

How to Use REDCap's e-Consent Framework

Having a clear and comprehensive consent process is essential to any research involving human subjects. REDCap's e-Consent framework provides the tools necessary to develop an e-Consenting process.

What is REDCap's e-Consent framework?

Electronic consent (e-Consent) is a platform using REDCap's survey features to consent research participants. This consent process can happen on site or remotely. This is a substitute for consenting on traditional paper documentation. Electronic consent forms can be completed via computer, mobile phone, or on a tablet.

When the e-Consent framework is enabled, the following will happen:

1. After a participant completes the consent form, a certification page will appear displaying an in-line PDF copy of the survey responses. They will be asked to confirm that all the information is correct. The e-Consent survey is **not** marked as complete until the participant has finished the certification step and submitted the survey.

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.


If any information above is not correct, you may click the 'Previous Page' button to go back and correct it.

<< Previous PageSubmit

2. A PDF snapshot of the completed consent form will be saved in the project's File Repository. The PDF snapshot will have a footer that includes the e-Consent Framework Options (e.g. name, date of birth) as additional documentation of the consenter's identity.

Using REDCap's e-Consent framework

1. Build your consent document in REDCap.
2. Enable the e-Consent settings in the e-Consent framework the way you need them to function in your project.
 - a. Enable the project to have surveys.



Not started

I'm done!

Main project settings

Disable ✔ Use surveys in this project? ?

Enable 🚫 Use longitudinal data collection with defined events? ?

Enable 🚫 Use the MyCap participant-facing mobile app? [Learn more about MyCap](#)

Modify project title, purpose, etc.

[VIDEO: How to create and manage a survey](#)

- b. Enable your consent form to be a survey.

Instrument name	Fields	View PDF	Enabled as survey	Instrument actions	Survey related options
Biomedical Research Consent Form	29		<input type="button" value="Enable"/>	<input type="button" value="Choose action"/>	

- c. On the Online Designer page, select the “e-Consent and PDF Snapshots” button to open the e-Consent options.

The screenshot shows the 'Data Collection Instruments' section with a sidebar on the left containing 'Create', 'Import', and 'Upload' buttons. The main area has 'Form options' and 'Survey options' sections. A button labeled 'e-Consent and PDF Snapshots' is highlighted with a red box.

- d. Select the “Enable the e-Consent Framework for a survey” to open the e-Consent settings and pick the relevant survey from the dropdown list that appears.

The screenshot shows the 'e-Consent Framework Settings' page. A green button labeled '+ Enable the e-Consent Framework for a survey' is highlighted with a red box. Below the button are several tabs: 'e-Consent active?', 'Edit settings', 'Survey', 'Location(s) to save the signed consent snapshot', 'Custom tag/category', and 'Notes'. A search bar is also visible.

- e. e-Consent settings include:
- i. “Allow eConsent responses to be edited”: If this is selected, users with “Edit survey answer privileges” for the consent form will be able to edit or add responses. Edited responses will not be reflected in the “File Repository” saved consent.
 1. We strongly discourage checking this box to ensure electronic consent documents are preserved should a project be audited.
 - ii. First name field: Select the variable where the participant’s first name is recorded. This is so the participant’s name can be included in the footer.
 - iii. Last name field: Select the variable where the participant’s last name is recorded. This is so the participant’s name can be included in the footer.
 1. If you want to capture the participant’s name in one field only, select it for either first or last name and leave the other option unselected.
 - iv. Date of birth field: Select the variable where the participant’s date of birth is recorded. This allows for extra validation of age and identity.
 - v. Custom tag/category for PDF Footer and Custom label for PDF header: Places to customize what text is shown in the saved PDF’s footer and header.
 - vi. Signature fields: Select any signature fields that should be erased if a participant uses “Previous page” while on the certification page.
 - vii. Location(s) to save the signed consent snapshot: PDFs are, by default, saved to the File Repository. They can also be saved to a specified File Upload field in the project.
 - viii. Snapshot file name: This allows the research team to customize the name of PDF snapshots.
 - ix. Optional notes: This note can be used for internal referencing and will appear in the right-most column of the e-Consent page.


- f. Once your settings are finalized, select “Save settings.”
- g. Optional consent form versions are added by pushing the “+ Add consent form” link after e-Consent settings are saved. You can use the “Add consent form” feature to add multiple consent forms that are selectively shown on the same e-Consent survey. This is best used for complex projects, such as multi-site studies where Data Access Groups (DAGs) are used or multi-language studies where consent forms will be presented in multiple languages. If the previous scenarios do not apply to your study, we ***do not recommend*** using this feature. If you need to use this feature, push the “+ Add consent form” button and enter the following information:

The screenshot shows the REDCap e-Consent interface. At the top, there are several tabs: 'e-Consent active?' (with a toggle switch), 'Edit settings' (with a pencil icon), 'Survey', 'Location(s) to save the signed consent snapshot' (with a folder icon), 'Custom tag/category', and 'Notes' (with a notepad icon). Below these tabs, the main content area displays the title '"Biomedical Research Consent Form"' and the identifier '(biomedical_research_consent_form)'. A red box highlights the '+ Add consent form' button. To the right of the main content, there is a 'File Repository' icon and a note that says 'This is a note'.

- i. # Consent form version: This is an open text space allowing you to keep track of what version of a consent form a participant is signing. Every time a change is made to the consent form, the version number needs to be ***manually*** updated in the survey settings.
- ii. Select a descriptive field from the dropdown next to “Placement of consent form.” This is the field where the different consent forms will be embedded. If there are no descriptive fields in the e-Consent survey, there will be no options in the dropdown menu.
- iii. Select which DAG and/or which participant language the consent form should appear for in the specified dropdown menus. If there are no DAGs or additional languages created, there will be no options in the dropdown menus.
- iv. Enter the text of the consent form in the rich text editor.
- v. Push the “Add new consent form” button.

Emailing a Copy to the Participant

Generally, participants should receive a copy of their signed consent form. REDCap can automatically email a copy of the signed PDF generated by the e-Consent framework to the participant. To do this, ensure that “Send confirmation email?” is marked “Yes” in the main survey settings and that the box to include a PDF of the completed survey as an attachment is checked.

 **Send confirmation email?**
(Email the respondent when they complete the survey)









Yes ▾












Provide email subject, email message, and (optionally) an attachment to be sent to respondent when they complete the survey. [How to use Piping here](#)

From: Research Study | hjberna2@illinois.edu ▾

Subject: Consent Form

Send test email

Paragraph ▾ | **B** | *I* |  |  |  |  |  |  |  | 

 |  |  |  |  |  |  |  |  |  | 

Here's a copy of your signed consent form.

Attachment: No file chosen


Include PDF of completed survey as attachment

⚠ WARNING: Since email is not considered a secure form of communication, the PDF attachment option is NOT recommended if the survey contains questions asking for identifying information (e.g., PHI).


📘 Note: Because the e-Consent Framework option is enabled on this page, the PDF included here will not be the full-length PDF but will be the 'compact' PDF, which omits unanswered questions and unselected choices.


There are several ways REDCap can know where to send the copy of the consent form. The method you use will depend on your research design and other aspects of your study.


1. Ask for the participant's email address on the consent form or another survey or form that will be completed **prior** to the consent form (such as a pre-screening survey). Designate that field to receive REDCap emails either:
 - a. At the project level: On the "Project Setup" page under "Enable optional modules and customizations."


 **Enable optional modules and customizations**


Optional

 Repeating instruments ?

 Auto-numbering for records ?

 Scheduling module (longitudinal only) ?

 Randomization module ?

 **Designate an email field for communications (including survey invitations and alerts) ?**

Field currently designated: **email** ("Participant's Email")


- b. At the survey level, on the "Survey Settings" page under "Survey Customizations."

Survey-specific email invitation field
Designate an email field for sending survey invitations for this survey only. [?](#)

sbr_email "Participant's Email" ▼

Note: This option will override the project-level email invitation field (if enabled on the Project Setup page) and will also override any email address originally entered into the Participant List. Also, if this field has no value and the project-level email field is enabled, then the project-level email field's value will be used instead.

2. Use the Participant List under “Manage Survey Participants” to enter the emails of participants. The consent form survey **must** be sent to participants using the “Compose Survey Invitations” feature from the Participant List for this method to work.
3. Let the participant enter their email after the confirmation page. To use this option, a project-level or survey-level email **cannot** be enabled.

 **Enter your email to receive confirmation message?**

A confirmation email is supposed to be sent to all respondents that have completed the survey, but because your email address is not on file, the confirmation email cannot be sent automatically. If you wish to receive it, enter your email address below.

* Your email address will not be stored

Using PDF snapshots

A PDF snapshot is an automatically generated PDF of a single instrument/survey, multiple instruments, or all the instruments within a record. PDF snapshots support both automatic snapshots and customizable triggers. While PDF snapshots are automatically created for surveys enabled as e-Consents, they can also be used separate from the e-Consent framework, or to compile several electronic consents into a holistic PDF.

1. Automatic snapshots: Automatically generates a snapshot of any survey with e-Consent framework enabled
 - a. To view snapshots, Click on “File Repository” from the panel on the left-hand side.
 - i. If you do not see the “File Repository,” in your left-hand menu, it means you do not have the correct user privileges to access the repository.
 - b. Click on the “PDF Snapshot Archive” tab.
2. Custom triggers for PDF snapshots
 - a. Add a new trigger by clicking the green “Add new trigger” button.

[Back to Online Designer](#)

[e-Consent Framework](#)

[PDF Snapshots of Records](#)

This page can be used to set up triggers for capturing PDF Snapshots of records. A PDF Snapshot is a REDCap-generated PDF file of a single instrument/survey, multiple instruments, or all the instruments of a given record. PDF Snapshots can be triggered when 1) a survey is completed, or 2) when specified conditional logic evaluates as True. When triggered, snapshots can be stored in the PDF Snapshot Archive folder in the File Repository and/or stored in a specified File Upload field. You may create as many triggers as you wish for capturing snapshots.

Triggers for PDF Snapshots

[+ Add new trigger](#)

Hide inactive

Active?	Edit settings	Name	Type of trigger	Save snapshot when...	Scope of the snapshot	Location(s) to save the snapshot	Snapshot ID
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- b. Define conditions for the trigger and specify the forms and/or surveys to be included in the PDF.

- c. Chose a storage location for the snapshot.
- d. Customize the file name; all file names will end with a timestamp that cannot be altered.

Add/Edit Trigger for PDF Snapshot ✕

Use the options below to create a trigger for capturing a PDF Snapshot of a record. The snapshot can be triggered by a survey being completed *or* when specified conditional logic becomes true (but not by both). You may provide the scope of the snapshot, which is simply which instruments/events you wish to include in the snapshot (one instrument, multiple instruments, or all instruments). When triggered, snapshots can be saved to the File Repository and/or a single File Upload field. Additionally, you may specify a custom prefix for the snapshot's file name when it is saved. You may create as many triggers as you wish, and you can deactivate/reactivate them at any time.

Name of trigger:

STEP 1: Trigger conditions - Define when the snapshot will be triggered.

Every time the following survey is completed:

-- OR --


When the following logic becomes true (only once per record): [How to use this](#)

`[event_1_arm_1][consent_complete] = '2' AND [event_1_arm_1][form_1_complete] = '2'`

(e.g., [enrollment_arm_1][age] > 30 and [enrollment_arm_1][sex] = "1")

STEP 2: Scope of the snapshot

Click the pencil in the text box below to select specific instruments/events to be included in the PDF.

 `[event_1_arm_1][consent],[event_1_arm_1][form_1]`

[TIP: Leave blank to include all instruments/events \(i.e., the entire record's data\).](#)

Save as Compact PDF (includes only fields with saved data)

Store the translated version of the PDF (if using Multi-language Management)