# How to Use REDCap's e-Consent Framework

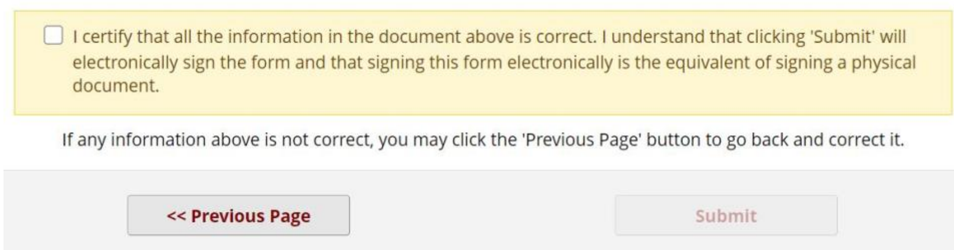
Having a clear and comprehensive consent process is essential to any research involving human subjects. REDCap offers a framework to electronically collect and store consent documents.

## 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:

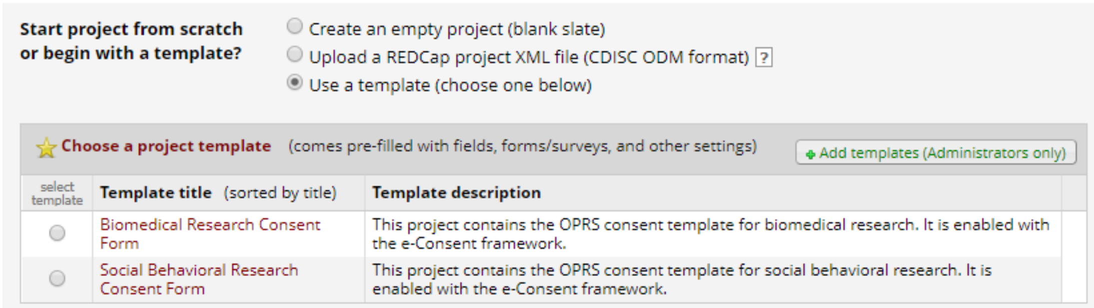
1. Before a participant completes the consent form, an extra certification page will appear displaying an in-line PDF copy of the survey responses. They will be asked to confirm that all the information on the PDF is correct. The survey is ***not*** marked as complete until the participant has finished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




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.)

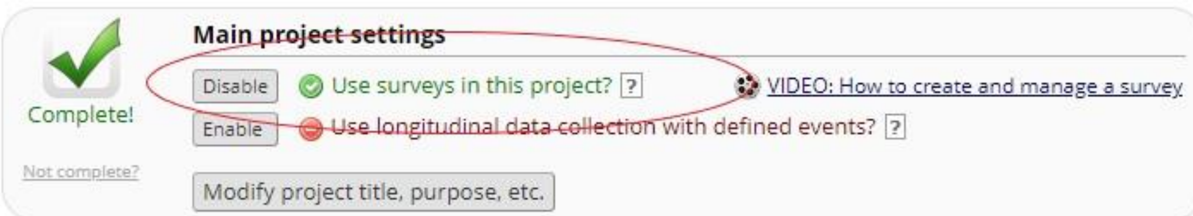
## Using REDCap's e-Consent framework

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.

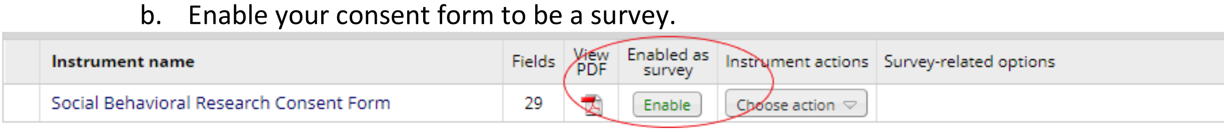



b. After creating a new project, import the data dictionary for the consent template you want to use (Biomedical or Social Behavioral) into the project.
   i. Templates are available for download from Box.
   ii. Instructions for using data dictionaries are available here.

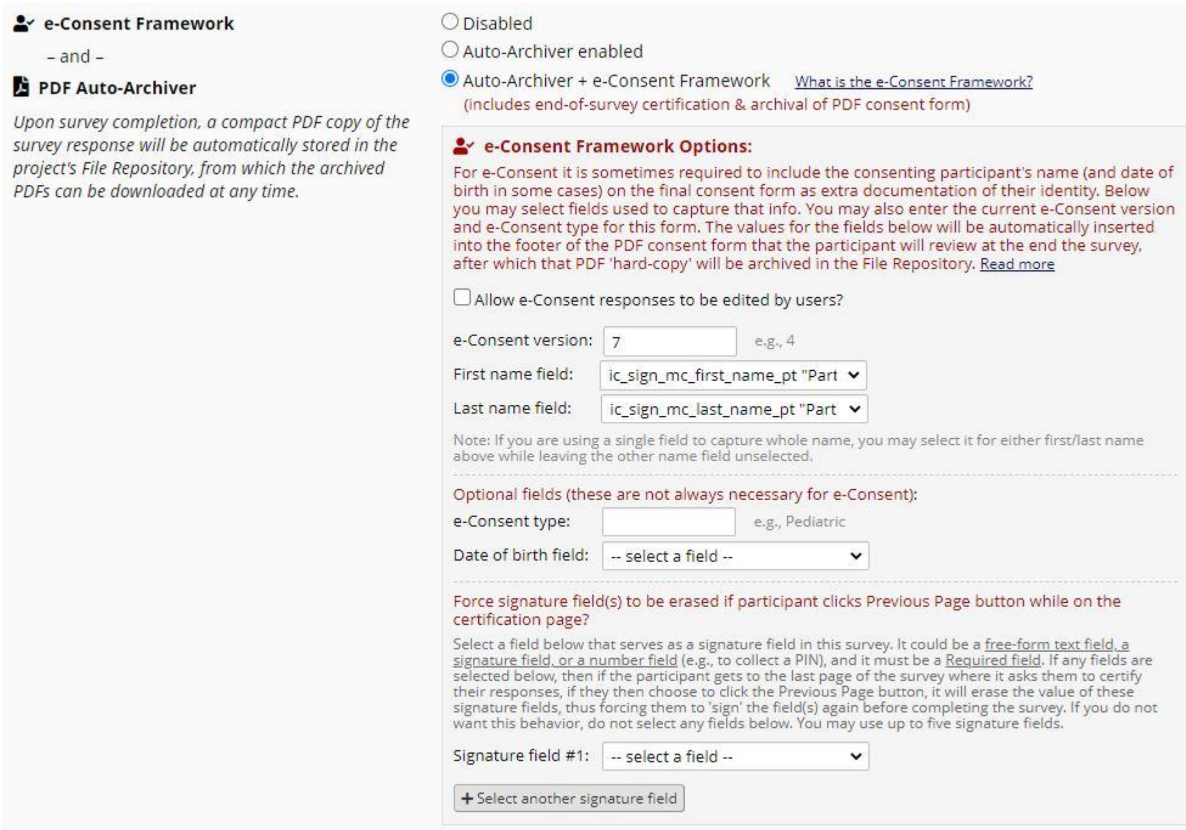
2. Set up the e-Consent features the way you need them to function in your project. If you followed Step 1a above, you can skip steps 2a-2c below, but you should still check that everything is enabled to meet your project's needs.
   a. Enable the project to have surveys.




   b. Enable your consent form to be a survey.



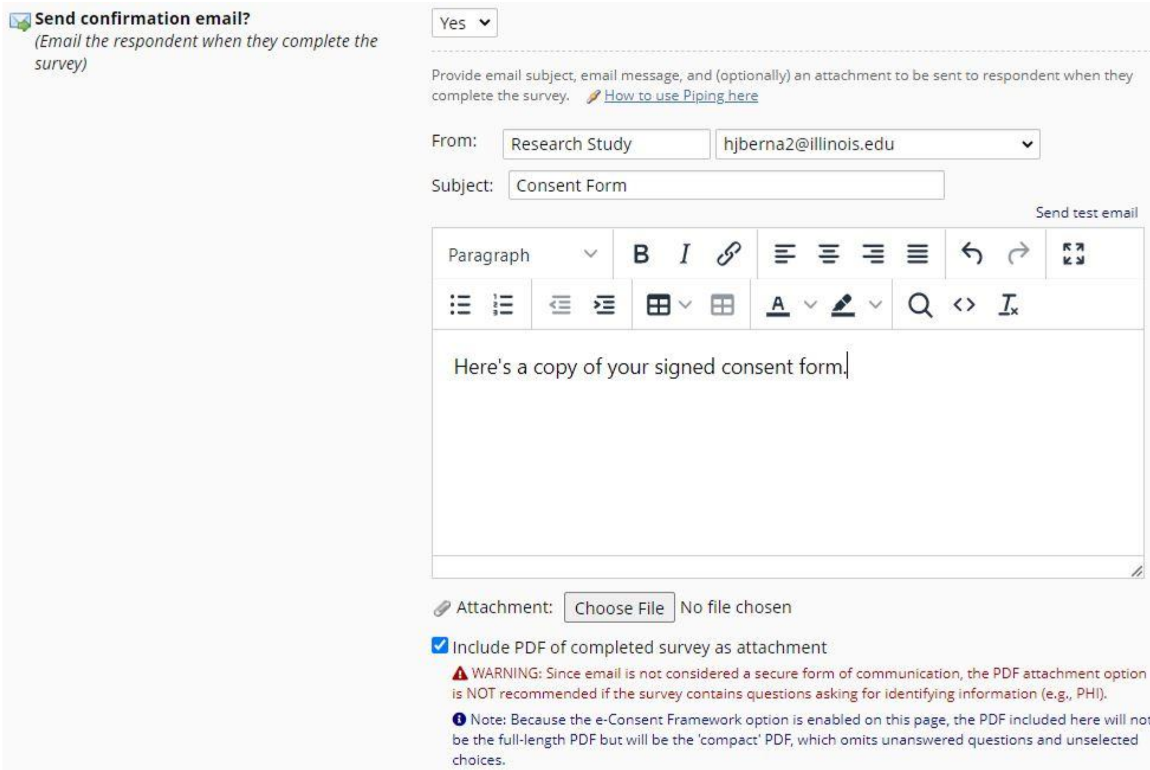

   c. On the Survey Settings page, enable the “Auto-Archiver + e-Consent Framework” feature.




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 ***<u>manually</u>*** 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.

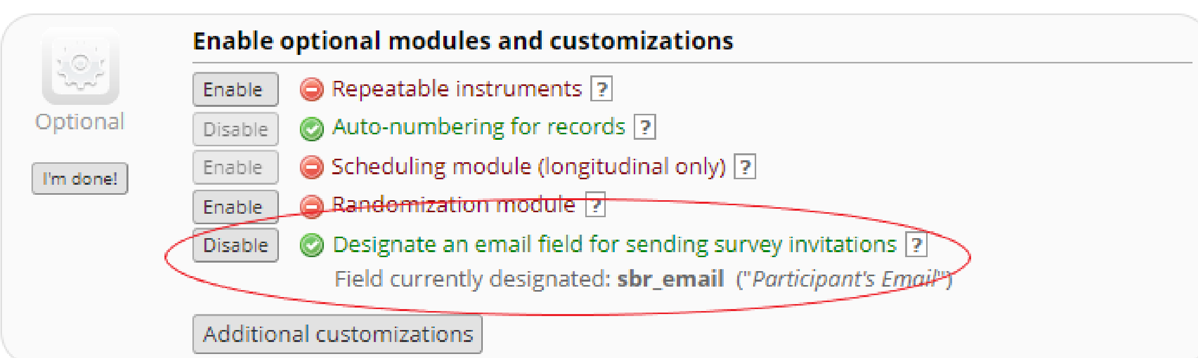
e. Establish how participants will receive a copy of their consent form. To do this, ensure that "Send confirmation email (optional)?" is marked "Yes" and the email will include a PDF of the completed survey as an attachment.



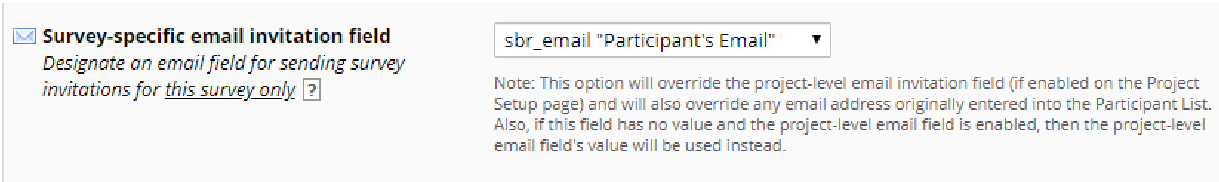

There are several ways REDCap can know where to send the copy of the consent form. The method you use will depend on your research design and other aspects of your study.

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."

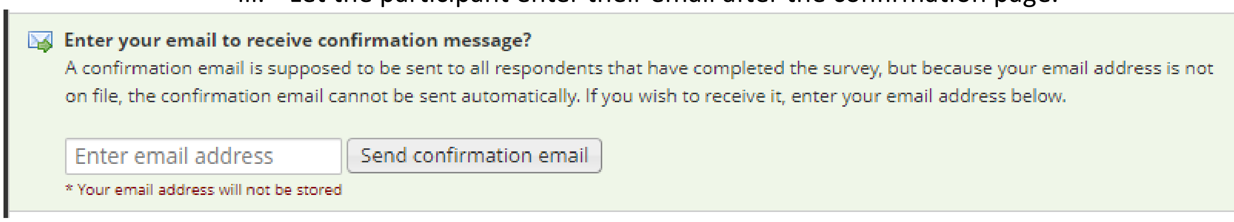


2. At the survey level, on the “Survey Settings” page under “Survey Customizations.”




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.




## 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.