

How to Use REDCap's e-Consent Framework

Having a clear and comprehensive consent process is essential to any research involving human subjects. REDCap offers a framework to electronically collect and store consent documents.

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

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 of the completed consent form will be saved in the project's File Repository. The saved PDF will have a footer that includes the following information:
 - a. The participant's name
 - b. The time and date of completion, recorded in Coordinated Universal Time (UTC)
 - c. The version number (optional, but recommended)
 - d. The participant's birthdate (optional)
 - e. The "type" of e-Consent (optional, but recommended if a project has multiple consent forms, such as parent, child, etc.)

Using REDCap's e-Consent framework

1. Build your consent document in REDCap. You can do this from scratch, or insert an Office for the Protection of Research Subjects (OPRS) template into your project in one of the following ways:
 - a. When you create a new project, select the consent template you want to use (Biomedical or Social Behavioral) from the list of project templates provided in REDCap.

Start project from scratch or begin with a template?

- Create an empty project (blank slate)
- Upload a REDCap project XML file (CDISC ODM format) [?](#)
- Use a template (choose one below)

★ Choose a project template (comes pre-filled with fields, forms/surveys, and other settings) [Add templates \(Administrators only\)](#)

select template	Template title (sorted by title)	Template description
<input type="radio"/>	Biomedical Research Consent Form	This project contains the OPRS consent template for biomedical research. It is enabled with the e-Consent framework.
<input type="radio"/>	Social Behavioral Research Consent Form	This project contains the OPRS consent template for social behavioral research. It is enabled with the e-Consent framework.

- b. After creating a new project, import the data dictionary for the consent template you want to use (Biomedical or Social Behavioral) into the project.
 - i. Templates are available for download from [Box](#).
 - ii. Instructions for using data dictionaries are available [here](#).
2. Set up the e-Consent features the way you need them to function in your project. If you followed Step 1a above, you can skip steps 2a-2c below, but you should still check that everything is enabled to meet your project's needs.
 - a. Enable the project to have surveys.

Main project settings

Complete! Not complete?

Use surveys in this project? [?](#) [VIDEO: How to create and manage a survey](#)

Use longitudinal data collection with defined events? [?](#)

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

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

- c. On the Survey Settings page, enable the "Auto-Archiver + e-Consent Framework" feature.

e-Consent Framework
- and -

PDF Auto-Archiver
Upon survey completion, a compact PDF copy of the survey response will be automatically stored in the project's File Repository, from which the archived PDFs can be downloaded at any time.

Disabled
 Auto-Archiver enabled
 Auto-Archiver + e-Consent Framework [What is the e-Consent Framework?](#)
 (includes end-of-survey certification & archival of PDF consent form)

e-Consent Framework Options:
For e-Consent it is sometimes required to include the consenting participant's name (and date of birth in some cases) on the final consent form as extra documentation of their identity. Below you may select fields used to capture that info. You may also enter the current e-Consent version and e-Consent type for this form. The values for the fields below will be automatically inserted into the footer of the PDF consent form that the participant will review at the end of the survey, after which that PDF 'hard-copy' will be archived in the File Repository. [Read more](#)

Allow e-Consent responses to be edited by users?

e-Consent version: e.g., 4

First name field:

Last name field:

Note: If you are using a single field to capture whole name, you may select it for either first/last name above while leaving the other name field unselected.

Optional fields (these are not always necessary for e-Consent):

e-Consent type: e.g., Pediatric

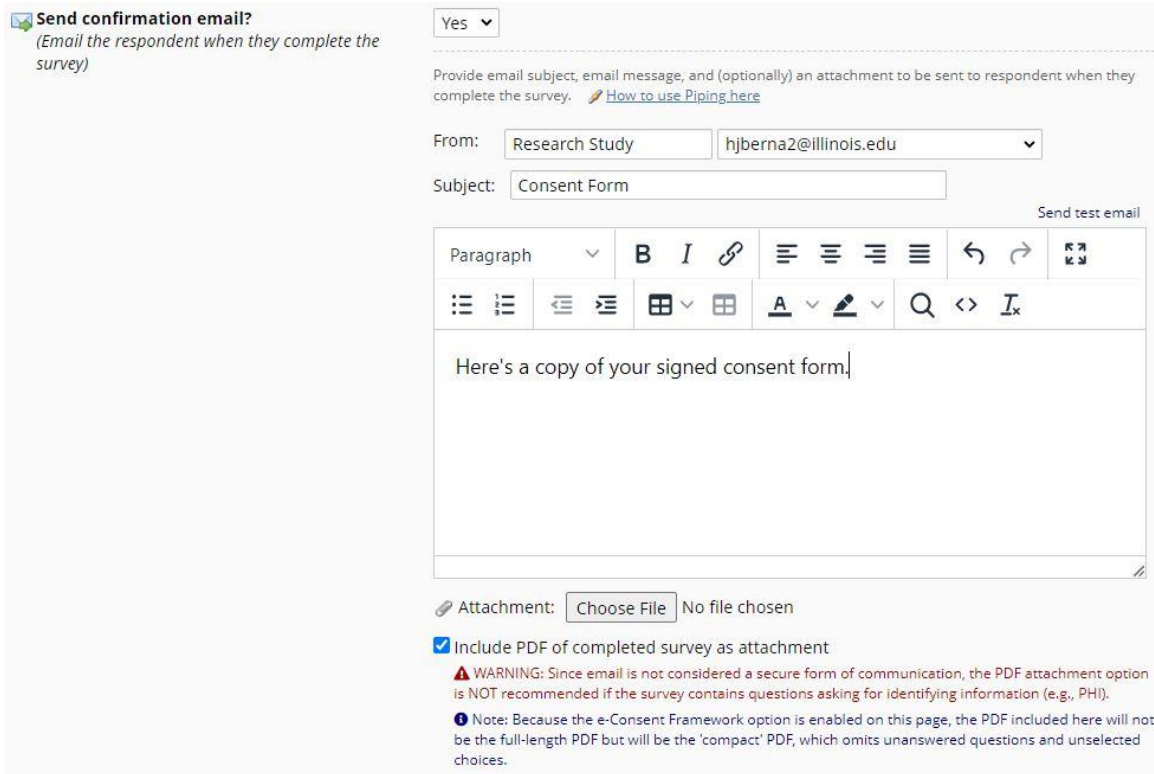
Date of birth field:

Force signature field(s) to be erased if participant clicks Previous Page button while on the certification page?
Select a field below that serves as a signature field in this survey. It could be a free-form text field, a signature field, or a number field (e.g., to collect a PIN), and it must be a Required field. If any fields are selected below, then if the participant gets to the last page of the survey where it asks them to certify their responses, if they then choose to click the Previous Page button, it will erase the value of these signature fields, thus forcing them to 'sign' the field(s) again before completing the survey. If you do not want this behavior, do not select any fields below. You may use up to five signature fields.

Signature field #1:

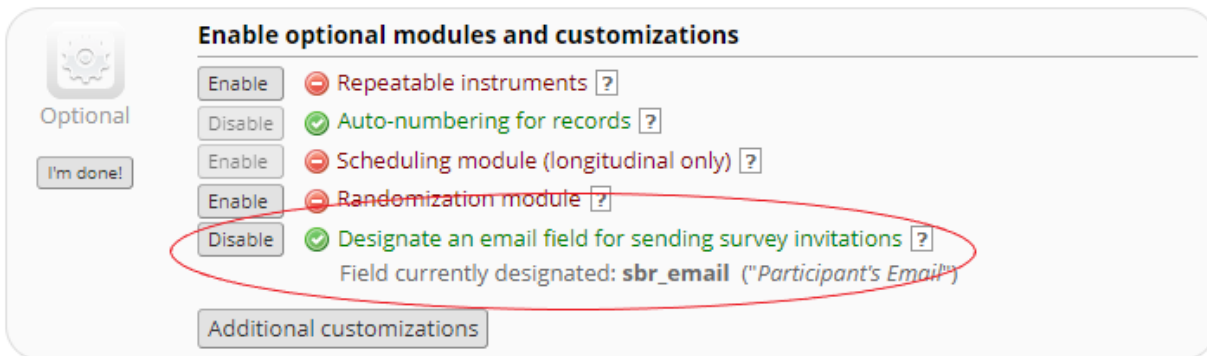
- d. e-Consent Framework Options include:
- i. "Allow eConsent responses to be edited": If this is selected, users with "Edit survey answer privileges" for the consent form will be able to edit or add responses. Edited responses will not be reflected in the "File Repository" saved consent.
 1. This should not be enabled if a project is subject to 21 CFR Part 11.
 - ii. e-Consent version: This is an open text space allowing you to keep track of what version of a consent form a participant signed. Every time a change is made to the consent form, the version number needs to be **manually** updated in the survey settings.
 1. OPRS recommends that versioning remain simple and increases sequentially (e.g., 1, 2, 3). Avoid dashes, periods, or letters.
 - iii. 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.
 - iv. 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.
 - v. e-Consent type: This is an open text space allowing you to categorize the consent form. If you have a study with multiple groups of participants (e.g. children, parents, teachers, etc.), this is a good way to keep track of which consent form a participant signed.

- vi. 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.
- e. Establish how participants will receive a copy of their consent form. To do this, ensure that “Send confirmation email (optional)?” is marked “Yes” and the email will include a PDF of the completed survey as an attachment.



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.

- i. 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:
 1. At the project level: On the “Project Setup” page under “Enable optional modules and customizations.”



2. 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.

- ii. 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.
- iii. Let the participant enter their email after the confirmation page.

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

Customizing your e-Consent

There are capital letters in square brackets throughout the consent templates to indicate where study-specific text needs to be inserted. In addition to this, there are other items that may need to be changed to make the e-Consent appropriate for your study. For instance, if participants are being consented remotely, collecting information about the research personnel who obtained consent on the eConsent form will be more difficult. Or if your participants will include people with mobility issues, using the “Signature” field may create accessibility issues and participants should type their name instead.

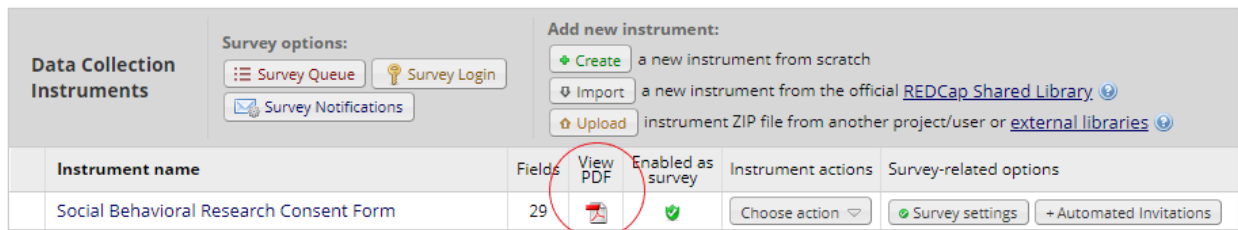
There are other ways you can customize your consent form to ensure participant comprehension and obtain consent.

1. Insert pictures and videos. If there is a procedure or data collection instrument you want participants to understand, inserting pictures and videos can be a good way to increase comprehension.
 - a. To insert pictures or videos, use the “Descriptive Text” field with the “Optional file attachment” features.
2. Add additional yes/no questions for optional study procedures, such as taking photographs, sharing data in a data repository, etc.
3. Add additional language as necessary. If there is additional information participants need that is not included in the base OPRS template, additional language templates are available [here](#).




Submitting to the IRB when using REDCap’s e-Consent feature

If you plan on using the e-Consent framework in REDCap, the following information can be included when submitting to the IRB.

- Section 14A (“Indicate all that apply for the consent/assent/parental permission process.”) – Mark “Written informed consent.” The e-Consent framework substitutes for a wet signature on a paper document, so a “Waiver of Documentation of Informed Consent” is **not** required.
- Section 14C (“Describe the method for obtaining consent/assent/parental permission.”) – Describe how the e-Consent framework will be used.
- When attaching a copy of the consent form for submission, you can export a PDF of the consent survey directly from REDCap. This can save time, as the consent form language only needs to be entered and edited in one location.



The screenshot shows the 'Data Collection Instruments' section of the REDCap interface. It includes a sidebar with 'Survey Queue', 'Survey Login', and 'Survey Notifications'. The main area has 'Add new instrument' options: 'Create', 'Import', and 'Upload'. Below is a table with columns: 'Instrument name', 'Fields', 'View PDF', 'Enabled as survey', 'Instrument actions', and 'Survey-related options'. The first row is for 'Social Behavioral Research Consent Form' with 29 fields. The 'View PDF' button is circled in red.

Instrument name	Fields	View PDF	Enabled as survey	Instrument actions	Survey-related options
Social Behavioral Research Consent Form	29			Choose action ▾	 Survey settings + Automated Invitations