Guidance for Using REDCap Electronic Informed Consent (eConsent)

BACKGROUND

What is eConsent?

eConsent is an electronic media/format that can be used to supplement or replace paper-based informed consent forms to provide information to a potential research participant or their legally authorized representative (LAR). It can also be used to obtain documentation of consent (signatures) and elevate the participant's comprehension of the consent information (via interactive components). It is important to note that the **consent process and investigator responsibilities remain the same regardless of the media/format** used to obtain consent.

Furthermore, these electronic processes may allow for rapid notification to the subjects of any modifications pertaining to the informed consent that may affect their willingness to continue to participate. Electronic processes may also promote timely entry of any eConsent data into a study database and allow for timely collection of the subject's informed consent data from remote locations.

What is REDCap (Research Electronic Data Capture)?

REDCap is a secure, web-based, HIPAA-compliant, data collection platform that can be used to develop and deliver study information to a potential study participant/LAR and obtain their agreement to participate (as applicable). The C. Kenneth and Dianne Wright Center administers the VCU REDCap platform. REDCap information and training can be found at: https://redcap.vcu.edu/ (VCU eID required).
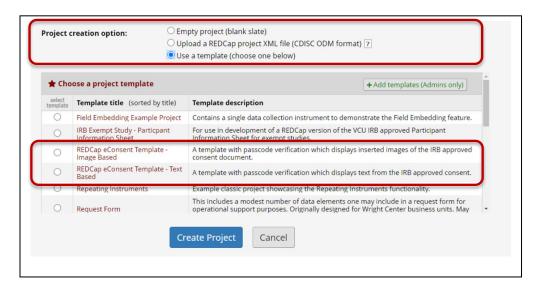
What is the REDCap eConsent Framework?

The REDCap 'eConsent Framework' is referred to as a 'framework' because enabling this option alone does NOT provide an eConsent process but merely provides the general framework or mechanism to allow you to provide eConsent to participants. An eConsent must still be created which includes VCU IRB approved consent language. This framework allows you to implement the eConsent process by providing standardized tools (certification screen + automatic storage of consent form as a 'hard-copy' PDF) while still providing the ability to customize the eConsent according to VCU IRB approval.

What are the REDCap eConsent Templates?

The eConsent templates (text or image based) are REDCap based projects which are comprised of four (4) instruments supporting the eConsent process including identity verification procedures (verification with an established passcode) for obtaining legally valid consent signatures.   Enhanced consent comprehension may also be supported within the template (eConsent instrument) through the use of interactive and visual elements.

The REDCap eConsent templates include the following functionality:

- the ability to consent participants/LARs in-person or remotely via computer, mobile phone, tablet or other digital interface
- the ability to incorporate visual and interactive elements into the consent process to increase comprehension and engagement
- provides for identity verification of all signers
- allows a participant/LAR to electronically sign their name (e.g. a stylus, a finger, or a mouse)
- automatically generates an associated date/time stamp upon participant/LAR signing
- enables participants/LARs to immediately download a PDF of the signed eConsent document or receive a PDF copy via email
- allows the Consenter and PI (or equally qualified Sub-Investigator) to sign their names following the participant/LAR signing with automatically generated associated date/time stamps
- automatically generates and auto-archives a PDF of the eConsent with all signatures
- facilitates Informed Consent Document version control
- REDCap eConsent Templates: identity verification with an established passcode

For support or assistance with building the eConsent instrument, request to consult with the REDCap team at https://go.vcu.edu/bicrequest

When may REDCap eConsent templates be used?

This guidance is intended for use by research studies that WILL require a signature (exempt studies have separate guidance recommendations) and for studies that WILL use interactive elements in the REDCap consent process.

Use of REDCap eConsent MUST be approved by the VCU Institutional Review Board (IRB) as part of the consent approval process and appropriate to the type of study and risk level of the particular research study prior to use.

This guidance is <u>NOT</u> applicable to the following types of studies:

- Signed consent for FDA regulated research as VCU's REDCap platform is not 21 CFR Part 11 validated which is required for all FDA regulated research. Please utilize the [Part 11 DocuSign platform](#) for this functionality.

- This guidance may be applicable to the assent discussion with children or decisionally impaired adults; however, assent signatures may <u>NOT</u> be obtained using electronic signatures because of complexities of identity verification in these populations. The IRB must approve a verbal assent process.

- Translated consent documents that are sometimes used when consenting persons with limited English proficiency. Short form consent documents could potentially be used in REDCap eConsent if an image-based template were used – consult the IRB prior to use.

- Signed consent from persons in foreign countries, due to the complexities of foreign requirements for legally valid signatures.

IRB SUBMISSION PROCESS:

IRB approval of the use of REDCap eConsent must be obtained <u>PRIOR</u> to development of the REDCap eConsent (use of REDCap eConsent templates are strongly recommended). **IRB approval for the REDCap eConsent functionality will occur as a <u>two-step</u> process:**

1. The IRB will review and approve the written content that is proposed for the consent process. After the consent document's content is approved, the eConsent can be built in REDCap using the eConsent framework and available templates.

2. The fully developed eConsent product must then be submitted to the IRB as an amendment <u>prior to beginning to consent participants</u>. The IRB will then review and give approval of the final layout, formatting, and presentation of the eConsent information, any interactive elements, and signature capture processes.

Step 1: The following items are to be included in the submission (initial or amendment) that <u>first proposes</u> to use REDCap eConsent functionality:

1. Prepare and submit a Word version of the consent document:

    a. Use the [IRB consent templates](#) to ensure you include all necessary elements of consent

    b. Refer to the REDCap eConsent template as you think about how to structure sections and content of the consent document. For example, if you plan to include a video that explains a study procedure, the textual material could be more concise.

    c. Above the signature block(s) include the REDCap eConsent Certification statement:

       "I certify that all the information in the document above is correct. I understand that clicking 'Submit' will electronically sign the form and that signing this form electronically is the equivalent of signing a physical document."

    d. Upload the Microsoft Word version of the consent document into the IRB submission to facilitate redlining/track changes for any edits needed.

Step 2: After the REDCap eConsent is built, submit an amendment with the final eConsent materials <u>as the participant will see them</u> for IRB review and approval

1. Submit PDF versions of all of the forms/surveys that make up the eConsent instrument for the IRB to verify the eConsent contains all necessary content and signatures.

2. The study team must complete and upload the [REDCap eConsent Settings Worksheet](#) (available on the IRB's Forms webpage) as a way to provide the IRB with information about settings, notifications, and functionality that relate to privacy, confidentiality, and consent. In the Worksheet, provide the following descriptions of the consent process (see [Appendix I](#) for guidance):

   a. A description of the consent discussion format: ***in-person, remote*** *(e.g. video conferencing, phone)**, or hybrid**.

      i. If there will be no eConsent discussion (i.e. exempt survey studies) describe how self-initiated access of consent forms will occur. For example, access on personal portable electronic devices using posted QR codes or web-links on study posters, brochures, or websites (*Please note: Use of this option will be rare for expedited and full board studies)*.

   b. A description of how the eConsent document will be provided to the participant/LAR for signing: ***in-person, remote*** *(e.g. email, text)**, or hybrid**.

   c. A description of how the participant/LAR will receive a copy of the signed eConsent document. The REDCap eConsent templates allow for participants/LARs to:

      i. directly download or print the eConsent PDF from the REDCap eConsent certification page

      ii. receive an email with the eConsent PDF attachment

         1. permission of the participant/LAR to use this option must be obtained and documented within the REDCap eConsent study project as email security cannot be controlled once sent

         2. the email/text should <u>NOT</u> include any identifiable health information (PHI)

         3. include that participants/LARs may be provided the eConsent document via email in the privacy/confidentiality section of the consent form

      iii. have the research team send a hard copy to a physical address

   d. a description of any other relevant information (e.g., use of translators for non-English speaking participants, use of witnesses when required for the consent process).

2. The amendment should also include a description of any supplemental comprehension components such as definitions, questions asked, or interactive elements for comprehension enhancement.

   a. Any supplemental informational materials including videos, photos, weblinks, and web-based presentations participants/LARs will view or receive during the eConsent process should also be provided to the IRB for review.

b. The IRB will not accept solely a weblink to the eConsent. The IRB's records must maintain documentation of all consent versions that are approved, so the final eConsent materials need to be submitted as an upload.

c. Several videos explaining common medical procedures are available from the STRIDE Project at:
https://www.youtube.com/channel/UCKOqWFdtVU7XsxWs2fpfvNQ

Step 3: After IRB approval, the REDCap eConsent template may be put into production and Implemented. Study teams should submit amendments as usual whenever consent revisions are made.

HOW DO YOU VERIFY THAT THE INDIVIDUAL(S) SIGNING IS THE INTENDED PERSON?

If any or all of the consent process takes place remotely and is not personally witnessed by study personnel, the process must include a method for identity verification to ensure that the person electronically signing the informed consent is the person who will be participating in the research study or is the person's LAR.

There are four possible verification methods that may be used. The method used will vary depending upon the study population, study, desired use of identifiers, and IRB approval.

1. **Verification with an Established Passcode (<u>templates utilize this option</u> and is most often used):** In this approach, an agreed upon passcode is communicated between the participant/LAR and the study team. This passcode is saved as part of the participant's record for verification use later. The participant/LAR at the time of accessing the eConsent form must then enter the provided passcode.

2. **Verification with Known Information:** In this approach, the study team chooses to add questions to answer at the time of accessing the eConsent form. These questions should be pre-established security questions such as "What is your favorite color?" or "What is the name of the street you grew up on?" The responses should be agreed upon by both the study team and the participant/LAR during an in person or remote (video conference or telephone) conversation. The answers will be saved as part of the participant's research record for verification use. To use this verification method, submit a request to consult with the REDCap team at https://go.vcu.edu/bicrequest

3. **Verification with a Passcode Based on Known Information:** In this approach, a study team who has collected sufficient demographic data can verify authentication without agreeing to a prior known passcode or information by simply informing the participant/LAR that a combination of their demographic data will be used as their passcode. This is a more robust form of authentication in the sense that no transmission of information between the participant/LAR and study team is required, because the information should already be known by both. For example, when obtaining eConsent a study coordinator who has collected or has access to the participant's date of birth, middle name, and street name may choose a combination of these variables to represent the passcode, which the participant/LAR would then be prompted to answer when accessing the eConsent. To use this verification method, submit a request to consult with the REDCap team at https://go.vcu.edu/bicrequest

4. **Verification with Identity Document Upload:** In this approach, a government specific identity verification would be required. The study team could verify identity using a government issued ID during the video conference by taking an image or screenshot during the conversation. Or the study team could implement a post-process verification method, which requires the participant/LAR to upload a picture or scanned version of a specific identity document such as a passport or state issued ID card to accompany the e-Consent submission. This method would require manual document review by the study staff to ensure the information matches what is expected. To use this verification method, submit a request to consult with the REDCap team at https://go.vcu.edu/bicrequest

The identity of the person obtaining consent and the PI (or equally qualified sub/co-investigator) will be verified when those individuals log into REDCap to sign the consent form.

APPENDIX I: Models of Using REDCap in the Informed eConsent Process

	Model A	Model B	Model C	Model D
Facilitated Consent Type	Fully virtual, may or may not be facilitated	Fully virtual with facilitator	In-person facilitation with electronic documentation	Hybrid B & C
IRB Review Type	Exempt and some expedited studies	Exempt studies that need signed HIPAA or FERPA consent Full board or expedited studies	Full board or expedited studies	Full board or expedited studies
Method of consent discussion using REDCap e-consent module	May or may not include a virtual discussion	Virtual discussion (facilitator and potential participant) engaged in informed consent discussion	In-person discussion (facilitator and potential participant) engaged in informed consent discussion	Virtual facilitator and potential participant engaged in *preliminary* informed consent discussion <u>In-person</u> follow-up informed consent discussion at visit
Method of documentation of informed consent using REDCap e-signature fields	*No signature required* Waiver of documentation of informed consent approved OR Exempt studies where consent signatures are not required	*Signature required:* Signed consent using electronic signature Facilitator e-signs as the person conducting consent discussion. PI e-signs later.	*Signature required:* Signed consent using electronic signature Facilitator e-signs as the person conducting consent discussion. PI e-signs later.	*Signature required:* Signed consent using electronic signature at the in-person follow-up Facilitator e-signs as the person conducting consent discussion. PI e-signs later.
Sample study types	• Online surveys • Phone interviews • Virtual tasks or educational interventions	• Exempt studies that need signed HIPAA or FERPA consent • Studies where the first visit involves only interactions • Studies consenting an LAR or 2nd parent who cannot be physically present at the study site • Studies with COVID patients	• Studies where the first activity involves an in-person intervention (e.g. blood draw) • Complex studies • Studies that only have one, in-person study visit • Studies with special or vulnerable populations	• Studies where the first study activity involves an in-person intervention (e.g. blood draw) • Studies with a preliminary consent presentation to a group or class and then individual study visits • Very complex studies
Research Team Guidance	[REDCap Exempt Information Sheet](#)	IRB Guidance for Using REDCap Electronic Informed Consent (eConsent) *[This document]*		
REDCap Templates	[Exempt Study - Participant Information Sheet](#)	REDCap eConsent Template - **Image Based** • A template with passcode verification which displays inserted images of the IRB approved consent document. REDCap eConsent Template - **Text Based** • A template with passcode verification which displays text from the IRB approved consent.		

APPENDIX II: REFERENCES

Family Educational Rights and Privacy Act (FERPA) is a Federal law that protects the privacy of student education records. The law applies to all schools that receive funds under an applicable program of the U.S. Department of Education.

FDA Use of Electronic Informed Consent in Clinical Investigations - Questions and Answers. Guidance for Institutional Review Boards, Investigators, and Sponsors. December 2016

Good Clinical Practice: ICH Harmonised Tripartite Guideline. E6. Guideline for Good Clinical Practice, Section 4.8 - Informed Consent of Trial Subjects

VCU IRB WPP# XI - Documentation of Informed Consent, Waiver of Documentation, and Required Signatures (Archived)

VCU/VCUHS Clinical Research Standard Operating Procedures: CR-RE-315: Informed Consent

Chen, Cindy et al. "Evaluation of a REDCap-based Workflow for Supporting Federal Guidance for Electronic Informed Consent." *AMIA Joint Summits on Translational Science proceedings. AMIA Joint Summits on Translational Science* vol. 2019 163-172. 6 May. 2019