

# e-Consent

## CCTS Biostatistics Core

September 2023

The e-Consent framework in REDCap is a module that helps you obtain participant consent electronically with a REDCap survey.

### Before You Start

IRB approval must be obtained before using REDCap e-Consent. Get IRB approval after reviewing the regulatory component. If you need any regulatory support related to the e-Consent process, submit a service request to CCTS: <https://research-ally.ccts.uic.edu/>

Before setting up e-Consent, consider whether you will start from a blank project or from an e-Consent template.

- **Option A.** If your consent document has already been finalized and approved by the IRB, you may want to start from a blank project.
- **Option B.** If you want to create a new REDCap project and draft your consent document based on a REDCap template, create a new project based on the e-Consent template included in the CCTS REDCap application. This template includes sample language and instructions, so substantial customization will be required.
- **Option C.** If you want to add the e-Consent template to an existing project, create a new project based on the e-Consent template. Then download the e-Consent instrument as a zip file and upload it to the existing project in the Online Designer.

### Create Your REDCap Project

#### Option A. Build Your Consent Form from Scratch

Log into REDCap and find the “New Project” tab in the top menu. Add your project title and select “Research” as the purpose. Enter information about the PI, project type, and IRB number, as applicable.

If you want to start with a blank project and your IRB-approved consent form, select “Create an empty project (blank slate)” (Figure 1). Then create a new instrument in the Online Designer and add the appropriate fields from your consent form. [See below for more information.](#)

**+ 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)

**★ 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 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 longitudinally over eight different events.
<input type="radio"/>	Multiple Surveys (classic)	Contains three surveys and a data entry form. Includes a pre-screening survey followed by two follow-up surveys to capture information from the participant, and then a data entry

Figure 1: Create a project from scratch

### Option B. Create a New Project from a Template

Log into REDCap and find the “New Project” tab in the top menu. Add your project title and select “Research” as the purpose. Enter information about the PI, project type, and IRB number, as applicable.

Select “Use a template (choose below)” and then choose the UIC CCTS-provided template called “Biological Consent Template with Additional Elements and HIPAA drop in text” (Figure 2). Then customize the consent form template in the Online Designer. You should edit the default text to include your study-specific language and delete unnecessary paragraphs. [See below for more information.](#)

**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)

**★ 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

REDCap 9.6.1 - © 2020 Vanderbilt University

Figure 2: Create a project from a template

### Option C. Add a Template Form to Your Existing Project

In some cases, your study may already have a REDCap project containing other data collection forms, such as screening and follow-up surveys. If you want to add the e-Consent template to an existing REDCap project, start by following the [Option B instructions](#) above. Then download the consent instrument as a zip file (Figure 3) and upload it to the existing project in the Online Designer (Figure 4).

Project Home · Project Setup  
Designer · Dictionary · Codebook  
Project status: Development

Project Home · Project Setup · **Online Designer** · Data Dictionary · Codebook

Create snapshot of instruments  
Last snapshot: never [?](#) [VIDEO: How to use this page](#)

The Online Designer will allow you to make project modifications to fields and data collection instruments very easily using only your web browser. NOTE: While in development status, all field changes will take effect immediately in real time.

**Data Collection Instruments**

Survey options: [Survey Queue](#) [Survey Login](#) [Survey Notifications](#)  
[Upload or download Auto Invitations](#)

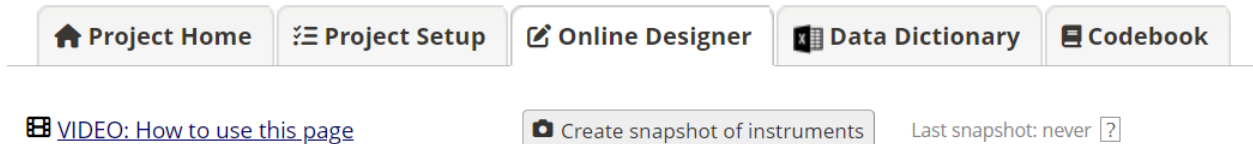
Add new instrument:  
[Create](#) a new instrument from scratch  
[Import](#) a new instrument from the official [REDCap Shared Library](#) [?](#)  
[Upload](#) instrument ZIP file from another project/user or [external libraries](#) [?](#)

Instrument name	Fields	View PDF	Enabled as survey	Instrument actions	Survey-related options
Biological_Consent_Template with Additional Elements and HIPAA drop in text	57			Choose action <a href="#">?</a>	<a href="#">Survey settings</a> <a href="#">Automated Invitations</a>

[Rename](#)  
[Copy](#)  
[Delete](#)  
[Download instrument ZIP](#)

Alerts & Notifications  
 Calendar  
 Data Exports, Reports, and Stats  
 Data Import Tool  
 Data Comparison Tool  
 Logging  
 Field Comment Log  
 File Repository  
 User Rights and DAGs  
 Customize & Manage Locking/E-signatures  
 Data Quality  
 API and API Playground  
 REDCap Mobile App  
 External Modules

Figure 3: Download a ZIP file of the consent form



The Online Designer will allow you to make project modifications to fields and data collection instruments very quickly. NOTE: While in development status, all field changes will take effect immediately in real time.

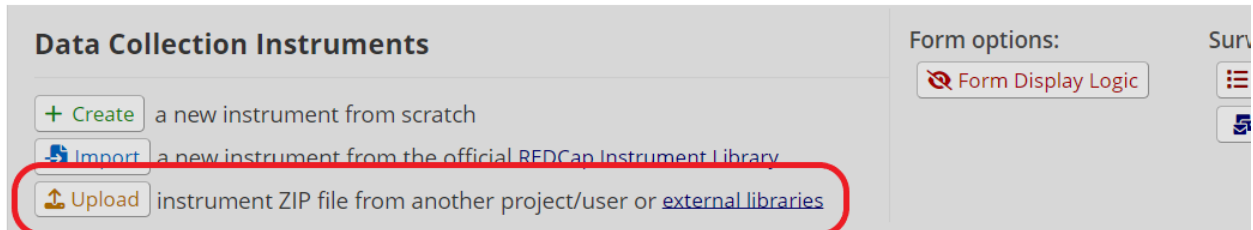


Figure 4: Upload the template to the existing project

## Build or Customize Your Consent Form

### Field Types

For **informational** consent form text and study descriptions, you can either:

- Save each page or the entire document as jpg or pdf files and upload them to Descriptive Text fields (up to 10Mb). Use the inline display option to show your images between sections and questions (Figure 5).
- Type or paste your text into Descriptive Text fields or REDCap field labels. Use the Rich Text Editor to edit and format text and add tables (Figure 6)

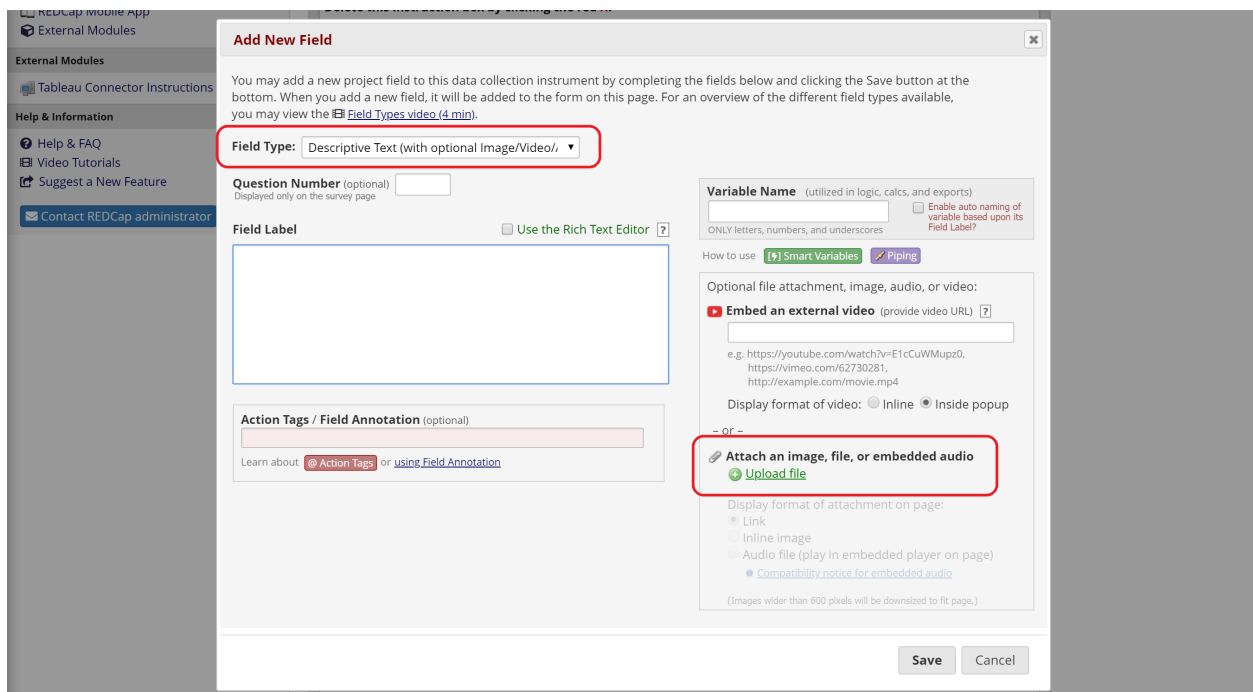
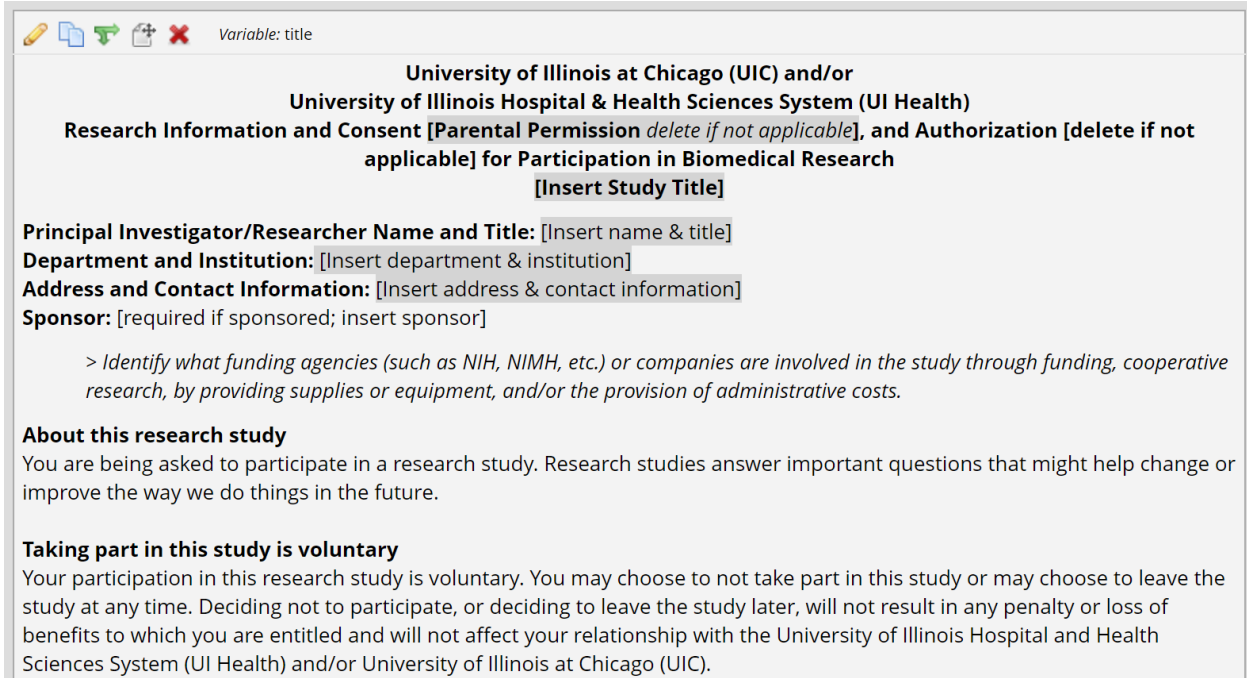


Figure 5: Upload a document or image



Variable: title

**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]  
**Address and Contact Information:** [Insert address & contact information]  
**Sponsor:** [required if sponsored; insert sponsor]

*> Identify what funding agencies (such as NIH, NIMH, etc.) or companies are involved in the study through funding, cooperative research, by providing supplies or equipment, and/or the provision of administrative costs.*

**About this research study**  
You are being asked to participate in a research study. Research studies answer important questions that might help change or improve the way we do things in the future.

**Taking part in this study is voluntary**  
Your participation in this research study is voluntary. You may choose to not take part in this study or may choose to leave the study at any time. Deciding not to participate, or deciding to leave the study later, will not result in any penalty or loss of benefits to which you are entitled and will not affect your relationship with the University of Illinois Hospital and Health Sciences System (UI Health) and/or University of Illinois at Chicago (UIC).

Figure 6: Descriptive text field

For **interactive** fields, use Text, Multiple Choice, Yes-No, and other field types. For example, you can ask for participants' agreement with a Yes-No field or gather e-signatures in a Signature field. Signature fields and image uploads are supported in REDCap.

**Add New Field**

You may add a new project field to this data collection instrument by completing the fields below and clicking the Save form on this page. For an overview of the different field types available, you may view the [Field Types video \(4 min\)](#).

**Field Type:**  ▼

- 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)
- Dynamic Query (SQL)

Figure 7: Other field types

### Survey Page Breaks

If your document is long, you can allow participants to click through multiple screens rather than scrolling. In Survey Settings, set the Question Display Format as “One section per page (multiple pages)” (Figure 8). Then, in the Online Designer, add a “Begin New Section (with optional text)” field between two paragraphs or sections to display them on separate pages (Figure 9).

**Survey Customizations:**

**Question Numbering**  
*For custom numbering, each question's number will be blank by default until manually added via the Online Designer or Data Dictionary.*

Custom numbered ▾  
 Question numbers will not display correctly if using auto numbering if some questions have branching logic employed. Question auto numbering has been automatically disabled because some of your survey questions use branching logic.

**Question Display Format**  
*One page or multiple pages? Section headers, which begin new sections on the instrument, will serve as the page break in a multi-page survey, in which each page will begin with a section header.*

All on one page ▾  
 All on one page  
 One section per page (multiple pages)

**Allow participants to download a PDF of their responses at end of survey?**  
*Display a button for the participant to download a PDF file of their responses for the survey they just completed.*

No ▾  
 This option will not be available if the Survey Auto-continue or Survey Queue auto-start option is enabled. Also, if a field utilizes the @HIDDEN action tag, it will not be displayed in the PDF.  
 ⓘ 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.

Figure 8: Survey Settings to show one section per page

**Add New Field**

You may add a new project field to this data collection instrument by completing the fields below and clicking the Save button at the bottom. When you add a new field, it will be added to the form on this page. For an overview of the different field types available, you may view the [Field Types video \(4 min\)](#).

Field Type: ---- Select a Type of Field ---- ▾

- 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)
- Begin New Section (with optional text)**
- Dynamic Query (SQL)

Figure 9: Adding a section header for page break

## Survey Settings

To enable e-Consent features in REDCap, the form must be set up as a survey. Make sure to enable the “Use surveys in this project” option in Project Setup. In the Online Designer, enable your consent form as a survey. If you’re starting with the e-Consent template project, the survey option should already be enabled.

Then open Survey Settings for your consent form (Figure 10). Scroll down to the e-Consent Framework section to enable e-Consent (Figure 11). Review the options and select the appropriate ones for your study. On the Survey Settings page, you can also add study-specific instructions and a study logo or IRB stamp.

The screenshot shows the REDCap Online Designer interface. The left sidebar contains navigation menus for 'Project Home and Design', 'Data Collection', and 'Applications'. The 'Designer' option is circled in red. The main content area shows the 'Online Designer' tab, which is also circled in red. Below the navigation, there are buttons for 'Create snapshot of instruments' and a link to a video. A note states: 'The Online Designer will allow you to make project modifications to fields and data collection instruments very easily using only your web browser. NOTE: While in development status, all field changes will take effect immediately in real time.' Below this is a section for 'Data Collection Instruments' with options to 'Create', 'Import', or 'Upload' new instruments. At the bottom, a table lists existing instruments. The 'Biological\_Consent\_Template with Additional Elements and HIPAA drop in text' instrument is listed with 57 fields and is enabled as a survey. The 'Survey settings' button for this instrument is circled in red.

Instrument name	Fields	View PDF	Enabled as survey	Instrument actions	Survey-related options
Biological_Consent_Template with Additional Elements and HIPAA drop in text	57			Choose action	Survey settings  Automated Invitations

Figure 10: Survey Settings



**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 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:

Figure 11: Auto-Archiver + e-Consent Framework

## Sending the e-Consent Survey to Participants

There are different options for sharing the e-Consent survey with participants.

### Using the Public Survey Link

A public survey link is only available when the consent survey is the first instrument in your REDCap project. This option is appropriate when the link needs to be shared with multiple people, for example in an email message or on a public website. Anyone who clicks the link can access the consent form and create a new record in your REDCap project. Note that a single person could access the survey multiple times using the same link.

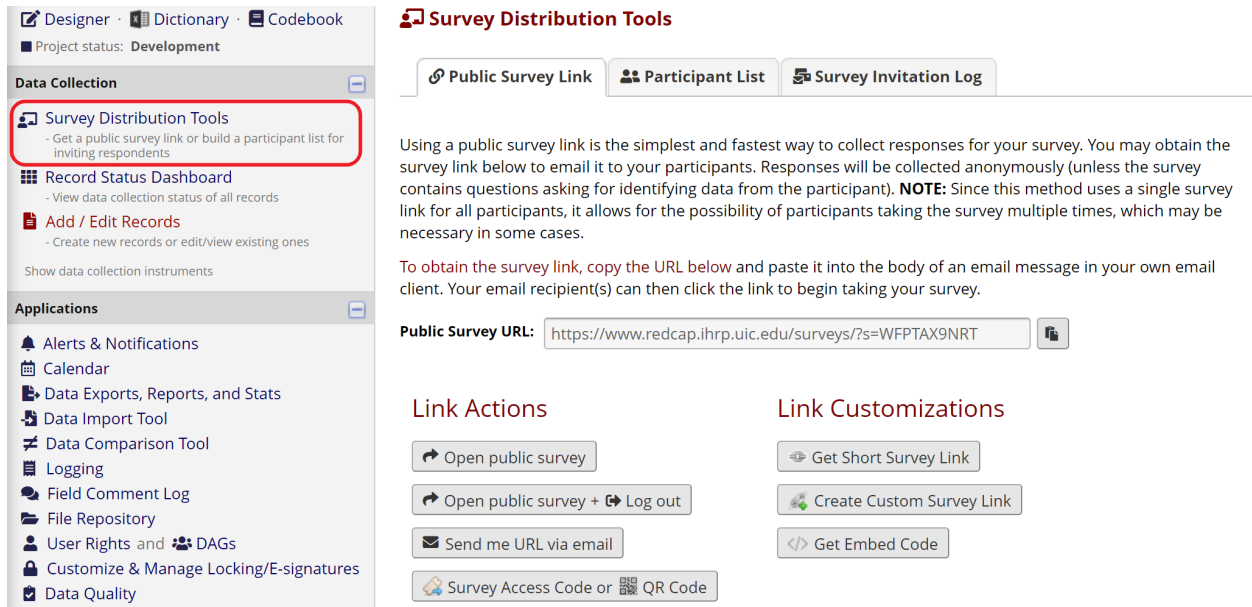


Figure 12: Public survey link

### Using Individual Survey Links

When you have individual participants' email addresses ahead of time, the e-Consent survey can be sent directly to each participant using a unique survey link. Each participant's response status can be tracked and you can follow up with participants individually based on their linked information.

To use this option, we recommend you start your project with a data entry form where study staff can enter your participants' information, including email addresses. Then, in Project Setup, enable the option "Designate an email field for communications (including survey invitations and alerts)" in Project Setup (Figure 13).

Then open the Participant List in Survey Distribution Tools. Participants' email addresses will automatically show up. From there, you can send the invitations by clicking "Compose Survey Invitations" (Figure 14).

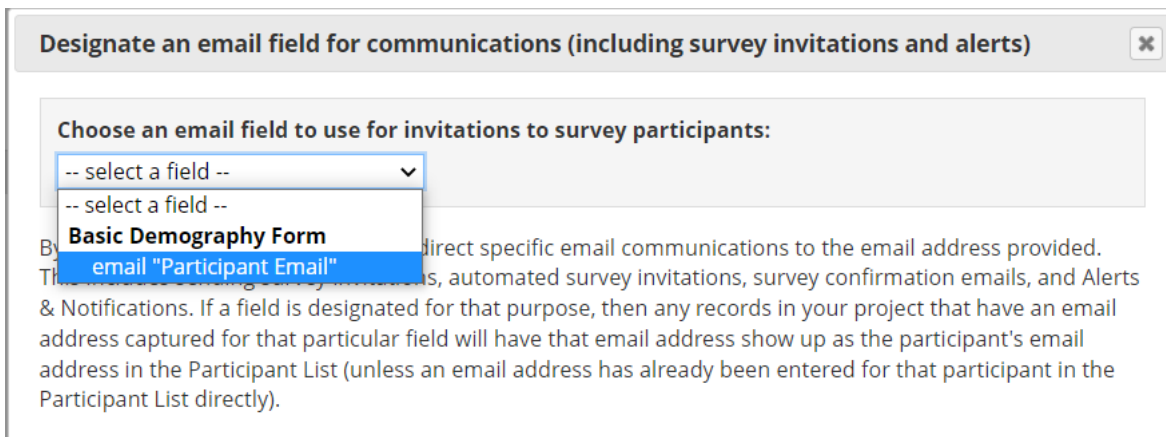


Figure 13: Designate a participant email field

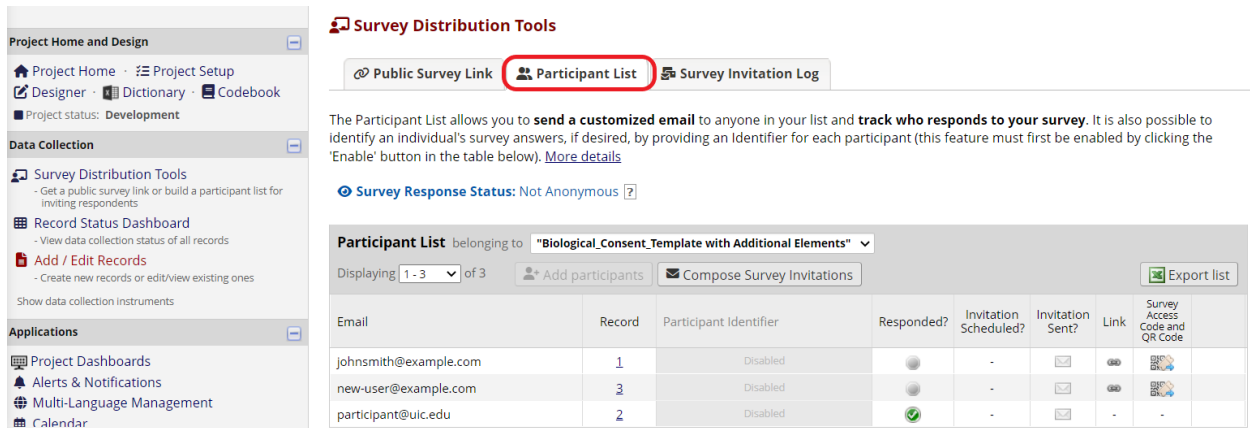


Figure 14: Participant List

### Using the Data Entry Form (Add/Edit Records)

When a study participant is unable to complete the consent form alone or doesn't have an email address available, study staff can open the e-Consent form on a study device and let the participant fill it out.

If the consent form is the first instrument in the project and a public survey link exists, follow the "Using a Public Survey Link" instructions above.

Otherwise, study staff should create a new record or open an existing record for the participant and navigate to the e-Consent data entry form linked to that record. Then, click "Open survey" in the Survey options menu. If the menu isn't visible on the data entry form, first click "Save and Stay" to initialize the e-Consent response.

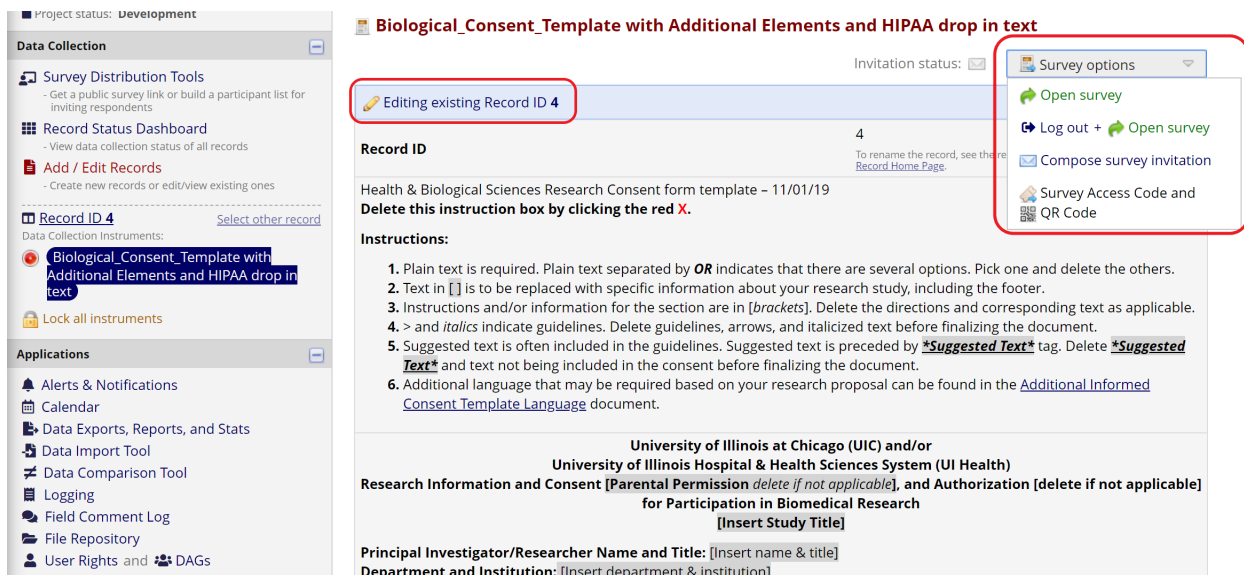


Figure 15: Open survey for an existing record

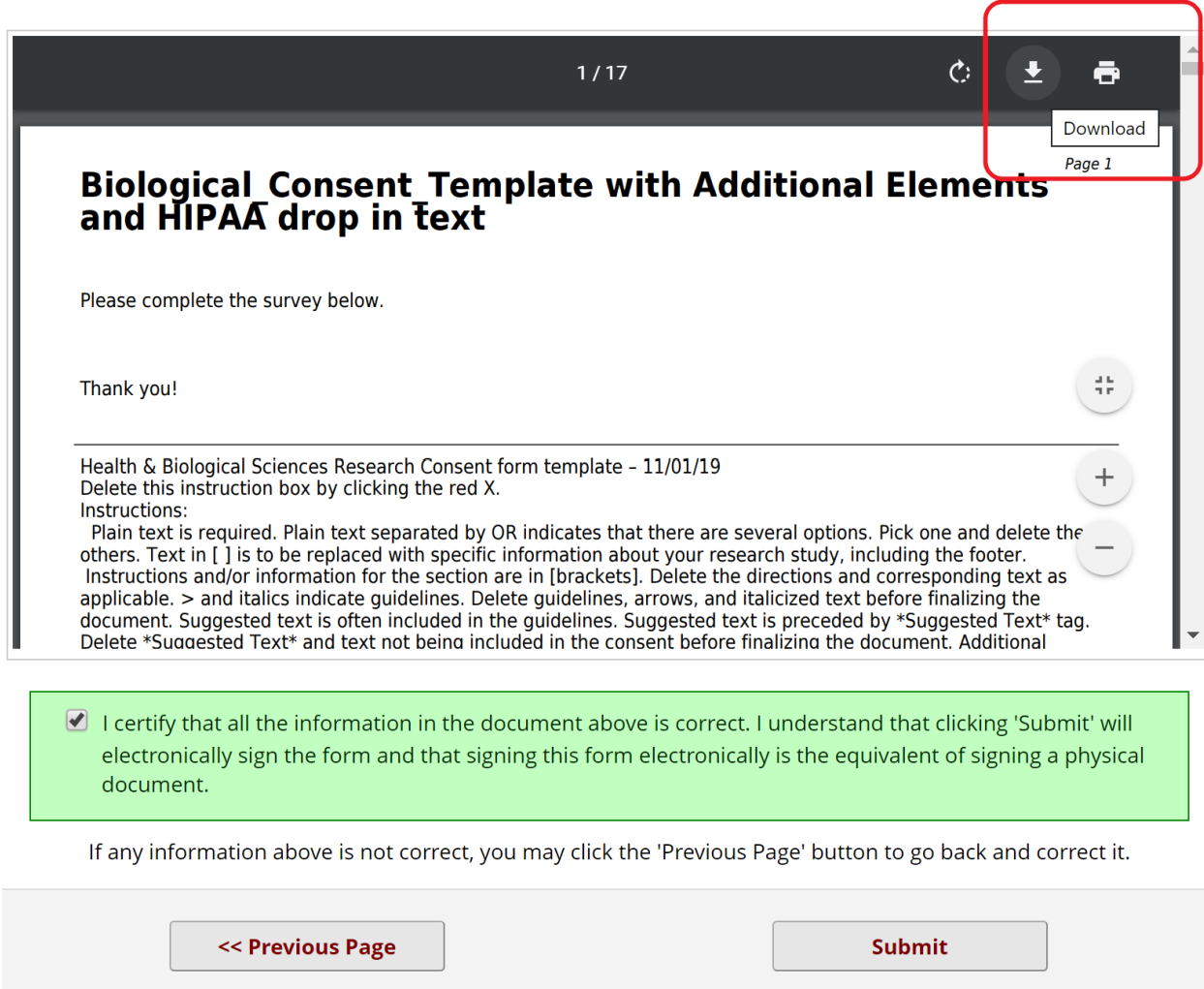
### Participant Certification

When the e-Consent framework is in place, participants will be asked to certify their information at the end of the consent form before submitting it. Participants will have the option to download their signed consent forms in pdf format.

## Biological\_Consent\_Template with Additional Elements and HIPAA drop in text

Resize font:  
+ | -

Displayed below is a read-only copy of your survey responses. Please review it and the options at the bottom.



1 / 17

Download  
Page 1

### Biological Consent Template with Additional Elements and HIPAA drop in text

Please complete the survey below.

Thank you!

---

Health & Biological Sciences Research Consent form template - 11/01/19  
Delete this instruction box by clicking the red X.

Instructions:  
Plain text is required. Plain text separated by OR indicates that there are several options. Pick one and delete the others. Text in [ ] is to be replaced with specific information about your research study, including the footer. Instructions and/or information for the section are in [brackets]. Delete the directions and corresponding text as applicable. > and italics indicate guidelines. Delete guidelines, arrows, and italicized text before finalizing the document. 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. Additional

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 Page      Submit

Figure 16: Consent form submission page

### Archived PDFs of e-Consent Forms

Submitted consent forms will be archived in the project's File Repository and accessible on the PDF Survey Archive tab. Study staff with adequate rights can view and download consent forms as needed.

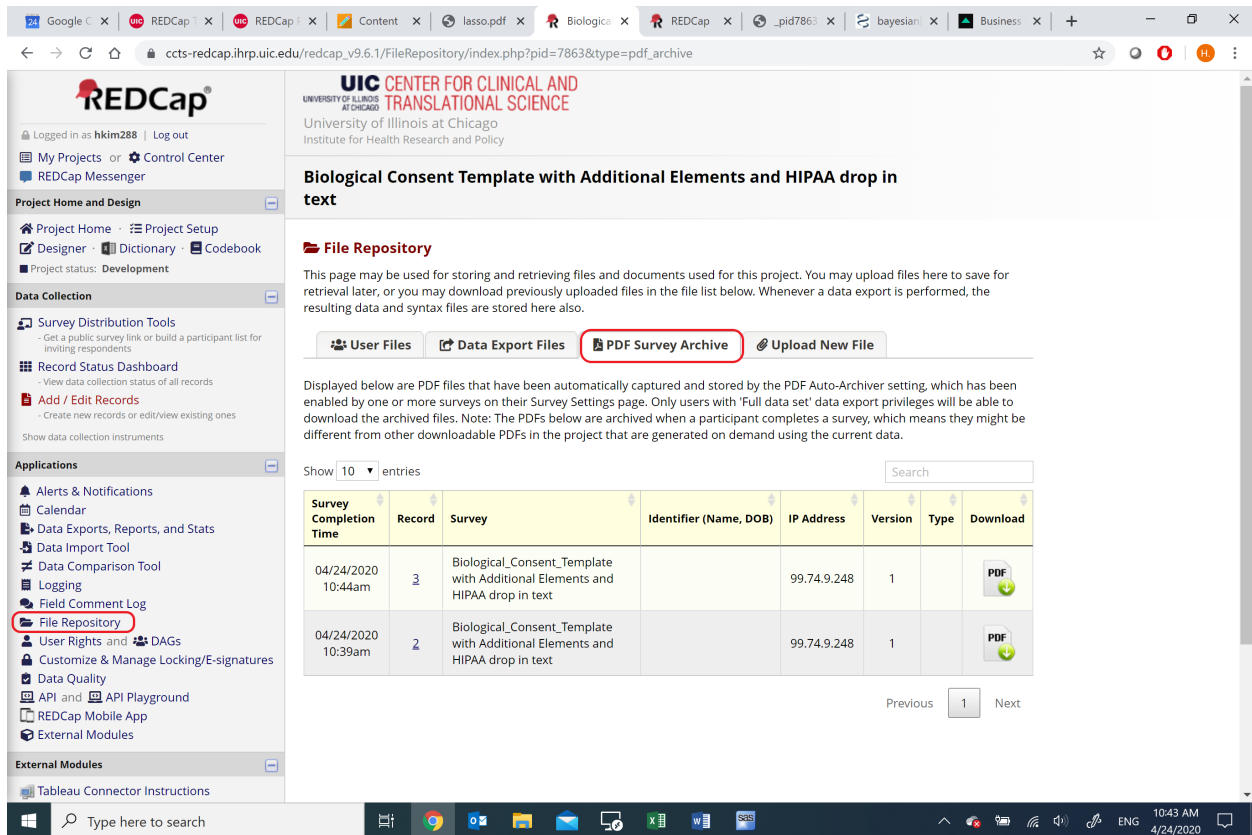


Figure 17: File Repository

## User Rights

Use the User Rights page to assign each study team member the appropriate level of access to the e-Consent form and the File Repository. Users with access to the User Rights page are responsible for adding other users and managing their access levels.

### Basic Rights

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

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
  - Execute rules[What is Data Quality?](#)

### 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
			<input checked="" type="checkbox"/>
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

Figure 18: User Rights