

Setting up e-Consent in REDCap: The Basics for a Consent Requiring a Signature

Background

For those who are navigating REDCap to create an e-consent document, the process can be a bit tricky. Thus, the Clinical Research Resources Office (CRRO) has developed a “Building a REDCap e-consent Guidance” for utilizing the REDCap e-consent capability. This guidance will take you step-by-step to build your e-consent from the IRB-approved stamped consent form. **This guidance is specifically intended for research that WILL require a signature on the consent form.** Under Massachusetts law, a person typing in their name on an electronic document constitutes a legally effective signature. REDCap will also allow an individual to sign their name using a stylus, a finger or the mouse. (Note that this guidance is NOT applicable to consent for FDA-regulated research, as electronic systems used to create and maintain research records for FDA-regulated research must be [Part 11 compliant](#).)

If you have comments about the “Building a REDCap e-consent Guidance,” suggestions on how to make the guidance easier to use, or other questions about e-consent please contact Mary-Tara Roth at the CRRO (mtroth@bu.edu).

Special thanks to Tasha Coughlin, the BUMC REDCap Administrator, for her help and expertise in developing this guidance!

Setting up your e-consent requiring a signature

1. If you plan to obtain e-signatures on your e-consent form, you should submit a consent form version to the IRB that does not contain the signature lines. Keep the consent form template wording: “By signing this consent form, you are indicating that....” (You would not keep this wording if you have IRB approval for Waiver of Documentation of consent.)
2. Save your IRB-approved and stamped PDF consent form as a jpeg or png file.
3. Sign on to REDCap and go to “My Projects.”
4. If you are starting a new project you should click “New Project” at the top menu. If you already have a project set up in REDCap, proceed to 5.0.
 - 4.1 Complete Project title, Purpose (research), PI info, Project notes, etc.)
 - 4.2 At the end of the page, choose “Create empty project (blank slate)” and press the blue “Create Project” button.

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)

★ 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 (2 arms)	Contains nine data entry forms (beginning with a demography form) for collecting data on two different arms (Drug A and Drug B) with each arm containing eight different events.
<input type="radio"/>	Multiple Surveys (longitudinal)	Contains three surveys and a data entry form. Includes a pre-screening survey followed by two follow-up surveys, one of which is a questionnaire taken weekly to capture participant information longitudinally over a period of... Show more

Create Project **Cancel**

5. At “My Projects” page, select the appropriate project that you are creating an e-consent for. This will bring you to the “Project Setup” tab.
 - 5.1 Under “Main Project Settings” within Project Setup tab select the “Enable” button for the question “Use surveys in this project?”

REDCap Logged in as mtroth | Log out

My Projects **Project Home** or **Project Setup** REDCap Messenger Project status: Development

Data Collection [Edit instruments](#)

Record Status Dashboard - View data collection status of all records

Add / Edit Records - Create new records or edit/view existing ones

Show data collection instruments ▼

Applications

Calendar Data Exports, Reports, and Stats

New study with e-consent

Project Home **Project Setup** **Other Functionality** **Project Revision History**

Project status: Development **Completed steps 0 of 7**

Main project settings

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

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

I'm done! **Modify project title, purpose, etc.**

Design your data collection instruments

Not started Add or edit fields on your data collection instruments. This may be done by either using the Online Designer (online method) or by uploading a Data Dictionary (offline method). Quick

- 5.2 Select “Online Designer” button under “Design your data collection instruments & enable your surveys.”
- 5.3 Rename “My First Instrument” by selecting “Choose action” drop down button to “Rename.” Name the instrument (your consent document) and then click the “Save” button.

[Project Home](#)
[Project Setup](#)
[Online Designer](#)
[Data Dictionary](#)
[Codebook](#)

[Create snapshot of instruments](#)
[VIDEO: How to use this page](#)

Last snapshot: never ?

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

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	Instrument actions
<input type="text" value="Consent Form"/> <input type="button" value="Save"/>	15		<div> Choose action ▾ <div> Rename Copy Delete Download instrument ZIP </div> </div>

6. Now build your consent form.
 - 6.1 Click on your newly named instrument (see 5.3 above).
 - 6.2 Click “Add field” button.

[Return to list of instruments](#)

Current instrument: **Consent form 1** [Preview instrument](#)

Variable: record_id

Record ID

NOTE: The field above is the record ID field and thus cannot be deleted or moved. It can only be edited.

- 6.3 Under the Field Type drop down, choose “Descriptive Text...”
- 6.4 Click on “Upload document.” Choose first page of your jpeg format consent form and upload the file. Then click on “In-line image.” Give the page a variable name (such as page_1). Save.
- 6.5 At bottom of first consent form page (the jpeg image), click the “Add field” button.

6.6 Follow the instructions in 6.3 and 6.4 above for all the consent form pages.

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: Descriptive Text (with optional Image/Video/)

Field Label

Variable Name (utilized in logic, calcs, and exports)
ONLY letters, numbers, and underscores
☐ Enable auto naming of variable based upon its Field Label?

How to use: [Smart Variables](#) [Piping](#)

Optional file attachment, image, audio, or video:

☒ **Embed an external video** (provide video URL) [?]
e.g. <https://youtube.com/watch?v=E1cCuWMup0>,
<https://vimeo.com/62730281>,
<http://example.com/movie.mp4>
Display format of video: ☐ Inline ☒ Inside popup

- OR -

☒ **Attach an image, file, or embedded audio**
[Upload document](#)

Display format of attachment on page:
☐ Link
☐ Inline image
☐ Audio file (play in embedded player on page)
[Compatibility notice for embedded audio](#)
(Images wider than 600 pixels will be downsized to fit page.)

Action Tags / Field Annotation (optional)
Learn about [Action Tags](#) or [using Field Annotation](#)

Save **Cancel**

Edit Field

Field Type: Descriptive Text (with optional Image/Video/)

Field Label ☐ Use the Rich Text Editor [?]
Consent Form Inline Image

Variable Name (utilized in logic, calcs, and exports)
ONLY letters, numbers, and underscores
☐ Enable auto naming of variable based upon its Field Label?

How to use: [Smart Variables](#) [Piping](#)

Optional file attachment, image, audio, or video:

☒ **Embed an external video** (provide video URL) [?]
e.g. <https://youtube.com/watch?v=E1cCuWMup0>,
<https://vimeo.com/62730281>,
<http://example.com/movie.mp4>
Display format of video: ☐ Inline ☒ Inside popup

- OR -

☒ **Attach an image, file, or embedded audio**
[RESEARCH CONSENT FORM_short.png](#) [X] Remove

Display format of attachment on page:
☐ Link
☒ **Inline image**
☐ Audio file (play in embedded player on page)
[Compatibility notice for embedded audio](#)
(Images wider than 600 pixels will be downsized to fit page.)

Action Tags / Field Annotation (optional)
Learn about [Action Tags](#) or [using Field Annotation](#)

Save **Cancel**

7. When finished uploading all jpeg format pages of the consent form, scroll to the top and click on the blue “Return to list of instruments” button. Then click on “Project Setup” tab.

[Return to list of instruments](#)

[Project Home](#) [Project Setup](#) [Online Designer](#) [Data Dictionary](#)

7.1 Under the section “Design your data collection instruments & enable your surveys” click on the “Online Designer” button.

- 7.2 You will see your consent form under the “Data Collection Instruments” table. Click “Enable” under “Enabled as survey.” This brings you to the “Set Up My Survey” tab (or if it is already set up, the tab is called “Modify survey settings”).

Sample Consent 2

Project Home Project Setup Online Designer Data Dictionary Codebook

Create snapshot of instruments VIDEO: How to use this page
Last snapshot: never ?

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
Sample Consent Template 1	22			Choose action	Survey settings + Automated Invitations
Sample Consent Template 2	23			Choose action	Survey settings + Automated Invitations
Sample Consent Template 3	8			Choose action	Survey settings + Automated Invitations
Sample Consent Template 4	0		Enable	Choose action	

- 7.3 Under “Basic Survey Options” fill in “Survey Title” and “Survey Instructions.” This information will appear at the top of your electronic consent survey page.. The instructions can be some simple instruction that makes sense within your consent process, such as: “Please review this electronic consent form with the study coordinator.”
- 7.4 Scroll down to “Survey Termination Options” at the bottom of the survey settings page. Next to “Survey Completion Text” provide the text you want to show to the participant after he/she provides an electronic signature. For example: “Thank you for your participation in this research study!” Click the “Save Changes” blue button on the bottom of this webpage.
- 7.5 To the right of the “PDF Auto-archiver” choose the third option: “Auto-Archiver + e-Consent Framework.”
- 7.6 Next to “e-Consent version” provide a version number.

8. Add electronic signatures. You can add text box fields for the participant to type in his/her first and last name, and/or you can add a signature field, allowing the participant to provide an e-signature using a stylus, finger, or mouse.

8.1 On the Online Designer tab, click on your consent form under the heading “Instrument name.”

8.2 Scroll down to the last page of your electronic consent form.

8.3 Click the “Add Field” blue button at the bottom of the page.

8.4 Select “Text Box...” from the dropdown menu.

8.5 Under the field Label type “First name.” Under “Variable Name” type “first_name”.

8.6 Complete the “Required?” And “Identifier?” fields as ‘Yes’. Click “Save.”

The screenshot shows the REDCap Online Designer interface. On the left, there's a list of existing fields: 'First Name' (Variable: first_name_3), 'Last Name' (Variable: last_name_3), 'Signature' (Variable: signature_3), and 'Date' (Variable: date_3). Each field has an 'Add Field' and 'Add Matrix of Fields' button. The main area displays the 'Edit Field' dialog box. The 'Field Type' is 'Text Box (Short Text, Number, Date/Time, ...)'. The 'Field Label' is 'Last Name'. The 'Variable Name' is 'last_name_3'. The 'Required?' field is set to 'Yes' and the 'Identifier?' field is set to 'Yes'. The 'Custom Alignment' is set to 'Right / Horizontal (RH)'. The 'Field Note' is empty. The 'Save' button is highlighted.

8.7 Continue and add Last name field following steps 8.2-8.6.

8.8 If you want to, you can add a Stylus Signature field in addition to the typed signature. In Field type, choose “Signature...” from the dropdown menu. Proceed as before with steps 8.5-8.6.

Edit 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: Signature (draw signature with mouse or fir)

Field Label: Signature

Variable Name: signature_3

Required?* ☒ No ☐ Yes

Identifier? ☒ No ☐ Yes

Custom Alignment: Right / Vertical (RV)

Field Note (optional):

Action Tags / Field Annotation (optional):

Save **Cancel**

8.9 Add a date field. Choose “Add field” blue button. Under “Field Type” choose “Text Box.” Complete “Field Label” and “Variable Name.” Under “Validation?” choose a date option from the dropdown menu (such as “Date (M-D-Y)). Complete additional fields as necessary.

8.10 You may also elect to setup a file download field, to allow the participant to download a hardcopy of the consent form.

Edit 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: Descriptive Text (with optional Image/Video)

Field Label: Consent Form Link

Variable Name: cf_link

Optional file attachment, image, audio, or video:

☒ Embed an external video (provide video URL)

Display format of video: ☐ Inline ☒ Inside popup

Attach an image, file, or embedded audio:

Display format of attachment on page:

☒ Link

Save **Cancel**

9. To view the consent form from the Subject view, select “Manage Survey Participants” from the left menu under “Data Collection.” Under “Link Actions” click on “Open public survey” (the first button).

The screenshot shows the REDCap interface. On the left, the 'Data Collection' menu is expanded, and 'Survey Distribution Tools' is highlighted. The main content area shows the 'Survey Distribution Tools' section with three tabs: 'Public Survey Link', 'Participant List', and 'Survey Invitation Log'. The 'Public Survey Link' tab is active. Below the tabs, there is a text box explaining that using a public survey link is the simplest and fastest way to collect responses, and that responses will be collected anonymously. A 'Public Survey URL' is displayed as <https://redcap.bumc.bu.edu/surveys/?s=77FNY7P8TF>. Below the URL, there is a checkbox for 'Protect the public survey using the Google reCAPTCHA feature'. At the bottom, there are two sections: 'Link Actions' and 'Link Customizations'. The 'Link Actions' section contains four buttons: 'Open public survey' (circled in red), 'Open public survey + Log out', 'Send me URL via email', and 'Survey Access Code or QR Code'. The 'Link Customizations' section contains three buttons: 'Get Short Survey Link', 'Create Custom Survey Link', and 'Get Embed Code'.

10. Please be sure to review the remaining steps prior to administering your e-Consent project.

- Survey design and distribution:
<https://redcap.bumc.bu.edu/index.php?action=help&newwin=1#ss57>
- Test your project thoroughly:
<https://redcap.bumc.bu.edu/index.php?action=help&newwin=1#ss37>

11. Move your project to production status.