

How to set up e-Consent in REDCap | 2020

1. Login to REDCap (<https://ccts-redcap.ihrp.uic.edu/>)

To create an e-consent project, the full access user right is required. If you need to set up your REDCap account, refer to this page: <https://ccts.uic.edu/tools/redcap/account-setup/>

Creating a consent form in REDCap is a similar process to set up a regular data entry form with the survey settings that requires basic understandings about REDCap features. If you are new to REDCap, please watch the introduction videos added in CCTS REDCap training resource page:

<https://ccts.uic.edu/tools/redcap/training/> and Vanderbilt training videos: <https://projectredcap.org/resources/videos/>

If you need REDCap e-consent consultation please submit your request here:

https://webapps.ccts.uic.edu/CCTS_Service_Requests/login.aspx

2. Before using REDCap e-consent, get the IRB approval after reviewing regulatory component.

IRB approval must be obtained before using REDCap e-consent. If you need any regulatory support related to e-consent process, submit your service request here: <https://ccts.uic.edu/services/regulatory/>

3. Some options to consider before starting.

- a. If you have the consent document approved before setting up in REDCap and don't need to use the general template, start from a blank form or project in REDCap. Then, you can add texts in REDCap form such as *Descriptive Text*, *Text*, *Radio Buttons* field types for study descriptions, other paragraphs and questions. Signature fields and image uploads are supported in REDCap.
- b. For the informational paragraphs except for some interactive fields asking participants agreement (yes/no) or e-signature in your approved consent document, you can either 1) save each page as image file such as .jpg and upload it in the REDCap form between sections and questions to show the original document as images, or 2) type in or copy/paste the texts in each REDCap text fields. Font edit options are supported similarly as in Word documents.
- c. You can use the eConsent template uploaded in the CCTS REDCap by creating a new project. This template includes all additional languages with some instructions, so substantial amount of customizations will be required.

4. Create a new project to download the eConsent Template

Once you log in to REDCap, find '**New Project**' tab on the top menu options. Then add project title and select 'Research' at Purpose of this Project. Information about PI, project type, IRB number should be entered as applicable.

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Figure 1. Create a project

REDCap Home My Projects **+ New Project** Help & FAQ Training Videos Send-It Messenger Control Center

+ Create a new REDCap Project

You may begin the creation of a new REDCap project on your own by completing the form below and clicking the Create Project button at the bottom.

Project title:
Title to be displayed on project webpage

Purpose of this project:
How will it be used?

Assign project to a Project Folder?

Project notes (optional):
Comments describing the project's use or purpose that are displayed on the My Projects page.

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)

a. Select a template

After adding the project info (title, purpose of this project, PI, IRB number), you can either select the template 'Biological Consent Template' UIC CCTS generated or start from a blank project if you have your own form to create.

Figure 2. Select a template

projects **+ New Project** Help & FAQ Training Videos Send-It Messenger Control Center

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Purpose of this project:
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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"/>	Basic Demography	Contains a single data collection instrument to capture basic demographic information.
<input checked="" type="radio"/>	Biological Consent Template with Additional Elements and HIPAA drop in text	generated on 4/24/20
<input type="radio"/>	Classic Database	Contains six data entry forms, including forms for demography and baseline data, three monthly data forms, and concludes with a completion data form.
<input type="radio"/>	Longitudinal Database (1 arm)	Contains nine data entry forms (beginning with a demography form) for collecting data

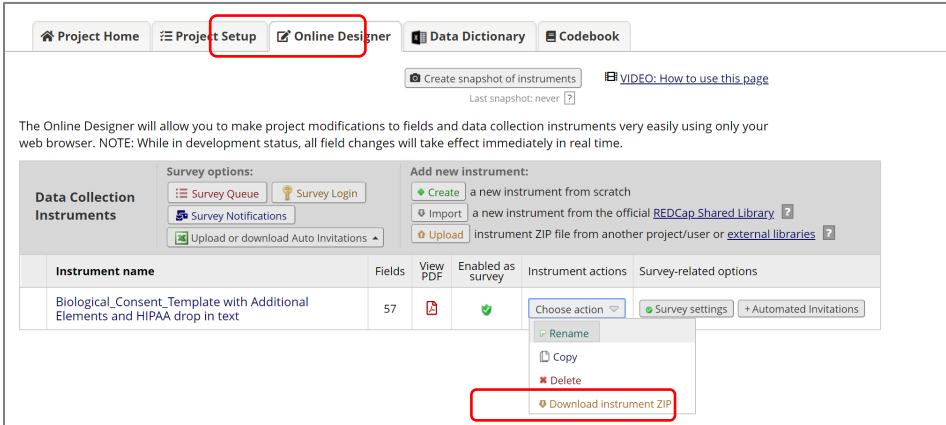
Create Project

b. Adding a template form to your existing project

A consent form can be added to your existing REDCap project where other data collection forms such as screening and follow-up forms are located. If you want to add a consent template form to another REDCap project, download the form as a zip file after creating a project using the consent template and upload it in Online Designer.

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Figure 3 Downloading a ZIP file of consent form

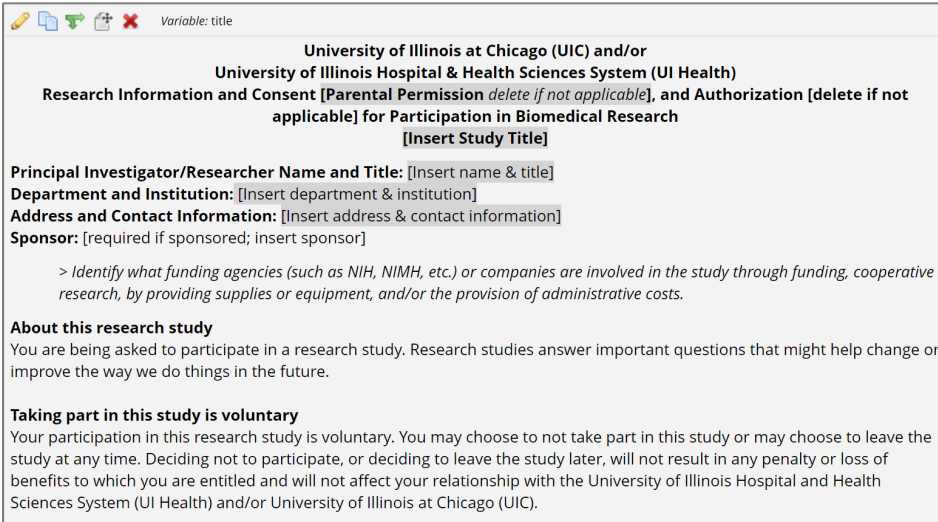


c. Customizing texts

You should edit your study specific languages and delete unnecessary paragraphs from the provided template in REDCap Online Designer.



Figure 4. Descriptive text field



5. Uploading image of document

Instead of adding texts in Filed Label, a pdf or other image file can be uploaded up to 10Mb using Descriptive Text field type.

Figure 5. Uploading a document of image

The screenshot shows the 'Add New Field' dialog box. The 'Field Type' dropdown is set to 'Descriptive Text (with optional Image/Video/Audio/File Attachment)'. The 'Field Label' is empty. The 'Action Tags / Field Annotation' is empty. The 'Variable Name' is empty. The 'Optional file attachment, image, audio, or video:' section has 'Embed an external video' selected. The 'Attach an image, file, or embedded audio' option is selected, with the 'Upload file' sub-option highlighted. The 'Display format of attachment on page:' section has 'Link' selected.

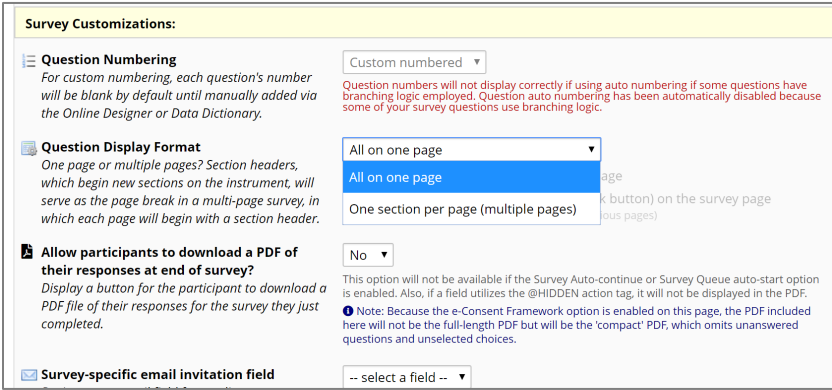
6. Survey page break

To display separate sections or paragraphs in different pages so that participants can move to the next pages instead of showing all in one screen requiring scrolls, add 'Begin new section' field and select 'Question Display Format as 'One section per page' in Survey settings.

Figure 6. Adding a section header for page break

The screenshot shows the 'Add New Field' dialog box with the 'Field Type' dropdown menu open. The menu items are: '---- Select a Type of Field ----', 'Text Box (Short Text, Number, Date/Time, ...)', 'Notes Box (Paragraph Text)', 'Calculated Field', 'Multiple Choice - Drop-down List (Single Answer)', 'Multiple Choice - Radio Buttons (Single Answer)', 'Checkboxes (Multiple Answers)', 'Yes - No', 'True - False', 'Signature (draw signature with mouse or finger)', 'File Upload (for users to upload files)', 'Slider / Visual Analog Scale', 'Descriptive Text (with optional Image/Video/Audio/File Attachment)', and 'Begin New Section (with optional text)'. The 'Begin New Section (with optional text)' option is highlighted in blue.

Figure 7. Survey Settings to show one section per page



7. Survey Settings

To enable e-consent features in REDCap, the form must be set up as a survey. Make sure to enable 'Use Survey in this project' option in Main Project Setting in Project Setup. Then, in Online Designer enable survey on the consent form. This default survey setting is already made in the e-consent template project, but when you add the consent form in other existing project enabling survey option will be needed.

Your study specific information and e-consent instructions including e-consent framework can be added and setup in Survey Settings at Online Designer. If you like to add study logo or IRB stamp, review Survey Design Options in Survey Settings.

Figure 8 Survey Setting for e-consent framework

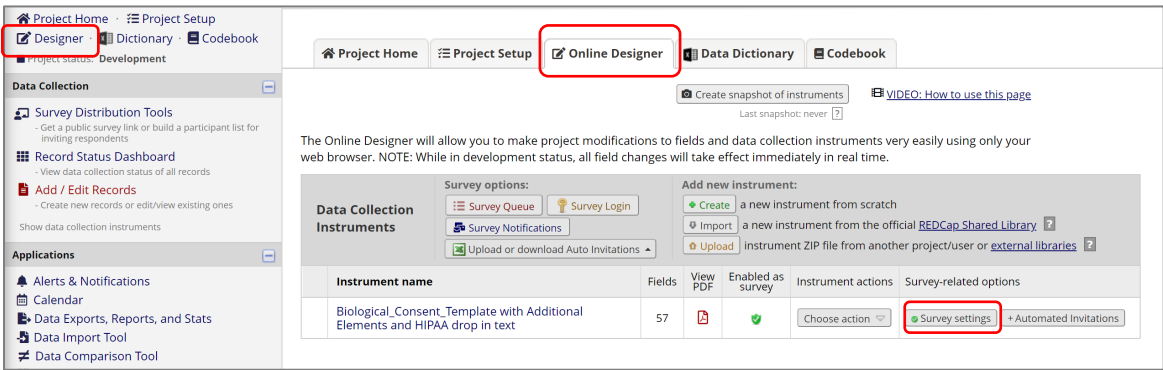


Figure 9 e-Consent Framework

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:

8. Sending consent form to participants

There are different options to send out the e-consent form to participants.

1) Using Public Survey Link

Public link is only available when the consent form is the first form in your REDCap project, and when the link needs to be sent to multiple people in one email message. So anyone who clicks the link can access the consent form for multiple times using the same link.

Survey Distribution Tools

Public Survey Link Participant List Survey Invitation Log

Using a public survey link is the simplest and fastest way to collect responses for your survey. You may obtain the survey link below to email it to your participants. Responses will be collected anonymously (unless the survey contains questions asking for identifying data from the participant). **NOTE:** Since this method uses a single survey link for all participants, it allows for the possibility of participants taking the survey multiple times, which may be necessary in some cases.

To obtain the survey link, copy the URL below and paste it into the body of an email message in your own email client. Your email recipient(s) can then click the link to begin taking your survey.

Public Survey URL:

Link Actions

Link Customizations

2) Using Survey Distribution Tool

When you have individual participant' email address the e-consent survey form can be sent to each participant using unique survey link so that the response status and follow-up can be done using the

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individually linked information. If there is a separate data entry form where the study participants' information including email address is entered by the study staffs, turn on the option 'Designate an Email field for sending survey invitations' in Project Setup. Then the participant list in survey distribution tool will automatically shows up all entered email address, and from there you can send the invitation.

Survey Distribution Tools

Public Survey Link | Participant List | Survey Invitation Log

The Participant List option allows you to **send a customized email** to anyone in your list and **track who responds to your survey**. It is also possible to identify an individual's survey answers, if desired, by providing an Identifier for each participant (this feature must first be enabled by clicking the 'Enable' button in the table below). Note: All survey responses collected are considered anonymous unless you 1) are using Participant Identifiers or 2) have enabled the designated email field for invitations. [More details](#)

Participant List belonging to: **[Initial survey] "Biological_Consent_Template with Additional Elements and HIPAA drop in text"** Remove all participants

Displaying: 1 - 4 of 4 Add participants Compose Survey Invitations Export list

Email	Record	Participant Identifier	Responded?	Invitation Scheduled?	Invitation Sent?	Link	Survey Access Code and QR Code
[No email listed]		Disabled		-			
[No email listed]		Disabled	✓	-			
[No email listed]		Disabled	✓	-			
[No email listed]		Disabled		-			

3) Using data entry form (Add/Edit Records)

When the study participants are unable to send the consent form by themselves or don't have email address available the study staff should open the e-consent form on their device and let them fill out the form. When the public survey link is not available and(or) the participant's information is already entered in the other form, the study staff can create a new record or open an existing record to go the survey page linked to the record. If you don't see Survey Options in data entry form, click 'Save and Stay'.

Figure 10. Open survey from data entry form (Add/Edit Records)

Biological_Consent_Template with Additional Elements and HIPAA drop in text

Invitation status: Survey options

Editing existing Record ID 4

Record ID: 4 To rename the record, see the Record Home Page.

Health & Biological Sciences Research Consent form template - 11/01/19

Delete this instruction box by clicking the red X.

Instructions:

1. Plain text is required. Plain text separated by **OR** indicates that there are several options. Pick one and delete the others.
2. Text in [] is to be replaced with specific information about your research study, including the footer.
3. Instructions and/or information for the section are in [brackets]. Delete the directions and corresponding text as applicable.
4. > and *italics* indicate guidelines. Delete guidelines, arrows, and italicized text before finalizing the document.
5. Suggested text is often included in the guidelines. Suggested text is preceded by ***Suggested Text*** tag. Delete ***Suggested Text*** and text not being included in the consent before finalizing the document.
6. Additional language that may be required based on your research proposal can be found in the [Additional Informed Consent Template Language](#) document.

University of Illinois at Chicago (UIC) and/or University of Illinois Hospital & Health Sciences System (UI Health)

Research Information and Consent [Parental Permission delete if not applicable], and Authorization [delete if not applicable] for Participation in Biomedical Research

[Insert Study Title]

Principal Investigator/Researcher Name and Title: [Insert name & title]

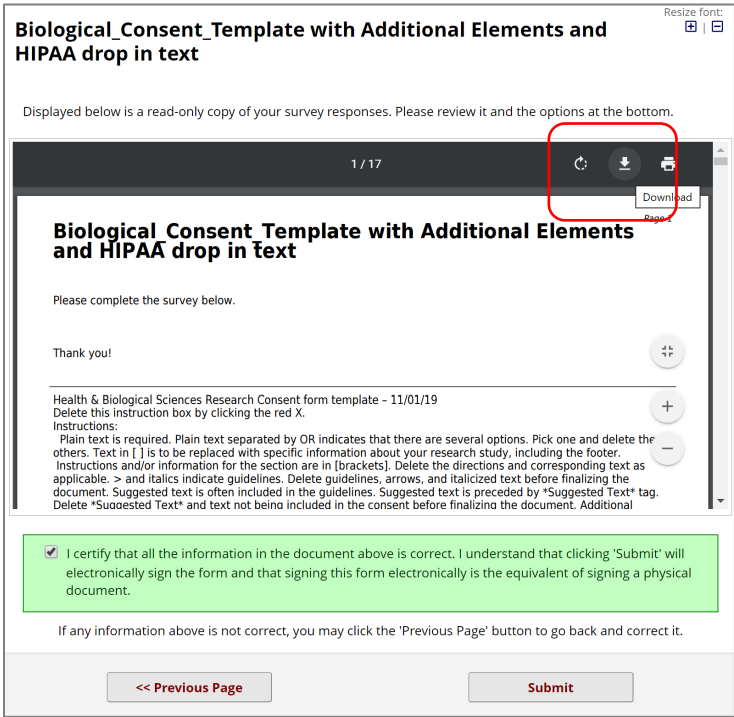
Department and Institution: [Insert department & institution]

Survey options:

- Open survey
- Log out + Open survey
- Compose survey invitation
- Survey Access Code and QR Code

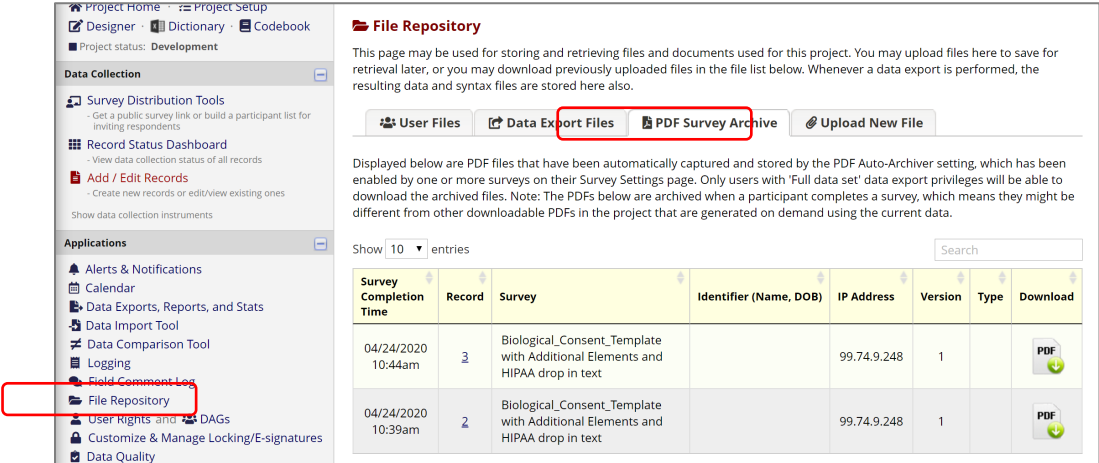
9. Study participants will look at the option to download the signed consent form in pdf. When e-consent framework is setup, at the end of consent form participant will be asked to certify the information before submitting. Downloading option is given as marked in the image below.

Figure 11. Consent form submission page



10. Archive of pdf consent forms

Submitted consent form will be archived in File Repository → PDF Survey Archive so that the study team with given access right can view and download when it is needed.



11. Setting up User Rights

The study team members should have corresponding access right on your e-consent form project in User Rights. The user who has the access to 'User Rights' must add other users and set up their access level.

Figure 12. User Rights

Basic Rights

Expiration Date (if applicable) (M/D/Y)

Highest level privileges:

- Project Design and Setup
- User Rights
- Data Access Groups

Privileges for data exports (including PDFs and API exports, reports, and stats):

Data Exports

- No Access
- De-identified*
- Remove all tagged Identifier fields
- Full Data Set

* De-identified means that all free-form text fields will be removed, as well as any date/time fields and Identifier fields.

Add/Edit/Organize Reports
Also allows user to view ALL reports (but not necessarily all data in the reports)

Stats & Charts

Other privileges:

- Survey Distribution Tools
- Calendar
- Data Import Tool
- Data Comparison Tool
- Logging
- File Repository
- Data Quality Create & edit rules
- [What is Data Quality?](#) Execute rules

Data Entry Rights

NOTE: The data entry rights "only" pertain to a user's ability to view or edit data on a web page in REDCap (e.g., data entry forms, reports). It has no effect on data imports or data exports.

	No Access	Read Only	View & Edit
Biological_Consent_Template with Additional Elements and HIPAA drop in text (survey)	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>

External Modules: Configuration Permissions

Privileges may be defined regarding whether the user can set or modify the configuration of an External Module that has been enabled on this project. Below are the currently enabled modules. NOTE: Only administrators may modify the module configuration permissions here.

- Date Calculated Fields*
- Field Notes Display**
- Tableau Web Data Connector**

*Permissions based on user's Project Design/Setup rights
**Module does not have project-level configuration options

Save Changes Cancel Remove user