



*Guidance on Developing REDCap E-Consent: Non-Exempt
Research Requiring a Signature*

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Background

This guidance will take you step-by-step on how to build your e-consent in REDCap from the IRB-approved stamped consent form. It is recommended that you utilize the e-consent project template, a pre-built REDCap project, that goes along with the guidance since it includes more or less all of the components addressed in this guidance (see “Getting Started”).

We also recommend that you review the [main guidance on e-consent/remote consent](#) and be familiar with FDA requirements, which are described in the main guidance if your study is a drug or device study.

This guidance is specifically intended for research that WILL require signatures 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 a mouse. If your study is non-exempt but IRB has approved a waiver of documentation of consent, please go to the CRRO website to access the [Guidance on Developing REDCap E-Consent: Minimal risk or Exempt Research Not Requiring a Signature and Exempt Research that Includes HIPAA authorization](#).

(Note that at this time 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 undergo validation procedures to be fully [Part 11 compliant](#). Although REDCap has the components to be Part 11 compliant, this validation has not been completed.)

Please note that though this guidance that has been created with best study practices in mind, you may need or want to change certain features or functionalities to match your own unique study needs and workflow. If you have any questions regarding how to make certain changes, please contact rchelp@bu.edu.

If you do not have a REDCap account, complete the REDCap User Agreement survey:

<https://redcap.bumc.bu.edu/surveys/?s=RYKEW4N4RX>

If you have comments or questions about the “Building a REDCap e-consent Guidance,” please contact Mary-Tara Roth at the CRRO (mtroth@bu.edu).

Brief Overview

If you are completely new to REDCap, we recommend that you look through the resources section, which has video tutorials on various topics: <https://redcap.bumc.bu.edu/index.php?action=training>

Below is a list of key terms to know before reading the guidance:

Instrument – A data collection tool that can be left as a form or enabled as a survey.

(Data Entry) Form – An instrument in which data can only be entered or collected by a REDCap user. (viewing method)

Survey – An instrument in which a research participant can enter data or answer questions without a REDCap account. Instrument is accessed through a URL. (viewing method)

Record – A record contains all the information for a unique participant. One record may contain many instruments.

Record ID – A unique identifier for each record in a project.

Survey Login – A way to increase security on private surveys by requiring participants to enter 1 to 3 specified login credentials in order to begin a survey. The credentials must already exist in the system for the survey login feature to be utilized, either by pulling them from a survey that has already been completed or by entering them on a form.

Online Designer – A way to build and edit instruments through a point-and-click interface.

Data Dictionary – CSV file that holds the architecture of a REDCap project. An alternative to the Online Designer for building or editing projects. Mainly used to save the project for future reference or project duplication.

Piping – Allows answers from previous questions to auto-populate or “pipe” into another place in a survey/form.

Action Tags – A method of customizing data entry for individual fields in a survey or form.

e-Consent Framework – survey setting option that allows for standardized method of obtaining consent and storing consent documentation with a certification and storage function which automatically generates a ‘hard-copy’ PDF of the signed form.

Project Template – pre-built REDCap project.

External Module - External Modules are add-on packages of software that can extend REDCap's current functionality, as well as provide customizations and enhancements for REDCap's existing behavior and appearance. Modules will need to be installed and enabled by a BUMC REDCap administrator. To request an External Module in REDCap, please complete this form: <https://redcap.bumc.bu.edu/surveys/?s=F8W4LLXJRP>

Getting Started

1. Save your IRB-approved and stamped PDF consent form as a .jpeg or .png file.
 - 1.1 Note: this approved consent form *will* contain signature lines applicable to this study.
2. Sign on to REDCap and go to “My Projects.” <https://redcap.bumc.bu.edu/>
3. To start a new project, you should click “New Project” at the top menu. If you already have a project set up in REDCap, proceed to section D. Creating a Standard e-Consent. **But we strongly**

recommend that you utilize the e-consent project template that goes along with this guide (see step 5 below)

4. Complete Project title, Purpose (research), PI info, Project notes, etc.

5. At the end of the page, choose “e-Consent for Non-Exempt Research” under “Choose a project template” and press the blue “Create Project” button.

5.1.1 This template provides you with a default layout to help you get started. Please note that the default template provides you with examples for both in-person e-consent and contactless e-consent. Also, the automatic survey feature has been enabled in this template. If you are not going to utilize this feature, disable it.

5.1.2 Edit the fields and survey settings accordingly for your study.

+ 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

Creating a Standard e-Consent

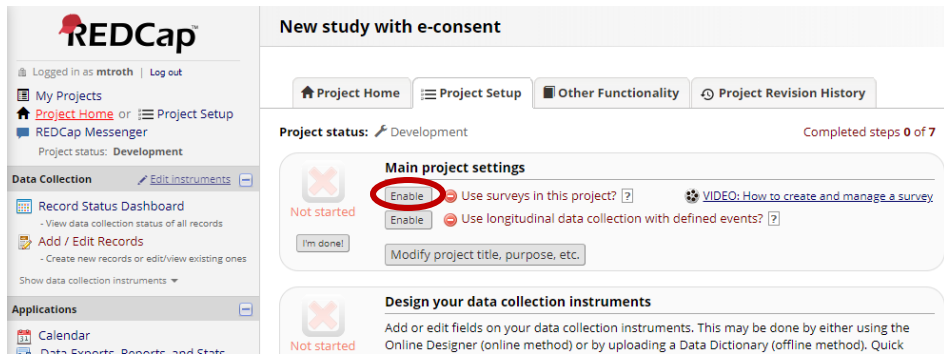
The section will incorporate signatures from both the participants and the study staff; this will go over in-person vs. contactless (remote) e-consent, include saving a PDF with both signatures in contactless e-consent setting.

I. Project Settings

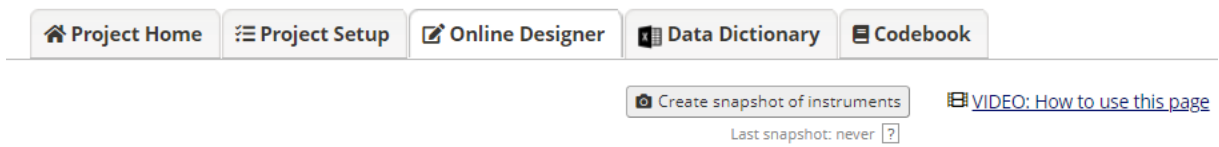
1. At the “My Projects” page, select the appropriate project that you are creating an e-consent for.

This will bring you to the “Project Setup” tab.

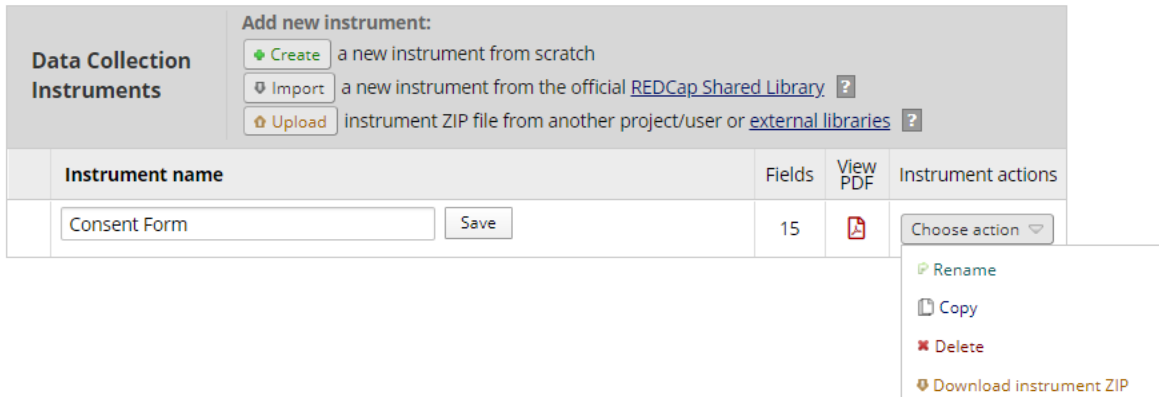
2. Under “Main Project Settings” within Project Setup tab, select the “Enable” button for the question “Use surveys in this project?”



3. Select “Online Designer” button under “Design your data collection instruments & enable your surveys.”
4. 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.

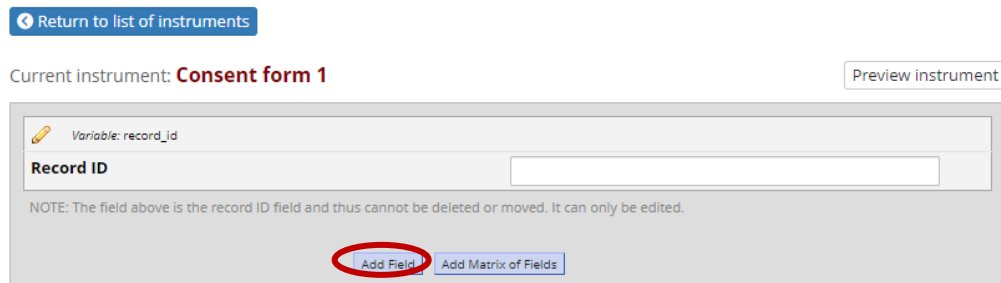


The Online Designer will allow you to make project modifications to fields and data collection instruments very easily using only your web browser. NOTE: While in development status, all field changes will take effect immediately in real time.



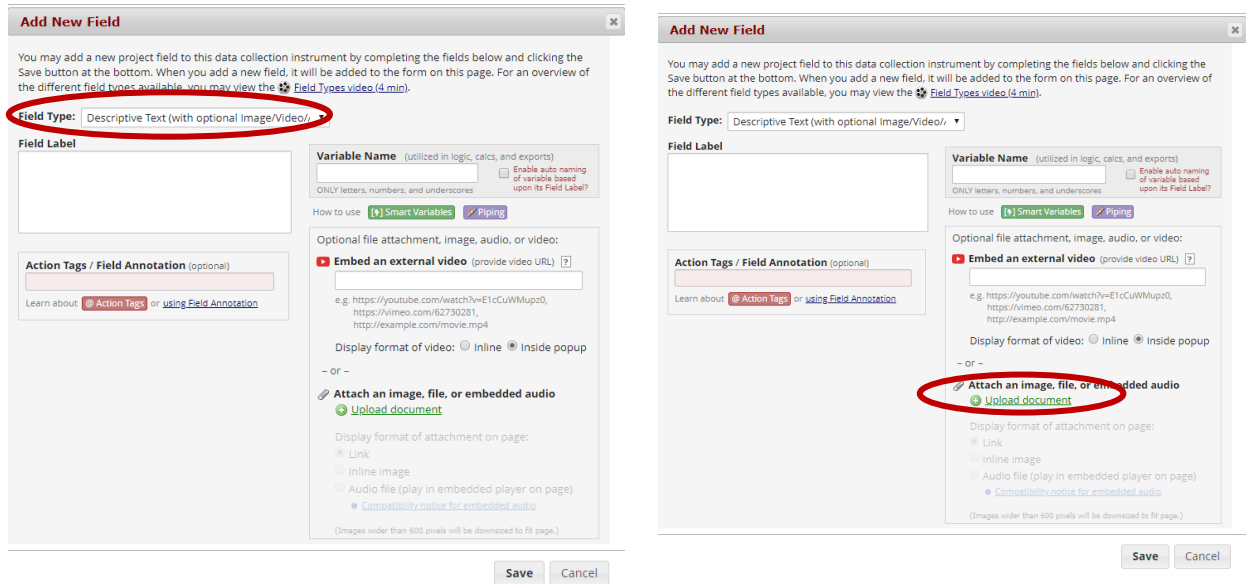
II. Creating the e-Consent instrument

1. Now to build your consent form, click on your newly named instrument.
2. Click “Add field” button.

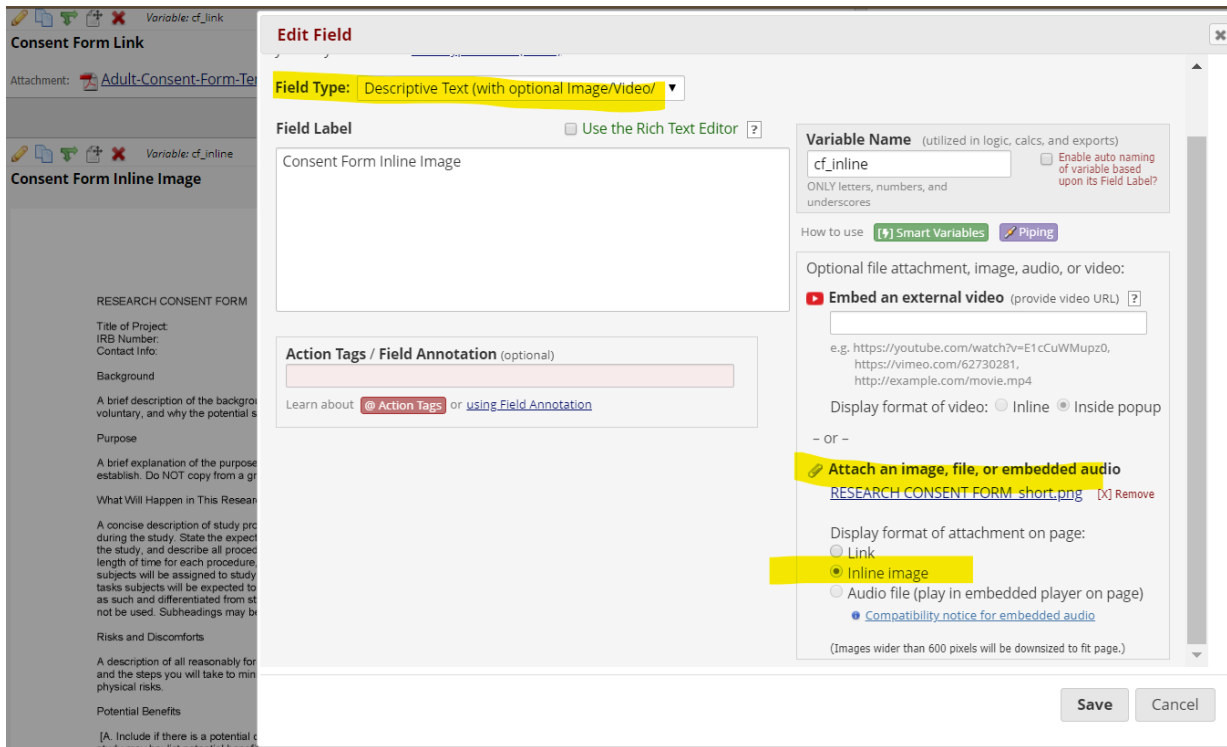


3. Under the Field Type drop down, choose “Descriptive Text.” You can keep the “Field Label” blank. It is not necessary to complete this field to upload the file.

- 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). Click save.
- At bottom of first consent form page (the jpeg image), click the "Add field" button.



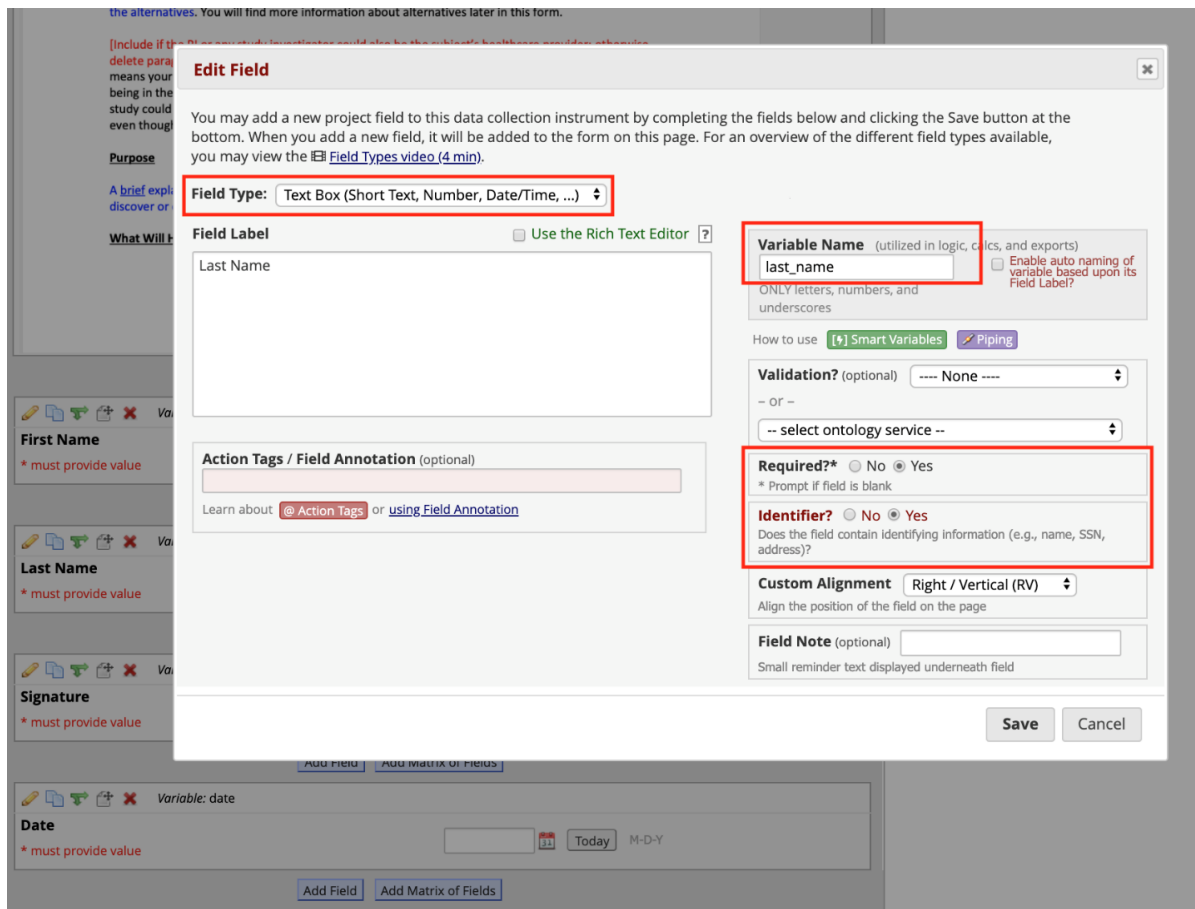
- Follow the instructions in above to add all the consent form pages.



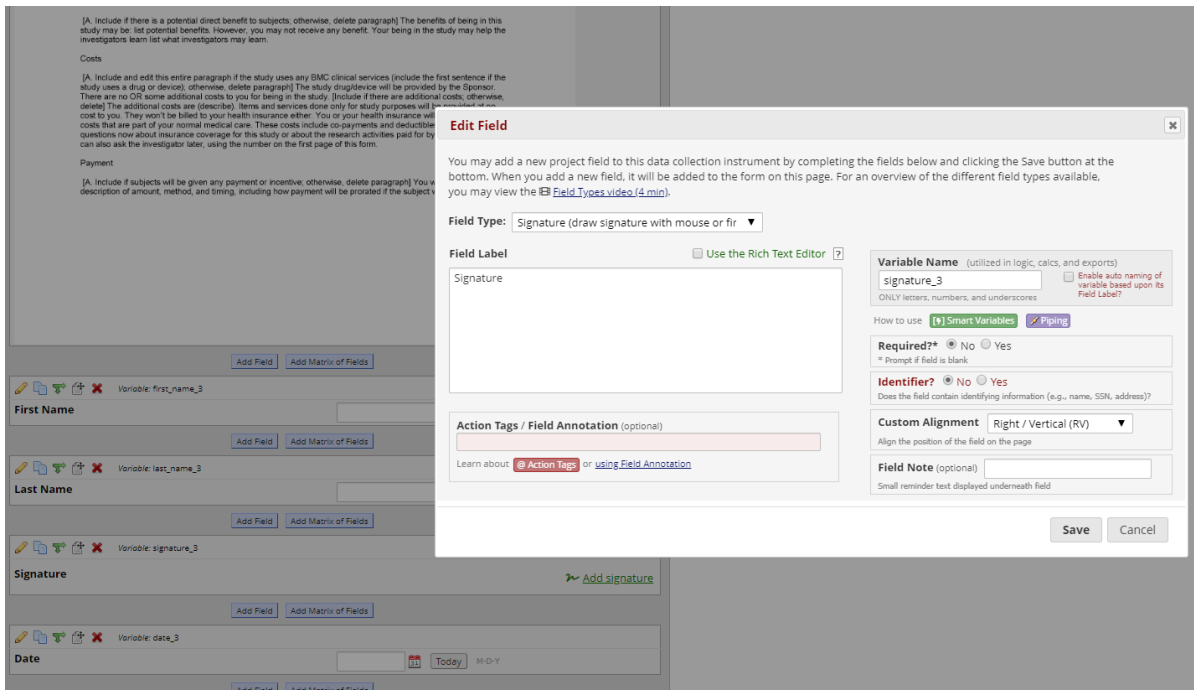
III. Adding fields in e-Consent instrument

You can add text box fields for the participant to type in their first and last name. Under MA Law, typing your name is considered a legal e-signature or you can add a signature field, allowing the participant to provide an e-signature using a stylus, finger, or mouse. Follow the steps below to add the necessary fields for the e-Consent instrument

1. On the “Online Designer” tab, click on your consent form under the heading “Instrument name.”
2. Scroll down to the last page of your electronic consent form.
3. Click the “Add Field” blue button at the bottom of the page.
4. Select “Text Box...” from the dropdown menu.
5. Under the Field Label type “First name.” Under “Variable Name” type “firstname”.
6. Complete the “Required?” and “Identifier?” fields as ‘Yes’. Click “Save.”

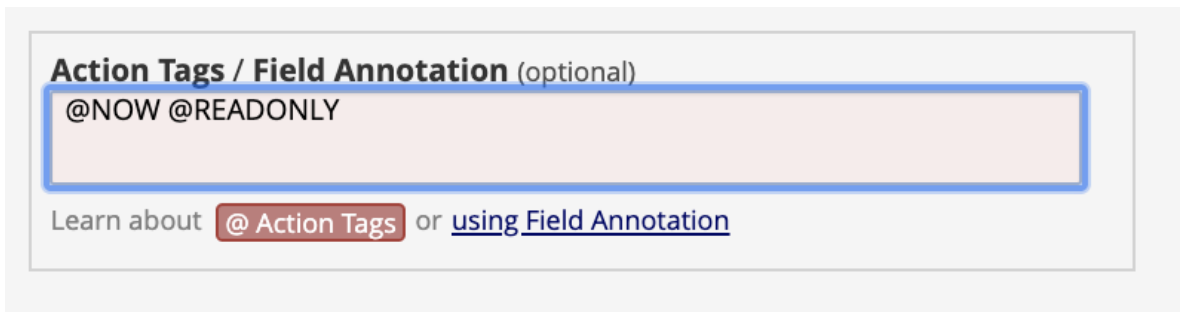


7. Continue and add Last name field following steps above.
8. Adding the Stylus Signature field is optional but is recommended as it offers an experience similar to providing a physical signature. In Field type, choose “Signature...” from the dropdown menu and proceed accordingly.
 - 8.1 If you are adding the signature field, complete the “Field Label” as follows: “Signature (if possible sign with finger, stylus or mouse).” Choose “No” for the “Required” box and choose “Yes” for the “Identifier” box.

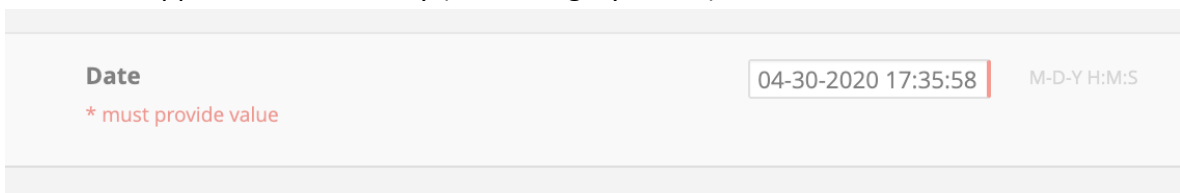


9. Now to add a date field, choose “Add field” blue button. Under “Field Type”, choose “Text Box.” Complete “Field Label” and “Variable Name.” Under “Validation?” choose a date option from the dropdown menu. We recommend that you use the “Datetime w/ seconds” option (e.g “Datetime w/ seconds (M-D-Y H:M:S)).

9.1 In addition, under “Action Tags/Field Annotation,” add the following Action Tags: @NOW and @READONLY. This causes the date field to be automatically generated and un-editable, reducing the potential for error

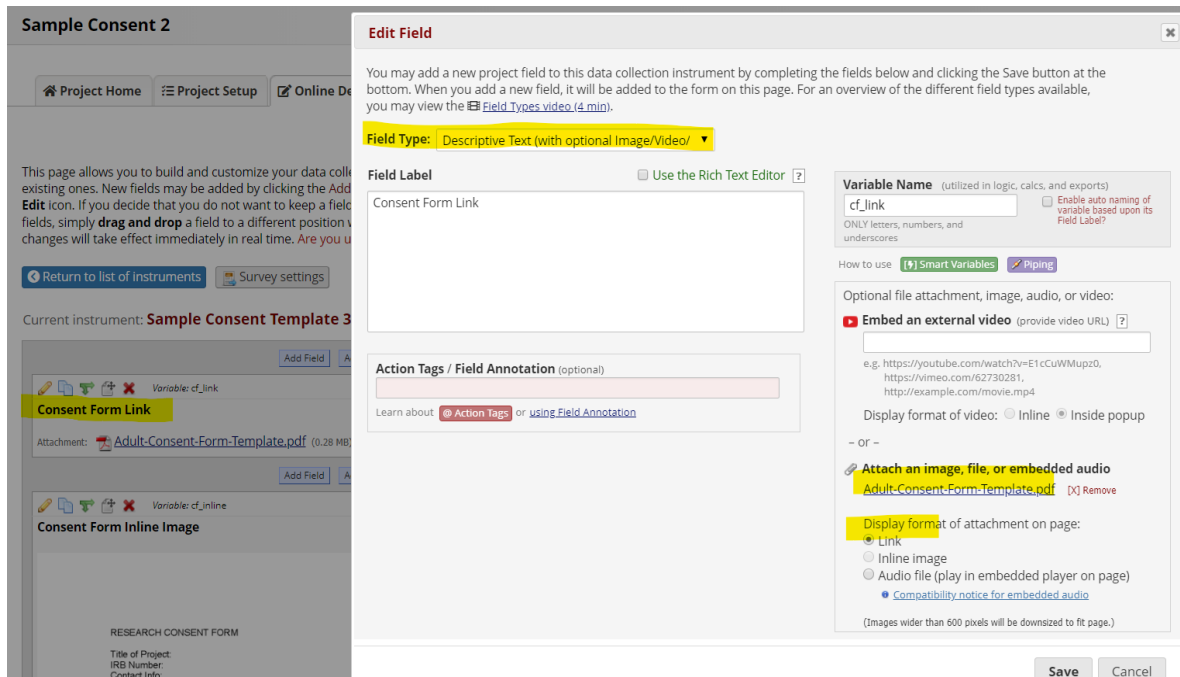


How it appears on the survey (it will be greyed out):

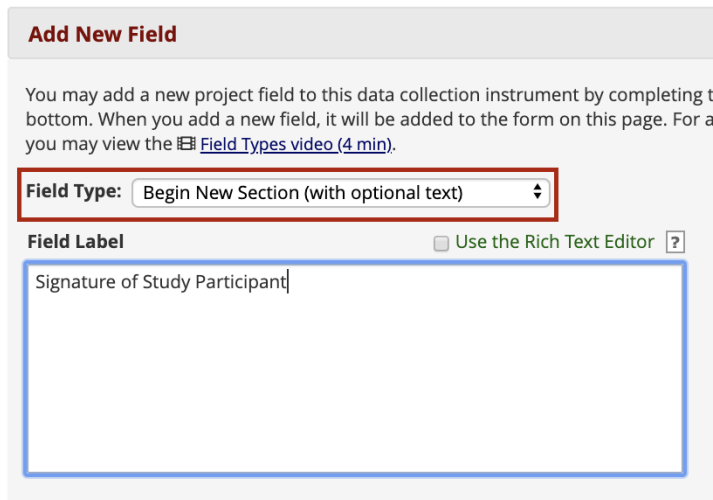


9.2 Complete additional fields as necessary.

10. You may also elect to set up a file download field, to allow the participant to download a hardcopy of the blank consent form.



11. To break up the sections, add a heading prior to the participant’s signature section. Click the “Add field” button and under “Field Type” choose “Begin New Section (with optional text)”



How it will look:

Signature of Study Participant	
First Name * must provide value	<input type="text"/>
Last Name * must provide value	<input type="text"/>

IV. Enabling survey feature and updating survey settings

1. Find your e-consent instrument 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			Choose action	

2. Under “Basic Survey Options” fill in “Survey Title” and “Survey Instructions.” This information will appear at the top of your electronic consent survey page. Adapt the instructions to suit your consent process; for instance: “Please review this electronic consent form with the study coordinator.”

Project Home | Project Setup | Online Designer | **Modify survey settings**

You may edit the survey's basic information by modifying the fields below and clicking the Save Changes button.

Modify survey settings for data collection instrument "Sample Consent Template 1" | Save Changes | Cancel

Survey Status: Survey Active
If offline, respondents will not be able take the survey.

Basic Survey Options:

Survey Title
Sample Consent Template 1
Title to be displayed to participants at the top of the survey page

Survey Instructions
(Displayed at top of survey after title)

Paragraph | B | I | | | | | | | |

Please complete the form below.
Thank you!

[How to use Piping here](#)

Survey Design Options: Copy design to other surveys

3. 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. Then click the “Save Changes” blue button on the bottom of this webpage.

3.1 For example:

“Thank you for your participation in the research study:

[Name of Study]

If you have any questions, please contact:


[Study Contact Name]:

[insert phone number xxx-xxx-xxxx and/or email xxxx@bu.edu or xxxx@bmc.org]

Please download the copy of your signed consent form below. *(It might be helpful to prompt the participant to download a copy of the informed consent here since the option to allow participants to download a pdf of their completed survey is turned on in the survey settings (see 6.5.2 below) and so the button to download will appear below this survey completion text)*

4. For further changes to the survey settings, scroll to the section “Survey Customization”. Below are a description and examples of what the options do:


4.1 Changing numbering of fields – this is to help you with the next step when creating the fields in the consent instrument. Under “question numbering,” you can either choose the options 1) “Auto-numbered” or 2) “Custom numbered.” Choose the custom-numbered option to remove numberings next to the fields added to the consent. See the examples below:


Signature of Study Participant	
1) First Name <small>* must provide value</small>	<input type="text"/>
2) Last Name <small>* must provide value</small>	<input type="text"/>
3) Signature (if possible sign with finger, stylus or mouse)	Add signature
4) Date <small>* must provide value</small>	<input type="text"/>  <input type="button" value="Now"/> M-D-Y H:M:S

Vs.

Signature of Study Participant	
First Name <small>* must provide value</small>	<input type="text"/>
Last Name <small>* must provide value</small>	<input type="text"/>
Signature (if possible sign with finger, stylus or mouse)	Add signature
Date <small>* must provide value</small>	<input type="text"/> <input type="button" value="Now"/> M-D-Y H:M:S

4.2 To allow the participant to download their completed consent, change the option to “Yes” for the question “Allow participants to download a PDF of their responses at end of survey?” When the participant completes and submits the consent, a button will show up for them to download a copy of their completed consent form.

 **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.

Yes 

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.

Thank you for your participation in this research study!

Download your survey response (PDF):

5. For e-consent instruments the e-Consent Framework must be turned on.

5.1 To the right of the “PDF Auto-archiver” choose the third option: “Auto-Archiver + e-Consent Framework.”

5.1.1 Note that the project’s File Repository, where the archived PDF copy of the signed e-Consent, is located on the left menu under “Applications.” Then click on the tab “PDF Survey Archive.”

5.2 IMPORTANT: The “Allow e-Consent responses to be edited by users?” should NOT be checked off.

5.3 Next to “e-Consent version” provide a version number. This is to help you keep track of the consent version utilized to consent the participants.

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: ▼

Send confirmation email (optional)?
(Email the respondent when they complete the survey)

No ▼

5.4 Enable signature erasing feature: under the “Force signature field(s) to be erased...,” click on the “+Select another signature field” and then from the “select a field” dropdown menu, select the fields “First Name” and “Last Name.” This feature will erase those two data entry fields if the participant returns to the consent page after viewing the confirmation page. That way, in case the participant makes any changes when they return to the consent page, the most up-to-date form will be signed.

5.4.1 NOTE: Only required fields will appear as options in the drop-down menu. Therefore, since the “Signature” field (signature with finger/mouse/stylus) is an optional field, it will not be listed in the drop-down menu.

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: first_name "First Name" ⬆

Signature field #2: last_name "Last Name" ⬆

+ Select another signature field

V. Modifying Consent instrument for in-person consent vs. contactless (remote) consent

If you are conducting the consent discussion with the participant in-person, where you will each be in the **same physical space**, proceed as before, starting at section D.III, to create the section for "Signature of Study Personnel" within the same instrument (example images below). If you are conducting a **contactless or remote consent discussion**, where the participant and the study staff are **not in the same physical space**, proceed to step 1 of this section.

The screenshot shows a configuration interface for a survey section titled "Signature of Study Personnel". At the top, there are two buttons: "Add Field" and "Add Matrix of Fields". Below the title, there are two more "Add Field" and "Add Matrix of Fields" buttons. The main content area contains four field configurations, each with a set of icons (edit, copy, paste, delete) and a variable name:

- First Name**: Variable: rx_first_name. Includes a text input field and a red asterisk with the text "* must provide value".
- Last Name**: Variable: rx_last_name. Includes a text input field and a red asterisk with the text "* must provide value".
- Signature (if possible sign with finger, stylus or mouse)**: Variable: rx_signature. Includes a green signature icon and a link that says "Add signature".
- Date**: Variable: rx_date. Includes a date input field, a "Now" button, and the format "M-D-Y H:M:S".

Each field configuration has its own "Add Field" and "Add Matrix of Fields" buttons at the bottom.

Signature of Study Participant	
First Name * must provide value	<input type="text"/>
Last Name * must provide value	<input type="text"/>
Signature (if possible sign with finger, stylus or mouse)	Add signature
Date * must provide value	<input type="text"/> <input type="button" value="Now"/> Y-M-D H:M:S
Signature of Study Personnel	
First Name * must provide value	<input type="text"/>
Last Name * must provide value	<input type="text"/>
Signature (if possible sign with finger, stylus or mouse)	Add signature
Date * must provide value	<input type="text"/> <input type="button" value="Now"/> M-D-Y H:M:S

For contactless consenting, it is necessary to create two separate e-Consent instruments, one for the participant to sign and one for the study personnel to sign (these two consent instruments will both be tied to the same record ID). This can be easily done by just copying the first instrument and modifying it for the study personnel.

1. Click on “Choose Action” button corresponding to the e-Consent instrument you just created and click the option “Copy.”

Instrument name	Fields	View PDF	Enabled as survey	Instrument actions	Survey-relate
Participant Consent Form	8			Choose action ▾ Rename Copy Delete Download instrument ZIP	Survey set

2. A window will pop-up. Update the fields accordingly and click the “Copy instrument” button.

Copy instrument ✕

To copy the instrument "Participant Consent Form", enter the name of the new instrument below. Also, since all variable/field names must be unique and cannot duplicate, this instrument's variables must be renamed when copied to the new instrument. Please enter a suffix that will be appended to all new variable names.

New instrument name:

Suffix appended to variable names:

Instrument name
Participant Consent Form
Study Personnel Consent Form

- Click on the newly created "Study Personnel Consent Form" instrument to edit the fields accordingly. For example, the section title should be updated from "Signature of Study Participant" to "Signature of Study Personnel."
- If the study team chooses, they can remove the consent form pages and the copy of the pdf link of the consent for the Study Personnel Consent Form instrument. However, it is recommended that the following sentence, as it is stated in your approved consent form, be added to the "Signature of Study Personnel heading: "I have personally explained the research to the above-named subject (who has read this consent form) and answered all questions. I believe that the subject understands what is involved in the study and freely agrees to participate." Check the language in your approved consent form and edit this section accordingly.

Signature of Study Personnel

I have personally explained the research to the above-named subject and answered all questions. I believe that the subject understands what is involved in the study and freely agrees to participate.

- To ensure that the study personnel are signing the consent form for the correct participant, you can use the REDCap "piping" feature so that the participant's information from the "Study Personnel Consent Form" instrument is auto-added. Piping pulls data from one instrument to another by referencing the variable name of the data. Please note that the participant consent form must be completed prior to the study personnel opening the consent form for the piping to work.
- Prior to the "Signature of Study Personnel" section heading, click "Add Field" and under "Field Type" choose "Descriptive Text."
- For the "Field Label" refer to the variable name from the "Participant Consent Form" instrument to pipe in the participant's First Name, Last Name, and Date of signature.

7.1 Name the variable name accordingly. For example, “pf_info.” Then click “Save.”

8. After the participant has completed the consent, study personnel should open their respective consent link. This is how it will appear to study personnel:

9. It is recommended that you add a field for “comments” or “notes,” where you can explain any situations that may come up during the consent process.

9.1 Click “Add field.” Next to “Field Type” scroll through the options and select “Notes Box (Paragraph Text).” Give an appropriate variable name and click “Save.”

10. As part of consent documentation, it is recommended that you add a field where the study staff will document that they have confirmed the participant’s identity.

10.1 The below image is just an example.

I confirmed the participant's identify by:
 * must provide value

Signature of Study Personnel

I have personally explained the research to the above-named subject
 the subject understands what is involved in the study and freely agrees to participate

verbally asking for their first and last name and DOB.
 checking their name and DOB on their driver's license
 checking their name and DOB on their government issued passport

10.2 **REMEMBER** to update the survey settings for the “Study Personnel Consent Form” setting as well!

10.2.1 **MOST IMPORTANTLY**, you need to make sure to update the “First Name Field” and “Last Name Field” on the e-consent framework setting so that they refer to the variable names from the “Study Personnel Consent Form” instrument.

10.2.2 On instructions for setting up Survey Settings, please go to section D.IV.

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:

11. Since the e-consent framework is turned on, the study personnel consent form must be completed as a survey for the file to be appropriately archived once completed.

11.1 Add a “Descriptive Text” field such as the one shown below as a reminder to the study staff who is completing the form to complete it as a survey.



11.2 Go to section D.VI for instructions on how to complete the study personnel form as a survey.

12. The overall survey for the Study Personnel Consent Form will look like this:

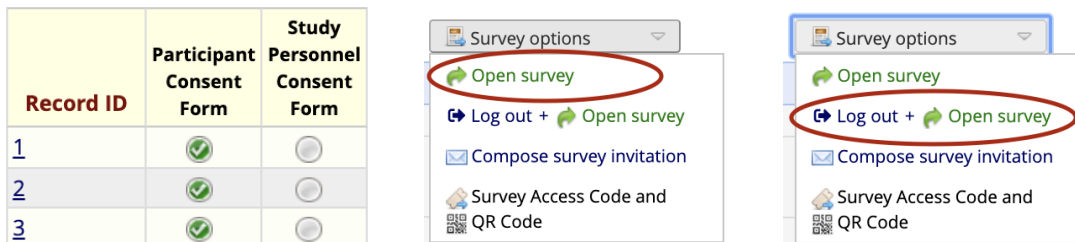
The image shows a screenshot of a web-based form titled 'Study Personnel Consent Form v1.0'. The form is organized into several sections:

- Participant Information:** Fields for 'Participant Name:' and 'Date of signature:'.
- Confirmation:** A section with a green background asking 'I confirmed the participant's identify by:' with a dropdown menu and a checkbox labeled 'click the checkbox to confirm'. A red asterisk indicates '* must provide value'.
- Signature of Study Personnel:** A blue header section with the text: 'I have personally explained the research to the above-named subject and answered all questions. I believe that the subject understands what is involved in the study and freely agrees to participate.'
- First Name:** A text input field with a red asterisk '* must provide value' and a label 'Printed name of person conducting consent discussion'.
- Last Name:** A text input field with a red asterisk '* must provide value' and a label 'Printed name of person conducting consent discussion'.
- Signature:** A section with the text 'Signature (if possible sign with finger, stylus or mouse)' and a green link 'Add signature'. Below it is a label 'Signature of person conducting consent discussion'.
- Date:** A date and time input field showing '10-22-2021 11:51:34' and a label 'M-D-Y:H:M:S'. A red asterisk indicates '* must provide value'.
- Comments:** A large text area for comments with an 'Expand' link at the bottom right.
- Navigation:** A 'Next Page >>' button at the bottom center.

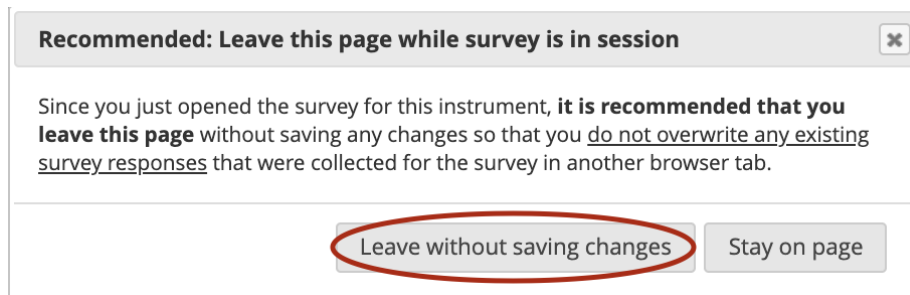
VI. Completing the Study Personnel Consent Form – Reminder for Contactless Consent

Since the e-consent framework is turned on for the Study Personnel Consent Form, it must be completed as a survey (the Participant Consent form will always be completed as a survey due to the nature of how it gets delivered to the participant).

1. To access the consent link for study personnel, go to the participant's record and click on the "Study Personnel Consent Form" instrument.
2. At the top of the form, find the "Survey Option" drop down and click on the "Open survey" option or the "Log out + Open survey" option to access the consent directly.



3. If you chose "Open survey" option, once you complete the e-consent survey and click "Close survey," it will lead you back to the original data entry form of the "Study Personnel Consent Form" and a pop-up will show up (below). You **MUST click "Leave without saving changes."** Clicking this option will save the changes made in the consent via the survey link. If you click "Stay on page" instead, the responses entered in the consent via the link will not be saved to the record.

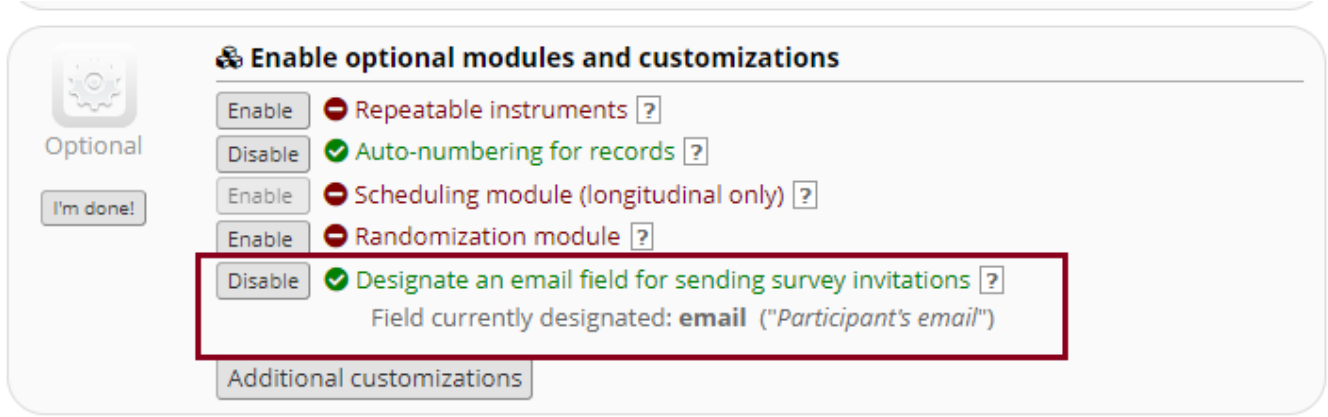


4. If you chose, "Log out + Open survey," **this will log you out of REDCap and direct you to the consent form to complete as a survey.** This is the safer method since it guarantees that changes made to the consent are saved and avoids the risk of not saving the changes unlike the other option noted previously (step 3).

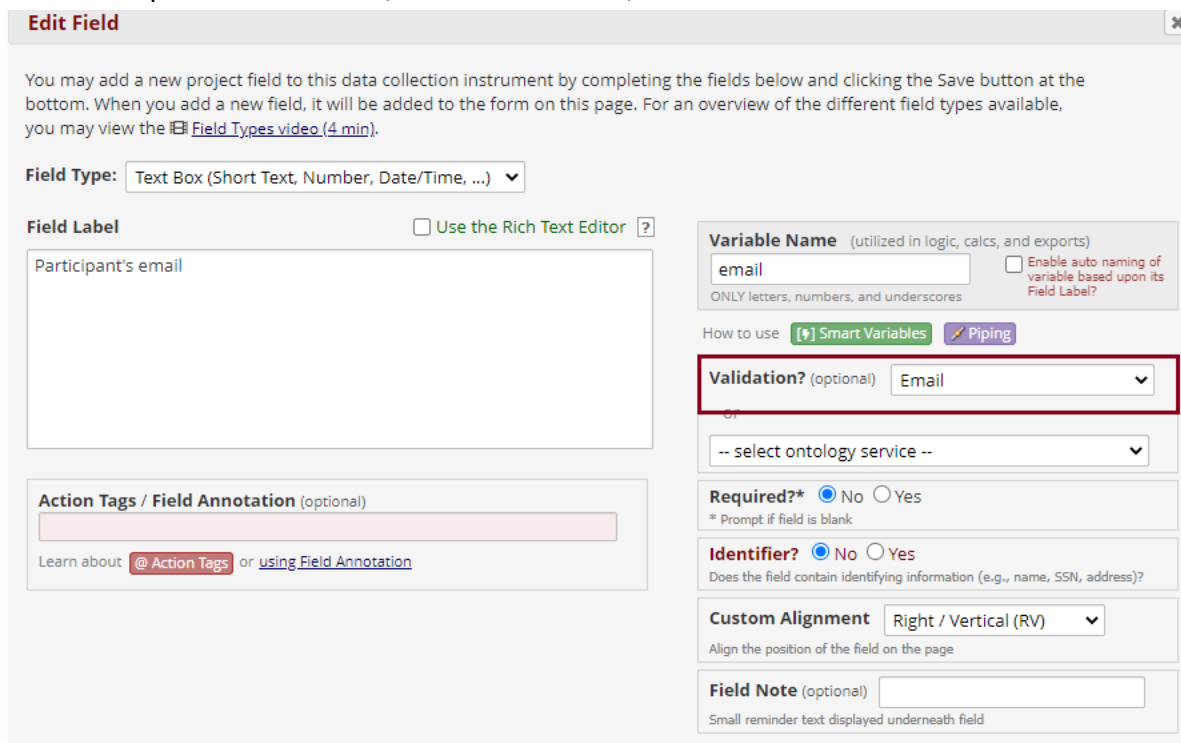
VII. Creating the Participant Information Instrument (Creating password for consent link and Using Survey Log-in feature)

To ensure that the e-consent link has been sent to the correct participant, a password/code to access the link must be sent via a separate email or be given to the participant via phone at the beginning of the informed consent process. This method utilizes REDCap's survey log-in feature which allows the study team to email the e-consent link to the participant from REDCap and also, create their own unique link code. There is also an option to automate the process of emailing the consent survey to the participant (please see section F to learn about this option).

1. Under “Enable Optional modules and customizations” enable “Designate an email field for sending survey invitations.”



2. Go to “Online Designer” and click “create a new record.” Name this instrument something like “Participant Information.” This is where you will enter the participant’s email and code.
3. Open the newly created instrument.
4. Click add field and add the two fields, “Participant’s email” and “e-Consent Code.”
5. For “Participant’s email” field, under “validation,” select “email.”



6. The completed instrument should look like this:

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.

Add Field Add Matrix of Fields

Variable: email

Participant's email

Add Field Add Matrix of Fields

Variable: code

Survey Code

Add Field Add Matrix of Fields

7. In “Online Designer” under “Survey options,” select “Survey Login.”

7.1 The changes that must be made are marked in red in the picture and listed below.

7.1.1 Enable the Survey Login.

7.1.2 For “Login field #1,” select “e-Consent Code” field.

7.1.3 For “Custom error message,” what is provided in the image below is just an example. Customize the message accordingly.

7.1.3.1 For “Apply the survey login to all surveys in project,” select “Only selected surveys.”

🔑 **Survey Login** ✕

You may enable a Survey Login page on one or more surveys that will force your survey respondents to authenticate (log in) on your surveys before they are allowed to view and complete the survey. [Tell me more](#)

Below, select the fields that you wish to serve as the login fields for the respondent to enter, as well as several other settings that control how the survey login is applied to the surveys in your project. NOTE: Once a respondent has logged in to a survey, they will not be prompted to enter their login credentials again if they return to that survey or begin another survey using the survey login within the following 30 minutes.

🔑 Enable Survey Login?	Enabled ▾
Fields to display on the survey login form	
Login field #1 <small>➤ Add another login field</small>	code "e-Consent Code" ▾
Customizations for survey login	
Minimum number of fields above that are required for login	1 ▾
Apply the survey login to all surveys in project?	Only selected surveys (set on Survey Settings) ▾
Custom error message: Provide a custom error message that will be displayed on the survey login form for when the user experiences issues, such as not being able to log in successfully, so that they may contact you for help. <small>EXAMPLE: "If you have any trouble logging in to the survey, please contact survey_admin@myinstitution.edu for help."</small>	<div style="border: 1px solid #ccc; padding: 5px;"> If you have trouble logging in to the survey, please contact Jung at jung@bu.edu </div> <small>HTML may be used in order to add links or to add style to text.</small>
Security settings for survey login (optional)	
Number of failed login attempts before respondent is locked out for a specified amount of time, which is set below.	0 <input type="text"/> 0 = Disabled
Amount of time respondent will be locked out after having failed login attempts exceeding the limit set above.	0 <input type="text"/> Minutes, 0 = Disabled

8. Now that survey login settings are all set, to enable the feature, go to Survey settings and go to “Enforce ‘Survey Login?’” field and select “Yes.”

🔑 **Enforce 'Survey Login'?**
(All respondents will be required to enter login credentials before beginning the survey and also any time they return to the survey again.)

▾

If set to 'Yes', this survey will employ the Survey Login feature according to its settings defined in the Online Designer.

VIII. Setting up the Multi Signature Consent External Module

Multi Signature Consent module allows you to define one or more instruments to merge into one PDF file. When each defined instrument is complete, a combined PDF with signatures (and other fields) from those instruments is generated, saved to a file upload field in the project, and also to the file repository for the project. You can couple this with an Alert and Notification to then send a copy of the combined PDF to a participant.

All modules need to be installed and enabled by a BUMC REDCap administrator. Please navigate to the External Modules, under the left Applications menu, and submit a request to have the Multi Signature Consent Module enabled or complete this form <https://redcap.bumc.bu.edu/surveys/?s=F8W4LLXJRP>.

Please contact Tasha Coughlin, tawatson@bu.edu, with your project ID (pid may be found in your project URL) if you have any issues regarding this step.

If you are utilizing the e-consent project template, we recommend that after enabling the external module in your project, set up the module configuration using the reference below. This will help you get started and understand how the module works.

If you are updating your e-consent project with this new module, go to step 1 of this section so that you have the additional items required to follow the module configuration example.

Configure Module: Multi Signature Consent ×

Project: e-Consent for Non-Exempt Research

Settings	Values
	1. Instruments to Merge: + -
1. Form: <small>* must provide value</small>	participant_consent_form_v10 ▼
	2. Instruments to Merge: + -
2. Form: <small>* must provide value</small>	study_personnel_consent_form_v10 ▼
File Field This is where the PDF will be saved in the record and it must be a file-upload field: <small>* must provide value</small>	signed_pdf - Complete and Signed ... ▼
Update Logic When this logic is true and one of the above forms is saved, then create the PDF. This logic should not be true until all forms are complete: <small>* must provide value</small>	[study_personnel_consent_form_v10_complete] = 2 and [participant_consent_form_v10_complete] = 2
Custom Header This header will appear in the upper-right corner of the PDF:	Multi-Signature Consent
Custom Footer This footer will appear on the bottom center of the PDF:	
Keep Page Breaks Normally page breaks between forms are removed. Check here to keep each form on a separate page in the PDF:	<input type="checkbox"/>

Keep Record ID Field Row
The record id is always in the header, but if you check this it will also be part of the PDF if on the first instrument:

Save in File Repository
Check to save a permanent copy in the local file repository:

Save to External Storage
Check to save a permanent copy in the external storage (the same location that is configured for the econsent module):

Save As This Survey In File Repository
If you check the previous option, set which survey you want this to appear as in the File Repository. If you are using the eConsent Framework on one of the surveys in this config, then be sure to select a different survey as you can only have one entry per record, per survey id in the File Repository. Will default to first form otherwise:

signed_consent_copy ▾

Enable Debug Logging
(optional) Requires installation and configuration of emLogger:

1. Create a new instrument and enable it as a survey. In the e-consent project template, we called it “Signed Consent Copy.”

Instrument name	Fields	View PDF	Enabled as survey	Instrument actions	Survey-related options
Participant Information	3		Enable	Choose action ▾	
Version Tracking	2		Enable	Choose action ▾	
Participant Consent Form v1.0	14			Choose action ▾	Survey settings Automated Invitations
Study Personnel Consent Form v1.0	8			Choose action ▾	Survey settings + Automated Invitations
Consent Form (participant and study personnel)	17			Choose action ▾	Survey settings + Automated Invitations
Participant Consent Form v2.0	13			Choose action ▾	Survey settings Automated Invitations
Signed Consent Copy	2			Choose action ▾	Survey settings + Automated Invitations

2. In that instrument, create a “File Upload” field. This is where the merged PDF will be saved.

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: File Upload (for users to upload files) ▾

Field Label: ---- Select a Type of Field ----

Complete all: Text Box (Short Text, Number, Date/Time, ...)

Action Tags: @ Action Tags or using Field Annotation

Use the Rich Text Editor ?

Variable Name (utilized in logic, calcs, and exports)

Enable auto naming of variable based upon its Field Label?

ONLY letters, numbers, and underscores

How to use: Smart Variables Piping Field Embedding

Required?* No Yes
* Prompt if field is blank

Identifier? No Yes
Does the field contain identifying information (e.g., name, SSN, address)?

Custom Alignment Right / Vertical (RV) ▾
Align the position of the field on the page

Field Note (optional)
Small reminder text displayed underneath field

Save
Cancel

Variable: signed_pdf

Complete and Signed Consent Form
Upload file

Testing out your e-Consent

I. How to test out the e-Consent link during Development Mode

Please note that if you've already enabled the Survey Login feature (section D.VII) and created the "Participant Information" instrument, you will not be able to utilize the public survey link since the first instrument will no longer be a survey. Once the Survey Login feature is turned on, you can still test out the consent links by creating fake records and using your own email.

1. To view the consent form from the Subject view, select "Survey Distribution Tools" from the left menu under "Data Collection." Under "Link Actions" click on "Open public survey" (the first button).

Utilizing Automated Survey Invitation (ASI) to send out e-Consent survey

I. Creating Version Tracking instrument (to keep track of consent versions for Automated Survey Invitation)

If you are utilizing Automated Survey Invitation (ASI), you need to set up a process to keep track of the informed consent versions. This is recommended in general even if you are not utilizing ASI in order to keep track of consent versions used.

To keep track of informed consent versions, create a Version Tracking instrument. The fields in this instrument will be utilized to set up the ASI (instructions in step 66).

1. Add a Text Box field to enter the informed consent version number.

1.1 It is recommended that you add a validation option for this field because if there is a blank space next to the value entered, this space will be treated as a character. So the field value "1.0" is different from "1.0_" (the underscore represents the blank space).

1.1.1 For the validation option, you can select "Number (1 decimal place)." So this field will have to be in the format "#.#"

1.1.1.1 If this validation is not met, the user will get an error message.

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: Text Box (Short Text, Number, Date/Time, ...) ▼

Field Label Use the Rich Text Editor ?

Version number

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

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

Validation? (optional) Number (1 decimal place) ▼

Minimum:

Maximum:

- or -

▼

Required?* No Yes
* Prompt if field is blank

Identifier? No Yes
Does the field contain identifying information (e.g., name, SSN, address)?

Custom Alignment Right / Vertical (RV) ▼
Align the position of the field on the page

Field Note (optional)
Small reminder text displayed underneath field

2. Add a “Yes/No” field where the study staff will confirm whether or not to email the consent form.
3. Your instrument should look like this:

[Return to list of instruments](#)

Current instrument: **Version Tracking**

Variable: version
✎ 📄 ↻ 🗑️ ✖

Version number

#.#

Variable: email_consent
✎ 📄 ↻ 🗑️ ✖

Email consent form Yes No

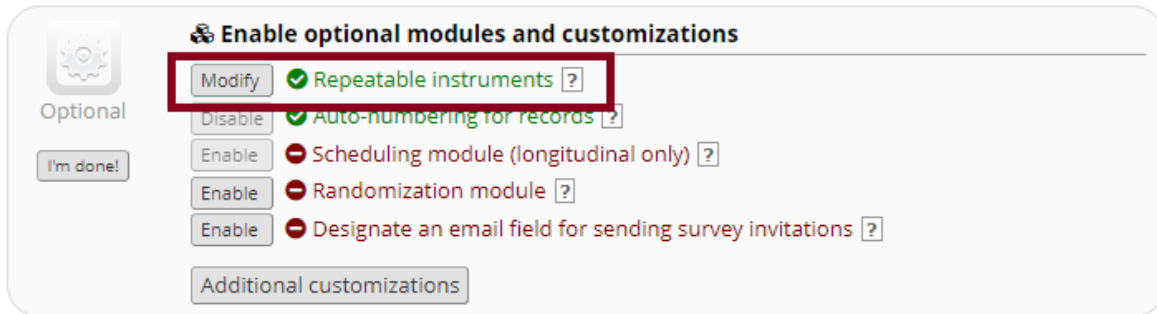
reset

4. Proceed to the next section to enable this instrument as a repeatable instrument. This is a necessary step!

II. Enabling repeatable instruments for Version Tracking instrument

This is a useful module when you make changes to your approved consent form that necessitate re-consenting subjects who are already enrolled. Enabling repeatable instruments allows one to create another instance of Version Tracking instrument for that participant rather than having to create a new record ID to document the re-consent. So, under a single record ID, you can have multiple signed consent forms.

1. Go to the “Project Setup” page and under “Enable optional modules and customizations” click the “enable” button next to “Repeatable instruments.”




2. This will open up a window where you can select which instrument you want to repeat and also add a custom label for that repeating instrument. You can customize the label using the variable names of the fields.

Repeatable instruments ✕

An excellent way to collect repeating data in REDCap is to use repeatable instruments and/or repeatable events. This is sometimes called one-to-many data collection. Some examples may include but are not limited to the following: data from multiple visits or observations, concomitant medications, adverse events, or repetitive surveys (daily, weekly, etc.).

Below you can specify a data collection instrument to be infinitely repeatable, which means that an instrument can be repeated over and over again (a different number of times for each record) even without enabling REDCap's longitudinal module. Once an instrument is set to repeat, you will see options on the Record Home Page to add another instance of the instrument for the currently selected record. All instances of a repeating instrument will then be displayed as a table near the bottom of the Record Home Page, thus allowing viewing of the instances and easy navigation within them.

Repeat this instrument?	Instrument name	Custom label for repeating instruments (optional)  Example: [visit_date], [weight] kg
<input type="checkbox"/>	Participant Information	<input type="text"/>
<input checked="" type="checkbox"/>	Version Tracking	<input type="text" value="[version]"/>
<input type="checkbox"/>	Participant Consent Form v1.0	<input type="text"/>
<input type="checkbox"/>	Study Personnel Consent Form v1.0	<input type="text"/>
<input type="checkbox"/>	Consent Form (participant and study personnel)	<input type="text"/>
<input type="checkbox"/>	Participant Consent Form v2.0	<input type="text"/>

Save Cancel

- To create a new instance, select the record for which you want to create the new instance and click on the “+” button or “+ Add new.” Below, you can see that the repeatable instruments are shown with the custom labeling ([version]).

Record ID 12

Data Collection Instrument	Status
Participant Information	
Version Tracking	
Participant Consent Form v1.0 (survey)	
Study Personnel Consent Form v1.0 (survey)	
Consent Form (participant and study personnel) (survey)	
Participant Consent Form v2.0 (survey)	

Repeating Instruments

Version Tracking (2)		
1		1.0
2		2.0
+ Add new		

III. Turning on Automated Survey Invitations (ASI)

This is to set up the ASI feature, which will automatically send the link to the e-consent form depending on specific conditions. **Please follow the specific conditions outlined in step 12.2 carefully!** The conditions that will trigger the ASI have been set so that the variables refer to the latest “instance” of the Version Tracking form (if there’s only one instance of the Version Tracking form, the latest instance is that first instance). When the specific conditions are met, REDCap will automatically send the link to the e-consent form to the participant’s email. The time or when the invitation gets sent can also be customized.

- In Online Designer, under “Survey-related options,” click on the button “Automated invitations.”
- Step 1: For the email subject line and body of the email, customize it for your study accordingly. Click on “Send test email” to see how the email will appear for the participant.
- Step 2: Enter the following conditions (note that this matches the variable names shown in step 11.3):
 - [email_consent][last-instance] = “1” and [version][last-instance]= “#. #”
 - For #.#, enter the corresponding consent version number for that e-consent survey.
- Step 3: Here you can set up when the invitation gets sent. In this example, it is set up as immediate. So, as soon as the “Participant Information” form is complete, REDCap will send out the e-consent invitation. It may take a few minutes for the participant to receive the email.

5. Step 4: Select “Active” to turn on automated invitations.

Define Conditions for Automated Survey Invitations (ASI)

Instructions: In this pop-up you may define your conditions for automated survey invitations that will be sent out for the survey (and event, if a longitudinal project) listed in the Info box below. [Tell me more](#)

Info
Survey title: Participant Consent Form v1.0

STEP 1: Compose message

From: (select any project user to be the 'Sender')

To: **[All participants who meet the conditions defined]**

Subject:

Compose
Preview
Send test email

Please take this survey.

You may open the survey in your web browser by clicking the link below:

If the link above does not work, try copying the link below into your web browser:

NOTE: You may modify or remove any text you wish in the Compose Message text box above. Make sure you include either [survey-link] or [survey-ur] in the text or else the participant will not have a way to take the survey.

You may use HTML formatting in the email message: bold, <u> underline, <i> italics, link, etc.

[How to use Piping in the survey invitation](#)

STEP 2: Conditions

Specify conditions for sending invitations:

When the following survey is completed:

AND

When the following logic becomes true:

(e.g., [age] > 30 and [sex] = "1")

[How do I use special functions?](#)

Test logic with a record:

Ensure logic is still true before sending invitation?

[How to use 'stop logic' to disable an automated invite](#)

STEP 3: When to send invitations AFTER conditions are met

Send immediately

Send on next at time H:M

Send after lapse of time: days hours minutes

Send at exact date/time: M/D/Y H:M

OPTIONAL: Enable reminders

Re-send invitation as a reminder if participant has not responded by a specified time?

IV. Sending out the e-consent invitation email

- Now that the survey-log-in feature and ASI have been enabled, create a new record in order to enter the participant’s email and e-Consent code.
- From the left menu, under “Data Collection” click on “Add/Edit Record” to create a new record.

Data Collection

- Survey Distribution Tools
- Get a public survey link or build a participant list for inviting respondents
- 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

- Next, navigate to the “Choose an existing Record ID” heading and under the “select record” drop down menu, click on the green “+Add new record” button and this will create a new and open up the new record.

Choose an existing Record ID

- Click on the “Participant Information” instrument and enter the participant email and e-Consent code. Select “Complete” for form status and save the form.

Participant Information

Editing existing Record ID 1

Record ID	1
Participant's email	<input type="text" value="jung@bu.edu"/>
e-Consent Code	<input type="text" value="test123"/>
Form Status	
Complete?	<input type="text" value="Complete"/>

Re-sending and troubleshooting survey invitation

I. Re-sending the e-Consent invitation email

1. In case the participant needs to be sent another email of the e-consent link, under “Data Collection,” click on “Survey Distribution Tools.”

Survey Distribution Tools

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). [More details](#)

Participant List belonging to "Participant e-Consent Form"

Displaying 1 - 1 of 1

Email	Record	Participant Identifier	Responded?	Invitation Scheduled?	Invitation Sent?	Link	Survey Access Code and QR Code
jung@bu.edu	1	Disabled	<input type="radio"/>	-	<input checked="" type="checkbox"/>		

2. Under “Compose message,” edit the subject line and body of the email accordingly. Do not delete the [survey-link] and [survey-url] smart variables.
3. Under “Participant List” select the record/email that needs the new invite and click “Send Invitations.”

✉ Send a Survey Invitation to Participants
✕

Info
Survey title: Participant e-Consent Form

When should the emails be sent?
 Immediately
 At specified time: M/D/Y H:M
The time must be for the time zone America/New_York, in which the current time is 09/25/2020 22:51.

Enable reminders
 Re-send invitation as a reminder if participant has not responded by a specified time?

Compose message
 From: jung@bu.edu
(select any project user to be the "Sender")
 To: [All participants selected from Participant List]
 Subject:

Compose
Preview
Send test email

Please take this survey.

You may open the survey in your web browser by clicking the link below:
[survey-link]

If the link above does not work, try copying the link below into your web browser:

NOTE: You may modify or remove any text you wish in the Compose Message text box above. Make sure you include either [survey-link] or [survey-url] in the text or else the participant will not have a way to take the survey.

You may use HTML formatting in the email message: bold, <u> underline, <i> italics, link, etc. [How to use Piping in the survey invitation](#)

- Select a previously sent email to load it in the Compose box -

Participant List Actions: -- check/uncheck participants --
(those who have not responded completely)

<input type="checkbox"/>	Email	(0 selected)	Participant Identifier	Scheduled?	Sent?	Responded?
<input type="checkbox"/>	jung@bu.edu (ID 1)			-		

Send Invitations Cancel

II. Accessing survey (e-consent) link if having issue with survey invitation delay

Sometimes the recipients do not receive the survey invitation email right away even when ASI is set-up to send the email immediately. To get around this issue, the best option is to access their survey link from the Participant List table under Survey Distribution Tools. Please note that if you have the survey login feature turned on, the participant will receive a prompt to enter the survey login code (i.e. e-consent code).

Participant List belonging to "Participant Consent Form v1.0"
 Displaying 1 - 27 of 27

Export list

Email	Record	Participant Identifier	Responded?	Invitation Scheduled?	Invitation Sent?	Link	Survey Access Code and QR Code
jung@bu.edu	26	Disabled		-			

1. On the right hand side menu, click on "Survey Distribution Tools." Make sure that you are looking at the correct participant list. By default it shows the participant list that belongs to the part survey instrument, which for in this example the first survey instrument is "Participant Consent Form v1.0."

Participant List belonging to "Participant Consent Form v1.0"
 Displaying 1 - 27 of 27

Export list

+ Add participants
✉ Compose Survey Invitations

Email	Record	Participant Identifier	Responded?	Invitation Scheduled?	Invitation Sent?	Link	Survey Access Code and QR Code
jung@bu.edu	26	Disabled		-			

2. Find the participant record and under “Link,” right click to copy the link address.
3. This link is specific to this participant’s record and will prompt them to enter their e-consent code.

What to do with updated/newly approved informed consent forms

1. When you have an updated approved informed consent, create a NEW e-consent survey. This can easily be done by copying the original or previous e-consent instrument.
2. Replace the informed consent pdf link and the images of the informed consent form pages.
3. Go to the survey settings and update the settings accordingly. Please refer to section D.IV.

Additional Capabilities

1. For studies with checkbox options such as recontact permission, biospecimen storage, etc.:
13. To break up the checkbox sections, add a heading prior to the participant’s signature section. Click the “Add field” button, and under “Field Type” choose “Begin New Section (with optional text)” and label the section appropriately.
14. To add the Yes/No options, click “Add Field” below the new section and choose “Multiple Choice – radio options.” Enter an appropriate “variable name.”
 - 14.1 Under the “Field Label”, you have the option to repeat the name of the optional section.
 - 14.2 Under “Choices,” type out the choices.
 - 14.3 Make sure to click “Yes” for “Required?”

The screenshot shows the configuration interface for a 'Multiple Choice - Radio Buttons (Single Answer)' field. Key elements include:

- Field Type:** Multiple Choice - Radio Buttons (Single Answer)
- Question Number (optional):** A text input field.
- Field Label:** A text input field containing 'Recontact', with a checkbox for 'Use the Rich Text Editor'.
- Choices (one choice per line):** A text area containing two options: '1, Yes, you may contact me again to let me know about a different research study.' and '0, No, you may <u>not</u> contact me to let me know about a different research study.' A link 'Copy existing choices' is present.
- Variable Name:** A text input field containing 're_contact', with a note 'ONLY letters, numbers, and underscores' and a checkbox for 'Enable auto naming of variable based upon its Field Label?'.
- How to use:** Radio buttons for 'Smart Variables' and 'Piping'.
- Required?*** Radio buttons for 'No' and 'Yes' (selected), with a note '* Prompt if field is blank'.
- Identifier?** Radio buttons for 'No' (selected) and 'Yes', with a note 'Does the field contain identifying information (e.g., name, SSN, address)?'.
- Custom Alignment:** A dropdown menu set to 'Right / Vertical (RV)'.
- Field Note (optional):** A text input field.

The screenshot shows the survey preview interface for the 'Optional sub-study/recontact section:'. Key elements include:

- Section Header:** Optional sub-study/recontact section:
- Buttons:** 'Add Field' and 'Add Matrix of Fields'.
- Field Label:** Recontact, with a red asterisk and note '* must provide value'.
- Choices:** Two radio button options: 'Yes, you may contact me again to let me know about a different research study.' and 'No, you may not contact me to let me know about a different research study.'
- Footer:** A 'reset' button.

15. If you have more than Yes/No options, it is recommended that you use the “Add Matrix of Fields” option instead of the “Add Field” option. The optional section found in the ICF template was used for the example below:

We would like to ask your permission to contact you again in the future. This contact would be after the study has ended. Please initial your choice below:

Yes No You may contact me again to ask for additional information related to this study

Yes No You may contact me again to ask for additional biological samples related to this study

Yes No You may contact me again to let me know about a different research study

Yes No You may contact me again to [list reason – or delete line](#)

- 15.1 Under “Matrix Header Text”, enter the name of the optional section.
- 15.2 Under “Field Label,” type the choices and give each of them an appropriate variable name. Make sure to click the checkbox for “Required?”
- 15.3 Under “Matrix Column Choice,” enter as shown in the image below (1, Yes; 0, No). The answer format should be “Single Answer (Radio Buttons)”.
- 15.4 Under “Matrix group name,” enter an appropriate variable name for this whole section, such as “recontact” or “optional_sec.”

Matrix Header Text (optional)

Optional sub-study/recontact section:

Expand

Matrix Rows Enable auto naming of variable based upon its Field Label?

Each row represents a different field with its own label and variable name.

Field Label	Variable Name <small>ONLY letters, numbers, and underscores</small>	Question Number <small>(optional)</small>	Required?*Field Annotation ?
You may contact me again to ask for additional informatio	add_inform		<input checked="" type="checkbox"/> <input type="text"/>
You may contact me again to ask for additional biological :	bio_sample		<input checked="" type="checkbox"/> <input type="text"/>
You may contact me again to let me know about a differer	diff_study		<input checked="" type="checkbox"/> <input type="text"/>
You may contact me again to list reason - or delete line	other		<input checked="" type="checkbox"/> <input type="text"/>

Add another row

Matrix Column Choices

Choices (one choice per line) [Copy existing choices](#)

1, Yes
0, No

[How do I manually code the choices?](#)

Other Matrix Info

Answer Format:
Single Answer (Radio Buttons) ▾

Ranking: [What is a ranked matrix of fields?](#)
 Allow only 1 choice to be selected per column (radio buttons only)

Matrix group name: ONLY letters, numbers, and underscores
recontact [What is a matrix group name?](#)

Save **Cancel**

How it appears to participants:

Optional sub-study/recontact section:

	Yes	No
You may contact me again to ask for additional information related to this study <small>* must provide value</small>	<input type="radio"/>	<input type="radio"/>
reset		
You may contact me again to ask for additional biological samples related to this study <small>* must provide value</small>	<input type="radio"/>	<input type="radio"/>
reset		
You may contact me again to let me know about a different research study <small>* must provide value</small>	<input type="radio"/>	<input type="radio"/>
reset		
You may contact me again to list reason - or delete line <small>* must provide value</small>	<input type="radio"/>	<input type="radio"/>
reset		

II. Enabling Twilio in REDCap

1. REDCap has the capability to send SMS text messages to survey respondents by using a third-party web service named Twilio. Costs associated with this service are managed from your Twilio

account. For more information about Twilio in REDCap, please visit the request link below. Please note that you need to obtain specific IRB approval to use Twilio.

1.1 Please follow this link to request the Twilio Module in REDCap:

<https://redcap.bumc.bu.edu/surveys/?s=HJPXWCME7H>

1.2 [IRB approval is required to use Twilio](#)

III. Additional External Modules

External Modules are add-on packages of software that can extend REDCap's current functionality, as well as provide customizations and enhancements for REDCap's existing behavior and appearance. Modules will need to be installed and enabled by a BUMC REDCap administrator. To request an External Module in REDCap, please complete this form:

<https://redcap.bumc.bu.edu/surveys/?s=F8W4LLXJRP>

Below are modules that may be useful in your study:

- Multi Signature Consent Module allows you to define one or more instruments to combine into one PDF. Please see section D.VIII for more details. To learn more visit:
https://redcap.bumc.bu.edu/redcap_v11.4.0/ExternalModules/?prefix=multi_signature_consent&page=README.md
- Auto Record Generation Module allows for a new record to be generated in another project (or the same project). Data fields can be transferred to the new record as well. To learn more visit:
https://redcap.bumc.bu.edu/redcap_v11.4.0/ExternalModules/?prefix=vanderbilt_auto_record_generation&page=README.md
- The Multilingual EM allows surveys and data entry forms to be translated into multiple languages. The module and your language choices should be set up first, before building your instruments. To learn more visit:
https://redcap.bumc.bu.edu/redcap_v9.3.0/ExternalModules/?prefix=multilingual&page=README.md

Checking project and moving to production status

1. Please be sure to review the remaining steps prior to finalizing 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>

1.1 Move your project to production status.

1.1.1 Go to the “Project Status” page and scroll to the bottom. Click “Move project to production.”



Not
started

Move your project to production status

Move the project to production status so that real data may be collected. Once in production, you will not be able to edit the project fields in real time anymore. However, you can make edits in Draft Mode, which will be auto-approved or else might need to be approved by a REDCap administrator before taking effect.

Go to [Move project to production](#)

Links to additional resources

- Please visit the [CRRO website](#), for more information on e-Consent. You will find other useful guidance such as:
[Using E-Consent at BMC and BU Medical Campus](#)
- [Guidance on Developing REDCap E-Consent: Minimal risk or Exempt Research Not Requiring a Signature and Exempt Research that Includes HIPAA Authorization](#)

Resources for REDCap:

- [REDCap FAQ](#)
- [REDCap Training Videos](#)
- BU Medical Campus/BMC REDCap email support: rchelp@bu.edu