*Version date July 25, 2024*

# How to Use REDCap's e-Consent Framework

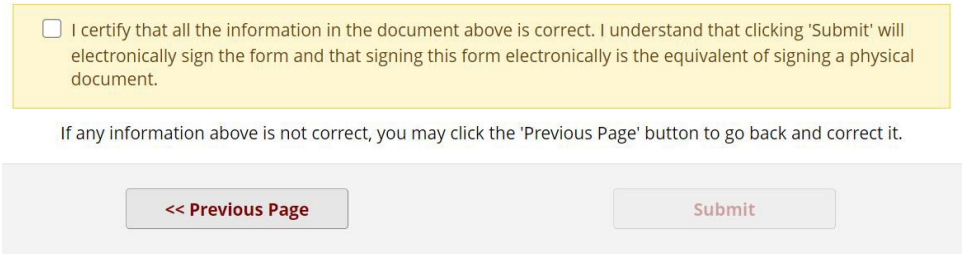
Having a clear and comprehensive consent process is essential to any research involving human subjects. REDCap's e-Consent framework provides the tools necessary to develop an e-Consenting process.

## 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:

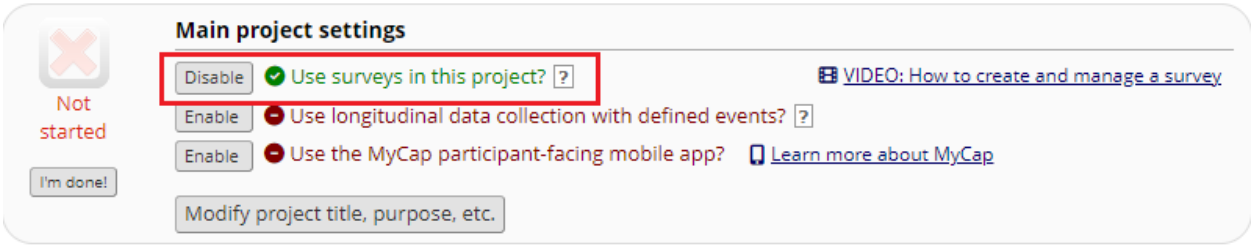
1. After a participant completes the consent form, a certification page will appear displaying an in-line PDF copy of the survey responses. They will be asked to confirm that all the information is correct. The e-Consent survey is ***not*** marked as complete until the participant has finished the certification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



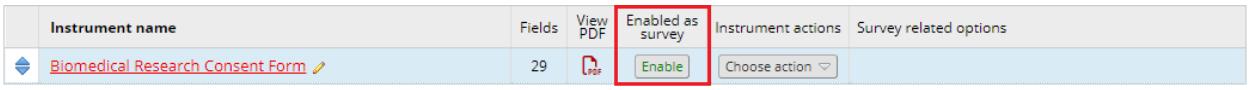

2. A PDF snapshot of the completed consent form will be saved in the project's File Repository. The PDF snapshot will have a footer that includes the e-Consent Framework Options (e.g. name, date of birth) as additional documentation of the consenter's identity.

## 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.

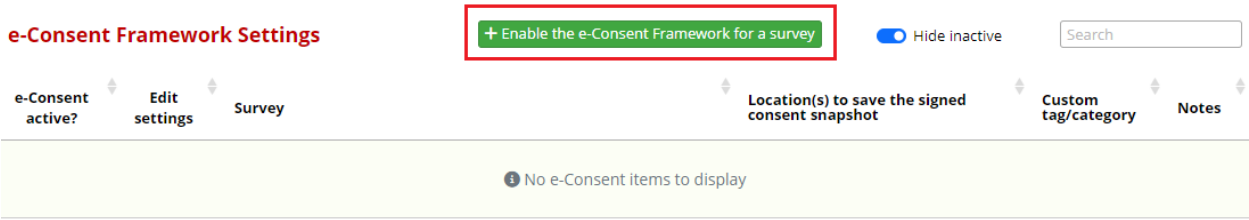



    b. Enable your consent form to be a survey.




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

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.



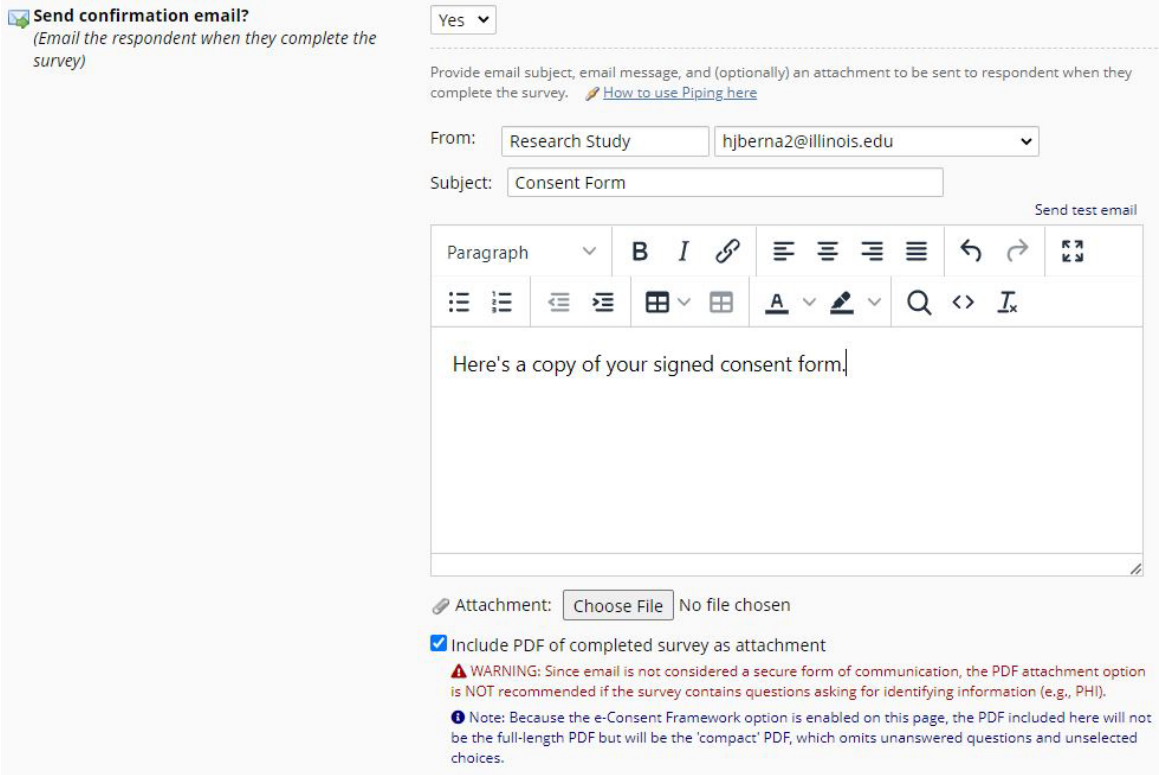

e. e-Consent settings include:
   i. "Allow eConsent responses to be edited": If this is selected, users with "Edit survey answer privileges" for the consent form will be able to edit or add responses. Edited responses will not be reflected in the "File Repository" saved consent.
      1. We strongly 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:

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.

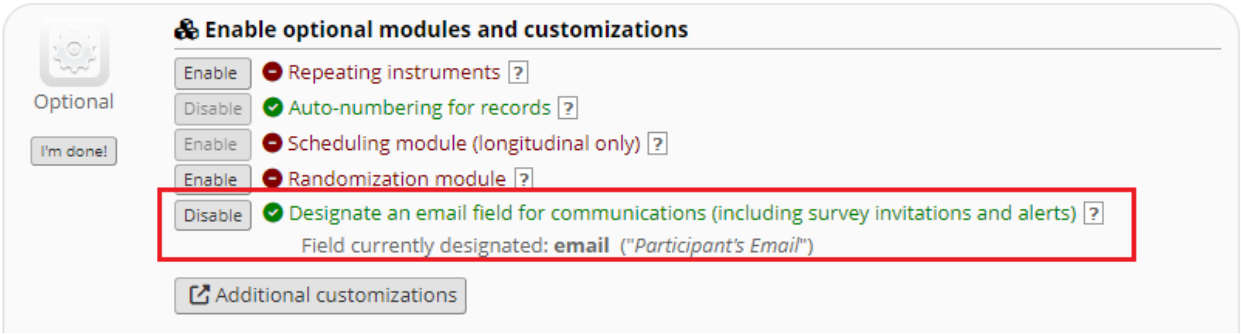
## Emailing a Copy to the Participant

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.

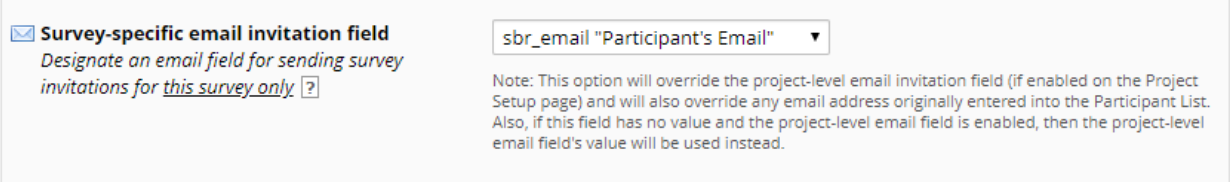



There are several ways REDCap can know where to send the copy of the consent form. The method you use will depend on your research design and other aspects of your study.

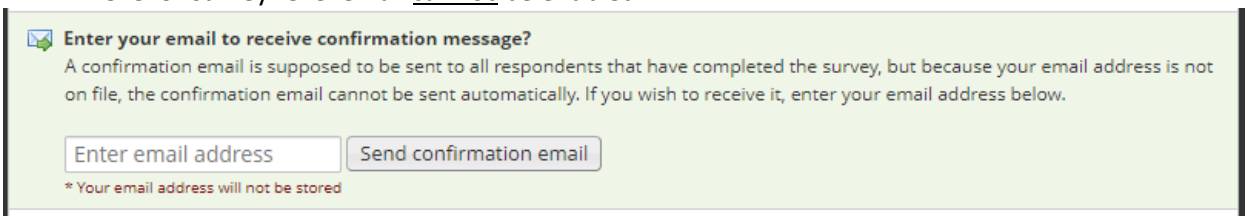
1. Ask for the participant's email address on the consent form or another survey or form that will be completed ***prior*** to the consent form (such as a pre-screening survey). Designate that field to receive REDCap emails either:
    a. At the project level: On the "Project Setup" page under "Enable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




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



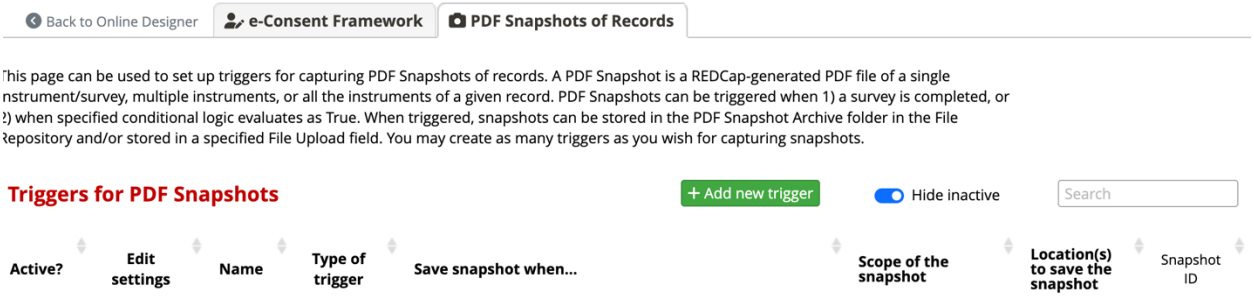

2. Use the Participant List under "Manage Survey Participants" to enter the emails of participants. The consent form survey ***must*** be sent to participants using the "Compose Survey Invitations" feature from the Participant List for this method to work.
3. Let the participant enter their email after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

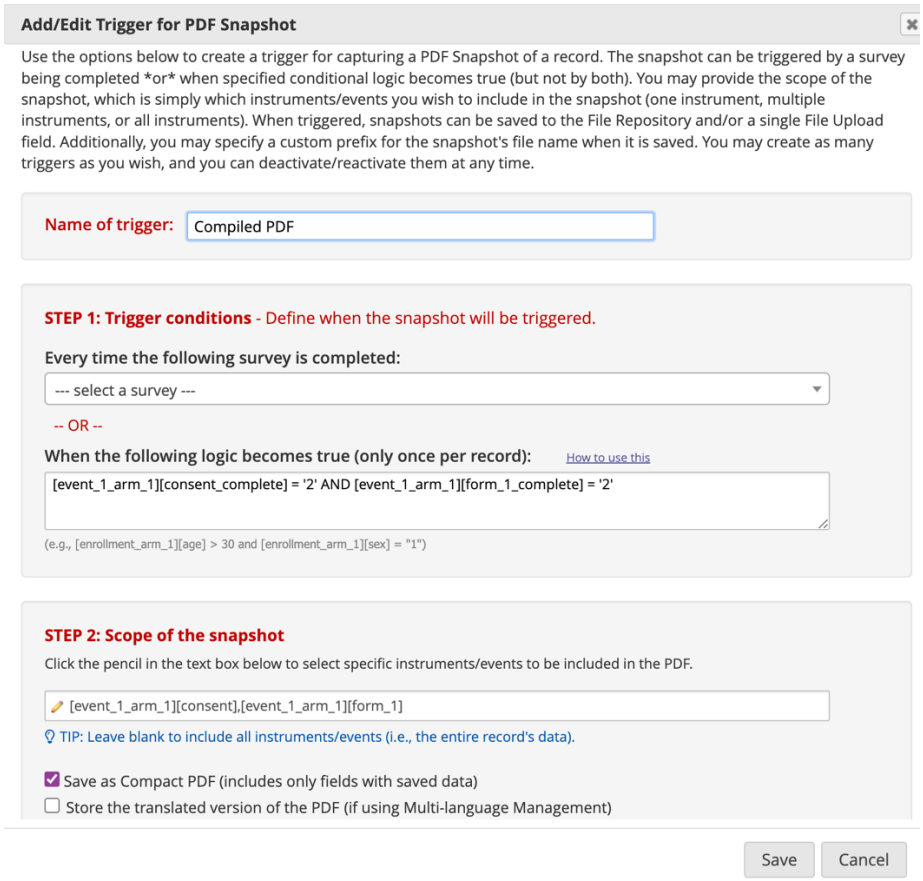



## Using PDF snapshots

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.




    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.