Electronic Consent For 21CFR Part 11 Compliant Studies

READ ME FIRST:
The instructions below are specific to the use of REDCap electronic consent **for 21CFR Part 11 Compliant Studies at CHOP**. If you are already familiar with setting up e-consent forms for CHOP studies, please be advised that there are many settings required that are **specific to Part 11 studies and may differ from your previous experience setting up REDCap e-consent forms.**

Please complete the Part 11 Consent Training and Attestation before starting to work on your e-consent forms.

At CHOP, only REDCap's e-consent module is validated to be Part 11 compliant. REDCap is not Part 11 validated for electronic data capture.

At CHOP, electronic consent (e-consent) can be used for a variety of research protocols, including for FDA-regulated studies to which 21CFR Part 11 applies. The study team must submit their plan for consent (including e-consent) for IRB approval.

Once the IRB has approved your study's use of e-consent, you can get started on your consent form in REDCap. Your consent form doesn't have to be finalized to start creating your REDCap form, but it should be in IRB review.

Steps for Creating Your Consent Form(s)

1. Study staff who will create or modify e-consents must first complete the Part 11 Consent Training and Attestation. The Training contains several user-friendly videos that, along with this guide, will help you create compliant consent forms. Access training at https://redcap.link/choppart11training

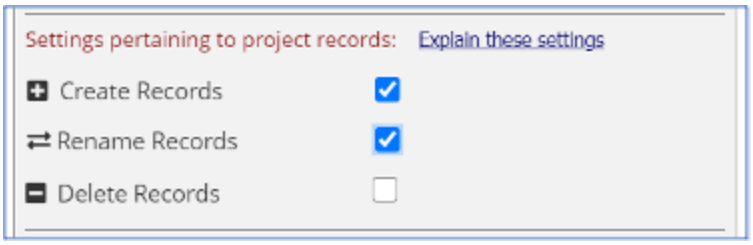
2. Create your REDCap project. There are several ways to start a project that will contain e-consents in REDCap.
    a. Create a project from scratch and create all consent forms as needed.
    b. Start with a template project, available from the New Project menu or as a downloadable XML file from the Part 11 Training website:

    (insert screenshots if we're planning to use template projects)

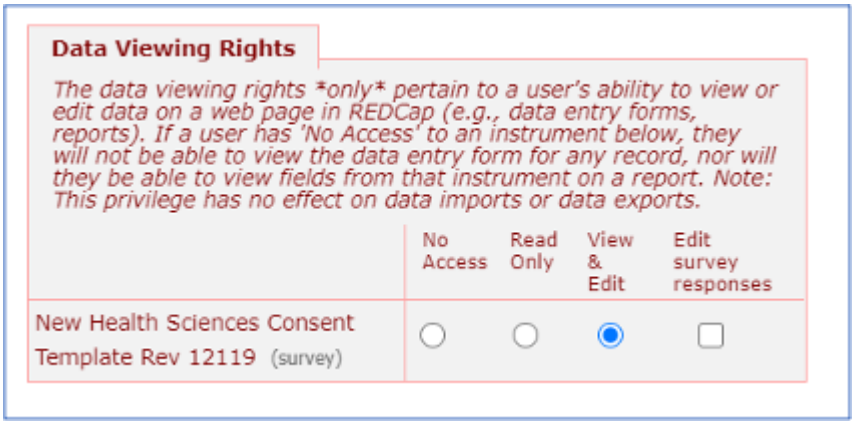
Electronic Consent For 21CFR Part 11 Compliant Studies

3. There are some User Rights considerations specific to Part 11 Studies. These are:

    a. Delete Records should NEVER be selected for any user or user role.



    b. Edit survey responses should never be selected for any user or user role



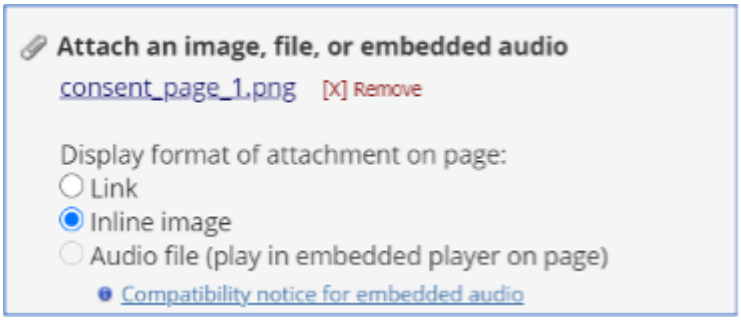
4. You'll create forms in your REDCap project for each consent form you need for that project. The forms you need will depend on whether you're administering a contactless consent, or administering a consent in-person on a shared iPad or other device.

Electronic Consent For 21CFR Part 11 Compliant Studies

Contactless consent: Separate forms are required for each person (or authorized representative) signing. This means you'll need a participant consent form, based on your paper consent, a staff attestation, and could also have a witness (which may be the interpreter) attestation.

In-person consent on a shared device: All individuals present can sign on a single form.

5. Insert the text of your consent form into your REDCap form. There are **two options** for getting the text of your paper consent form into REDCap:
    a. Take the text directly from your approved consent and **copy-paste** into Descriptive Text fields within your Informed Consent form. You can use one long Descriptive Text field, or split the text up into several fields. You may want to use section breaks and HTML to manipulate your text in this process.
    b. Take **screenshots** of the individual pages of your consent form and upload individually into Descriptive Text fields in your form, displaying each as Inline images:



There are positives and negatives to both approaches, and you'll need to choose what works best for your study:

Electronic Consent For 21CFR Part 11 Compliant Studies

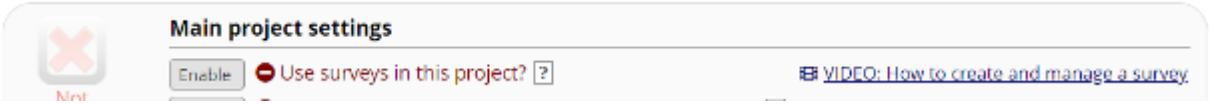
	Pros	Cons
Copy/paste text method	• Works well across devices • Eliminates redundant fields	• Copying/pasting/HTML can lead to human error
Screenshot method	• Exact copy of paper consent – no possibility of copy/paste error • Already formatted, doesn't need additional formatting in REDCap	• Need to include signature page images, but also need to re-create signature fields in REDCap – can look redundant • Need to test thoroughly on phones and tablets to make sure screenshots are readable

6. Use **signature fields** within your project to obtain subject signatures. These fields must be made **required**. You can have up to five signature fields on one consent form.

7. All **date fields** must use @TODAY and @READ-ONLY action tags so that they will be automatically filled in and not editable.

Electronic Consent For 21CFR Part 11 Compliant Studies

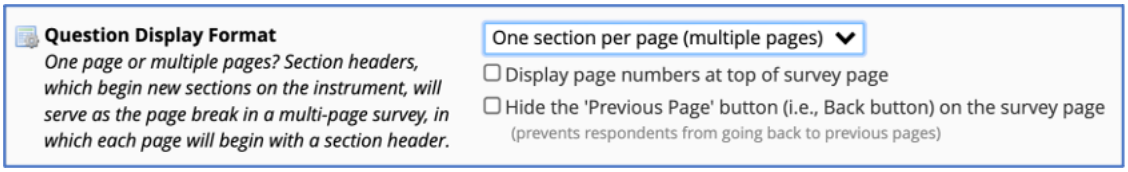
8. **Enable surveys overall for your project**, then enable the Consent form(s) as survey(s) – this includes staff/witness (interpreter) attestation forms. To enable surveys overall for the project (if you haven't already), navigate to the "Project Setup" tab and click "Enable" next to "Use surveys in this project". If your project is already in Production mode, you'll need to contact a REDCap administrator to turn this feature on for you:



Then **enable your Informed Consent Form(s) as survey(s)** within the Online Designer:

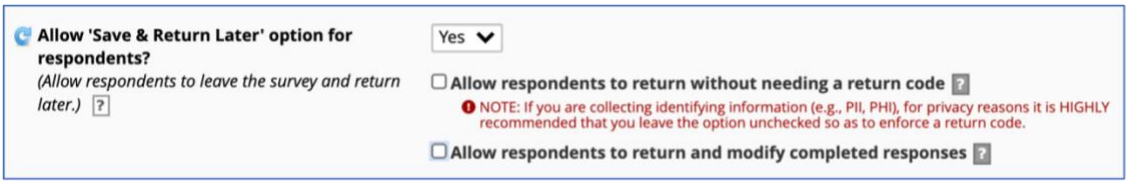
Refer to the Enable Surveys document on the REDCap Intranet page for more guidance if needed.

9. Once you have enabled your Informed Consent form as a survey, you'll need to set the **Survey Settings**. Most of the survey settings are at the research team's discretion, but those listed below are vital to Part 11 Compliance:
    a. Question display format
        i. If survey setting "Question Display Format: Once section per page" is utilized, then Previous Page option must **not** be disabled.

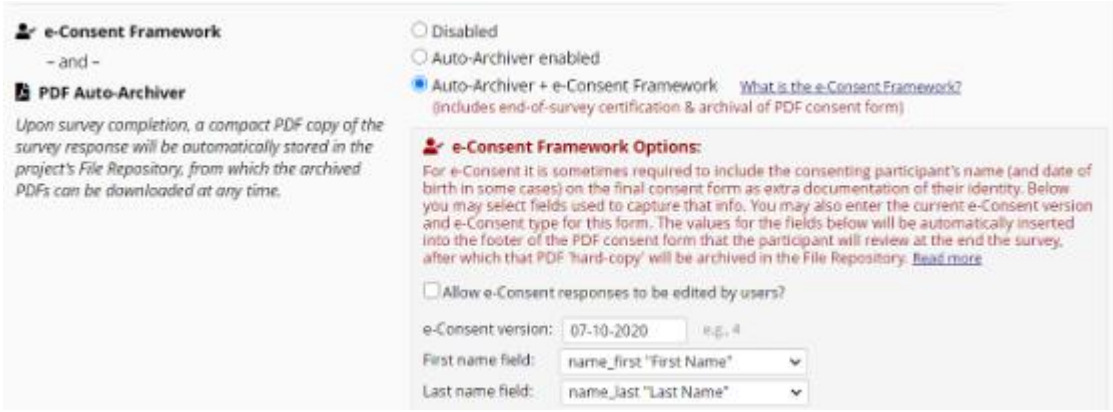


Electronic Consent For 21CFR Part 11 Compliant Studies

b. Allow 'Save & Return Later' option for respondents?
   i. To allow for stopping and continuing at later time, enable this option. Additional options "Allow respondents to return without needing a return code" and "Allow respondents to return and modify completed responses" must **not** be enabled for Part 11 e-Consent surveys:



10. **Enable the Auto-Archiver + e-Consent Framework** on the Survey Settings page:

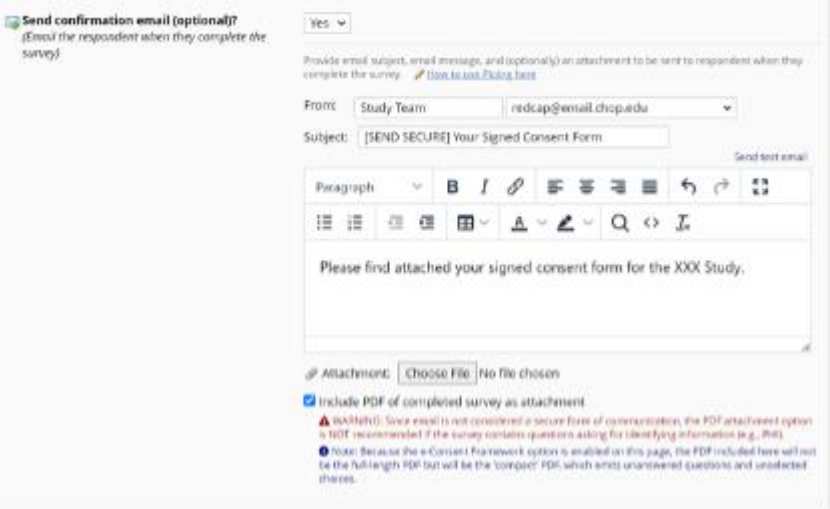


For Part 11 studies, the "Allow e-Consent responses to be edited by users" must NOT be checked off. Contactless consent will require a separate attestation form that study staff will sign, eliminating the need for editing the consent form once the participant has signed.

Additionally, the setting to force signature fields to be erased if the participant clicks the "Previous Page" button on the certification page **must be turned on for all signature fields in the consent form or attestation.**

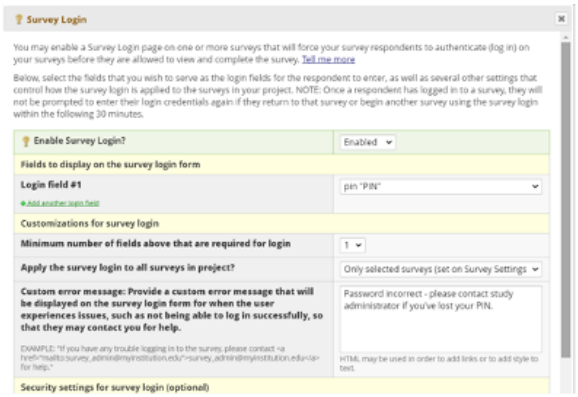
Electronic Consent For 21CFR Part 11 Compliant Studies

11. Set your project up to email a copy of survey to participant – also set at the bottom of the survey settings. This automated email ensures that Consent forms always include PHI, so you **must** use [SEND SECURE] in your subject line for security:



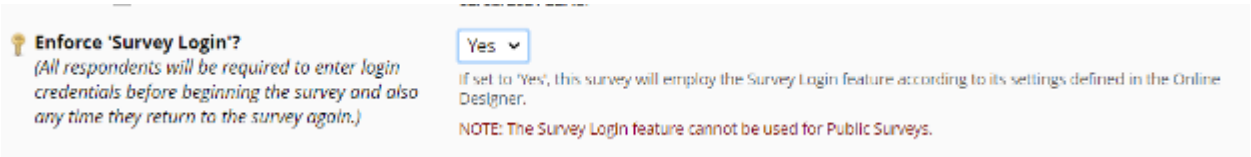
12. **FOR CONTACTLESS CONSENT ONLY:**
Follow steps 5 through 11, including setting up the automated email to go to the participant/authorized representative, for staff/witness consent attestations in addition to participant consent form.

13. Part 11 Studies also require the use of the Survey Login feature when sending e-consents to participants in order to verify participants' identities.
Create a Participant Information instrument that study staff will fill in as a data entry form before sending the consent form to the participant. This form will contain the subject email address and a subject PIN that they will use to log into the survey.
The PI or study coordinator will need to verbally give the participant a PIN over the phone. You'll set the survey login up to use the PIN field as your login field:

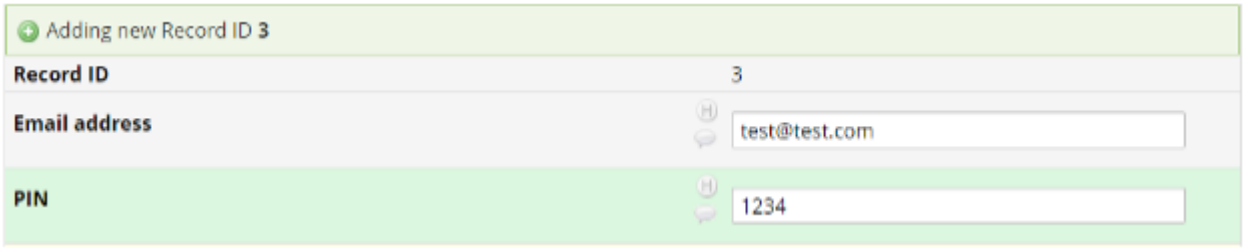


Electronic Consent For 21CFR Part 11 Compliant Studies

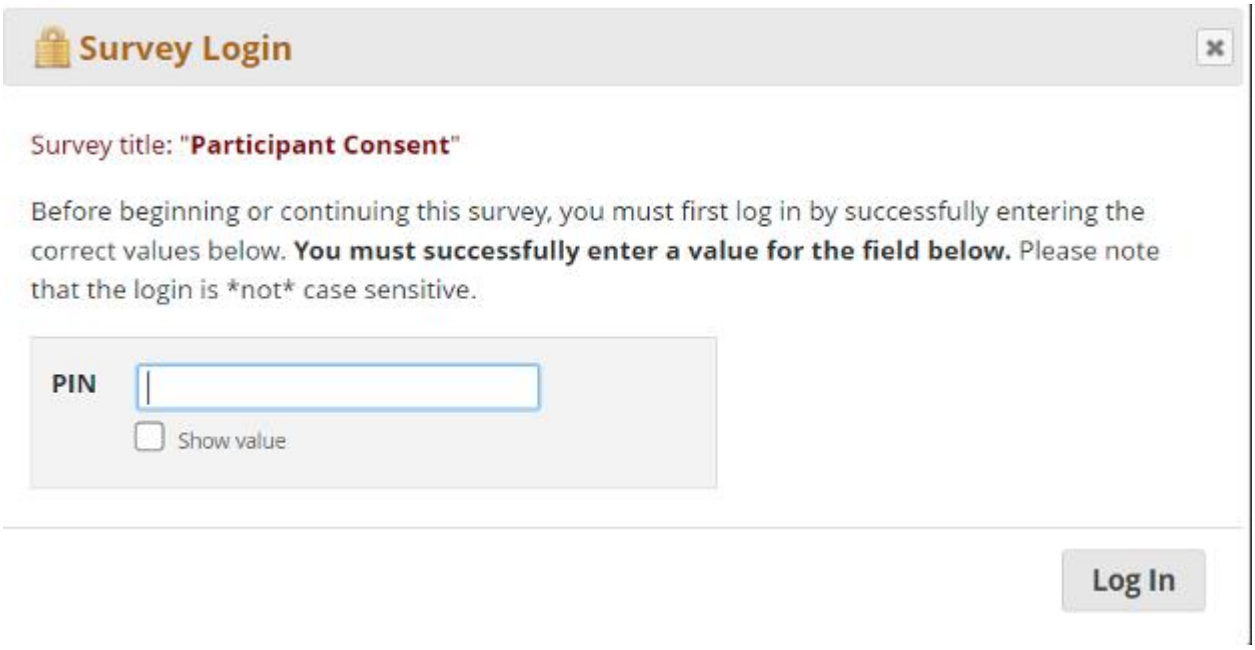
Then, in Survey Settings for the Participant Consent instrument, turn on "Enforce Survey Login":



For each participant, you'll need to add the PIN and give it to them before sending them the consent survey:



The participant will need to enter the PIN given to access the survey:



Electronic Consent For 21CFR Part 11 Compliant Studies

14. **FOR CONTACTLESS CONSENT ONLY:**
    Once the participant or authorized representative has completed their consent form, the staff member(s) who consented them will need to fill out their own attestation(s). These must be **opened and filled out as surveys** in order to go through the e-consent framework.

    In order to open each form as a survey, navigate to the Record Home Page for the previously consented record. Once there, click inside the bubble for the Staff Attestation:

Choose Open survey from the Survey options dropdown menu:

The form will open as a survey, and you can fill it out including the e-consent framework.

If there's a need to send an witness (interpreter) their attestation, you can follow the same process, but choose "Compose survey invitation" to send them their attestation form.

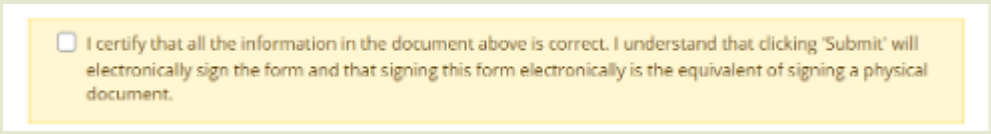
Electronic Consent For 21CFR Part 11 Compliant Studies

15. When your e-consent is set up, the IRB may want to see a PDF of the completed consent form in REDCap. You can download a blank PDF of the form from the Online Designer:

If there's extensive branching logic, the IRB may want you to provide different versions depicting the different consent scenarios. If that's the case, you can enter a consent using test data to show the branching logic, then download the PDF from within that record.

Once enabled, the e-consent framework provides:

- An end-of-survey certification notifying the participant that signing the e-consent form is the equivalent of signing a paper document:



- Auto-archival of the signed PDFs in the project's File Repository as well as in a Secure Vault (SFTP site) specifically for Part 11 consent forms
- Space to include the e-consent version and the participant's first and last name on the PDF

Electronic Consent For 21CFR Part 11 Compliant Studies

Additional considerations

Version Control

- Will you be consenting over a long period of time and therefore changing the consent with new language and fields?
    - If yes, consider using **additional version control** besides the version option within the eConsent framework. There are two options for this:
        - **Separate instruments:** Create a new instrument for each new consent form. This is an easy option if there will only be a couple updates- you'll "retire" old consents by taking the survey offline and moving the instrument to the bottom of your list of instruments (in Online Designer).
        - **Single consent with branching logic:** If you will have many consent versions, you might want to keep a single consent form and use branching logic to show/hide changes to any language. To do this, you must use a hidden "Version" multiple choice field that is defaulted to the current version. Descriptive text fields with new or changed language can use branching logic to be hidden/shown based on the version. Any new version number must be added to the multiple choice list, and the @DEFAULT action tag must be updated accordingly.

Branching Logic

- You can use branching logic to set up your consent form so that participants only see the fields they need to fill out.