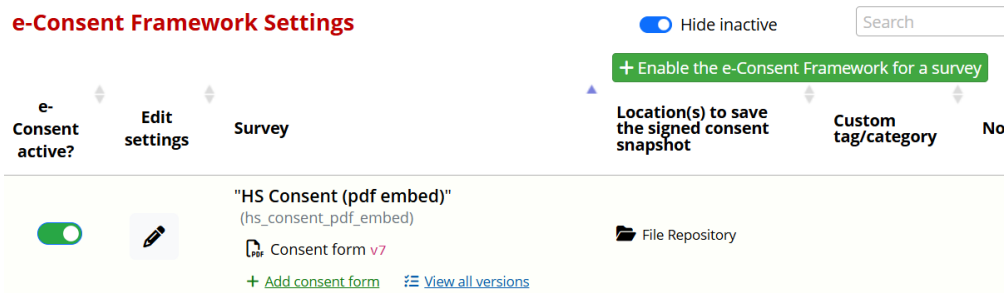
GENERAL GUIDANCE

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

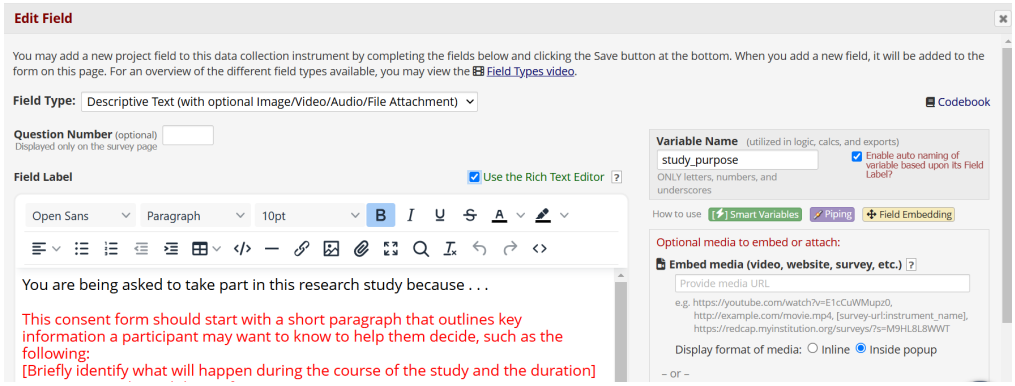
- Secure electronic signatures for adult participants, parents, legal guardians, children, witnesses, and study personnel.
- Automatic archiving of signed consent documents with date and time stamps for audit purposes.
- Flexibility to accommodate optional components in research procedures (e.g., opt-in 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 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 CFR 21 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



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 TO SUBMIT

All consent documents to be used in the eConsent process should be submitted to the IRB.

- **Consent Documents:** If both standard paper consent and eConsent will be used, both the standard and eConsent documents with matching content language should be submitted. For amendments with revisions to consent language, both clean and tracked versions for standard paper consent and eConsent should be included. Please note, it is recommended that the eConsent is submitted to the IRB in Word or PDF format.

- **REDCap Signature Fields:** For eConsent using PDF upload in “e-Consent Framework Settings” specifically, the signature fields (e.g. Participant Signature, Date etc) should be removed and replaced with the following text, “Electronic signature(s) will be obtained in the following section.” Additionally, screen shots of the signature fields in REDCap should be uploaded to ensure alignment with the standard paper consent. One screenshot should be provided for each person signing the consent (e.g. participant, KSP, witness etc). See below for acceptable screenshots for Redcap signature fields (from online designer or pdf export of the instrument)

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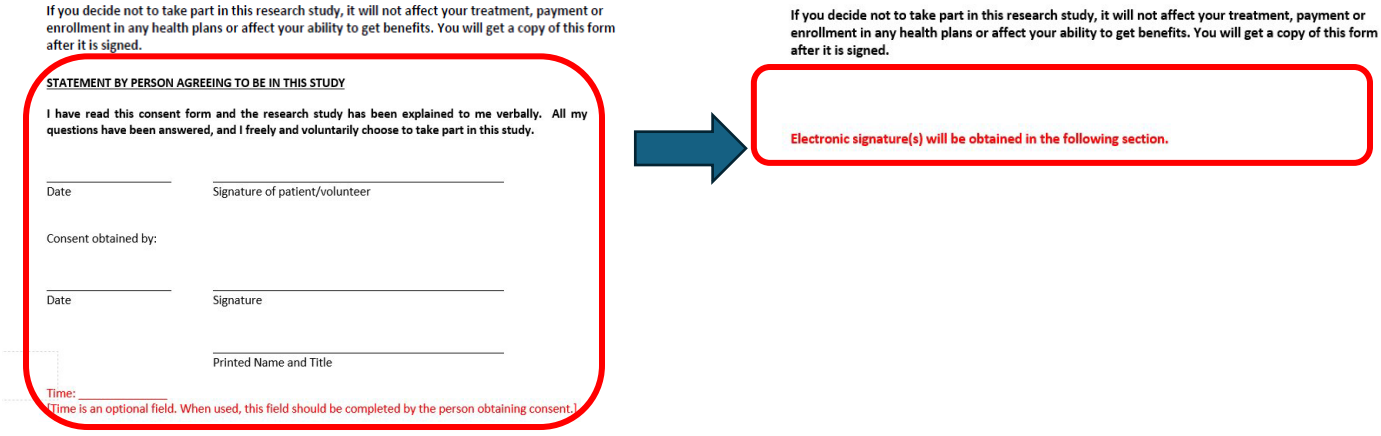
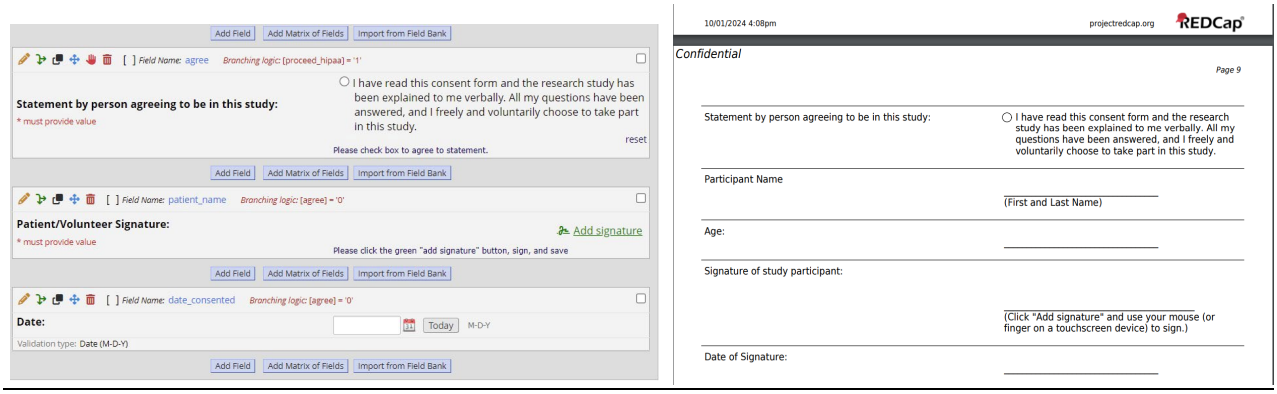
PLEASE NOTE, following IRB approval, the approved eConsent document stamped with the IRB approval and expiration date should be uploaded to REDCap.

Example of changing paper signature fields to Redcap pdf upload



Example screenshots of Redcap signature fields: online designer vs pdf export



IRB APPLICATION TEMPLATE LANGUAGE

Please ensure the eConsent Framework is enabled for all eConsents in REDCap and add the following template language the Consent section of the Application to describe the specific steps for obtaining consent electronically. This language may be used as-is or can be modified to be specific to the study 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.

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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).