
*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. **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 have 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 done.)

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).

Creating your REDCap project

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. 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 4.0.
 - 3.1 Complete Project title, Purpose (research), PI info, Project notes, etc.
 - 3.2 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.
 - 3.2.1 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 features have been enabled template. If you are not going to utilize this feature, disable it.
 - 3.2.2 Edit the fields and survey settings accordingly 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
☐	Basic Demography	Contains a single data collection instrument to capture basic demographic information.
☐	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.
☐	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.
☐	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**

Enabling Survey mode for REDCap Project

4. 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.

4.1 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 Exporter](#) [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](#)

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

Design your data collection instruments

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

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

4.3 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.

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
Consent Form Save	15		Choose action ▼ Rename Copy Delete Download instrument ZIP

Creating the consent form instrument

5. Now, build your consent form.

- 5.1 Click on your newly named instrument (see 4.3 above).
- 5.2 Click “Add field” button.

[Return to list of instruments](#)

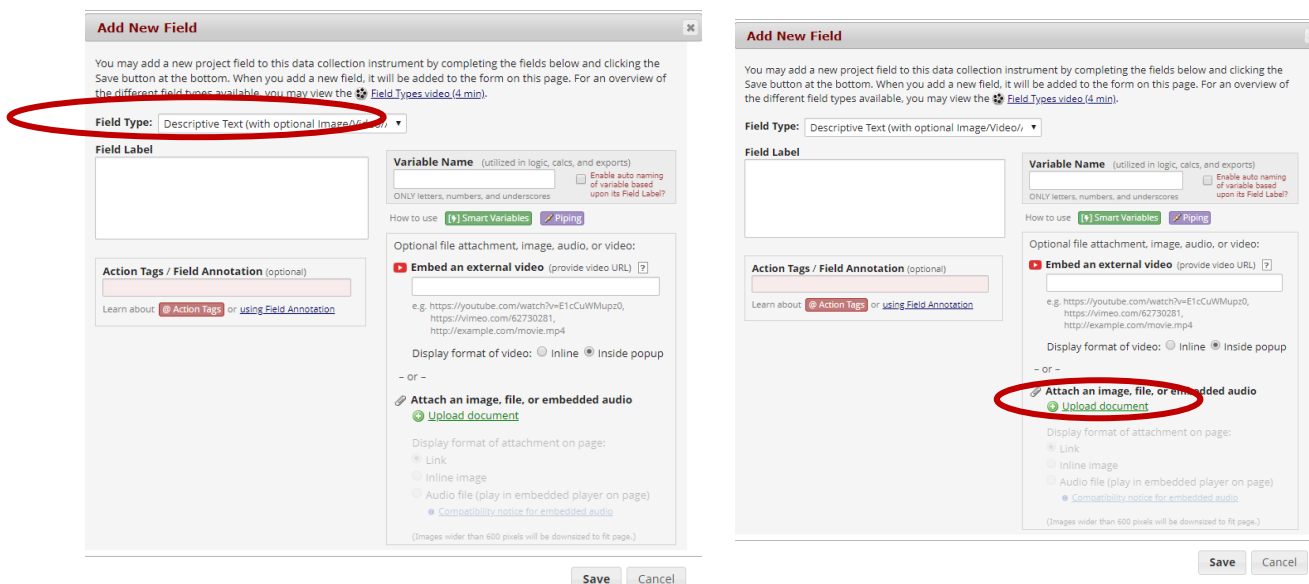
Current instrument: **Consent form 1** [Preview instrument](#)

Variable: record_id

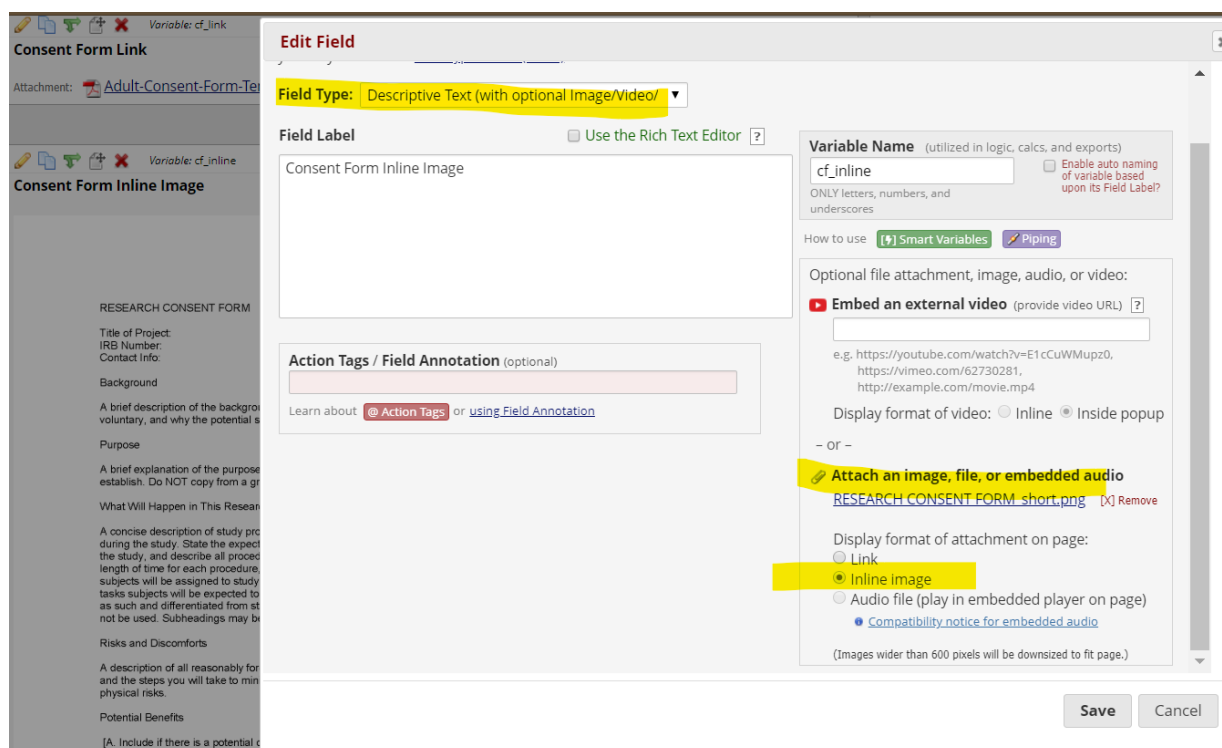
Record ID

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

- 5.3 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.
- 5.4 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). Click save.
- 5.5 At bottom of first consent form page (the jpeg image), click the “Add field” button.



5.6 Follow the instructions in 5.3 and 5.4 above for all the consent form pages.



Adding fields in e-Consent instrument

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

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

- 6.2 Scroll down to the last page of your electronic consent form.
- 6.3 Click the “Add Field” blue button at the bottom of the page.
- 6.4 Select “Text Box...” from the dropdown menu.
- 6.5 Under the Field Label type “First name.” Under “Variable Name” type “firstname”.
- 6.6 Complete the “Required?” and “Identifier?” fields as ‘Yes’. Click “Save.”

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
Last Name

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

How to use Smart Variables Piping

Validation? (optional) ---- None ----
-- OR --
-- select ontology service --

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

- 6.7 Continue and add Last name field following steps 6.3-6.6.
- 6.8 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. Proceed as before with steps 6.5-6.6.
 - 6.8.1 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.

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 [iED 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**

6.9 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. We recommend that you use the “Datetime w/ seconds” option (e.g “Datetime w/ seconds (M-D-Y H:M:S)).

6.9.1 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

Action Tags / Field Annotation (optional)

@NOW @READONLY

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

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

Date

* must provide value

04-30-2020 17:35:58 M-D-Y H:M:S

6.9.2 Complete additional fields as necessary.

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

Sample Consent 2

Project Home | Project Setup | Online Data Collection

This page allows you to build and customize your data collection instrument by adding, editing, and deleting existing ones. New fields may be added by clicking the **Add** icon. If you decide that you do not want to keep a field, simply **drag and drop** a field to a different position. Changes will take effect immediately in real time. Are you sure you want to delete this field?

Return to list of instruments | Survey settings

Current instrument: **Sample Consent Template 3**

Consent Form Link

Attachment: Adult-Consent-Form-Template.pdf (0.28 MB)

Consent Form Inline Image

RESEARCH CONSENT FORM

Title of Project:
IRB Number:
Contact Info:

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 ☐ Use the Rich Text Editor

Consent Form Link

Action Tags / Field Annotation (optional)

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

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

cf_link ☐ Enable auto naming of variable based upon its Field Label?

ONLY letters, numbers, and underscores

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=E1cCuWMupz0>,
<https://vimeo.com/62730281>,
<http://example.com/movie.mp4>

Display format of video: ☐ Inline ☒ Inside popup

– or –

Attach an image, file, or embedded audio

Adult-Consent-Form-Template.pdf [\[X\] 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.)

Save Cancel

- 6.11 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)”

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: Begin New Section (with optional text)

Field Label ☐ Use the Rich Text Editor

Signature of Study Participant

How it will look:

Signature of Study Participant

First Name

* must provide value

Last Name

* must provide value

For studies with checkbox options such as recontact permission, biospecimen storage, etc.:

- 6.12 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.
- 6.13 To add the Yes/No options, click "Add Field" below the new section and choose "Multiple Choice – radio options." Enter an appropriate "variable name."
 - 6.13.1 Under the "Field Label", you have the option to repeat the name of the optional section.
 - 6.13.2 Under "Choices," type out the choices.
 - 6.13.3 Make sure to click "Yes" for "Required?"

The screenshot shows the configuration interface for a 'Multiple Choice - Radio Buttons' field. The 'Field Type' is set to 'Multiple Choice - Radio Buttons (Single Answer)'. The 'Question Number' is optional and displayed only on the survey page. The 'Field Label' is 'Recontact', with an option to 'Use the Rich Text Editor'. The 'Choices' section shows 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.' The 'Variable Name' is 're_contact', with a note to 'ONLY letters, numbers, and underscores'. The 'Required?' field is set to 'Yes'. The 'Identifier?' field is set to 'No'. The 'Custom Alignment' is set to 'Right / Vertical (RV)'. The 'Field Note' is optional and displayed underneath the field.

The screenshot shows the 'Optional sub-study/recontact section' configuration interface. It features a yellow header with a pencil icon and a red 'X' icon. Below the header, there are two buttons: 'Add Field' and 'Add Matrix of Fields'. The 'Variable' is set to 're_contact'. The 'Recontact' section is highlighted in red, with a note '* must provide value'. The 'Choices' section shows two 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.' A 'reset' button is located at the bottom right.

- 6.14 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](#)

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

Matrix Header Text (optional)

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 ONLY letters, numbers, and underscores	Question Number (optional)	Required?*	Field Annotation ?	
You may contact me again to ask for additional informatio	add_inform	☐	☒		✖
You may contact me again to ask for additional biological :	bio_sample	☐	☒		✖
You may contact me again to let me know about a differer	diff_study	☐	☒		✖
You may contact me again to list reason – or delete line	other	☐	☒		✖

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

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?](#)

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 * must provide value	☐	☐
		reset
You may contact me again to ask for additional biological samples related to this study * must provide value	☐	☐
		reset
You may contact me again to let me know about a different research study * must provide value	☐	☐
		reset
You may contact me again to list reason - or delete line * must provide value	☐	☐
		reset

Modifying Consent instrument for in-person consent vs. contactless consent

- 6.15 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 step 6.3 to create the section for “Signature of Study Personnel” within the same instrument (example images below). If you are conducting a **contactless consent discussion**, where the participant and the study staff are **not in the same physical space**, proceed to Step 6.16.

[Add Field](#)
[Add Matrix of Fields](#)

Signature of Study Personnel

[Add Field](#)
[Add Matrix of Fields](#)

First Name
* must provide value

[Add Field](#)
[Add Matrix of Fields](#)

Last Name
* must provide value

[Add Field](#)
[Add Matrix of Fields](#)

Signature (if possible sign with finger, stylus or mouse)

[Add signature](#)

[Add Field](#)
[Add Matrix of Fields](#)

Date
* must provide value

M-D-Y H:M:S

[Add Field](#)
[Add Matrix of Fields](#)

Signature of Study Participant	
First Name * must provide value	
Last Name * must provide value	
Signature (if possible sign with finger, stylus or mouse)	Add signature
Date * must provide value	Now Y-M-D H:M:S

Signature of Study Personnel	
First Name * must provide value	
Last Name * must provide value	
Signature (if possible sign with finger, stylus or mouse)	Add signature
Date * must provide value	Now M-D-Y H:M:S

6.16 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.

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

6.17 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: Study Personnel Consent Form

Suffix appended to variable names: _sp

Copy instrument Close

Instrument name
Participant Consent Form
Study Personnel Consent Form

6.18 Click on the "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."

6.18.1 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.

Add Field Add Matrix of Fields

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.

6.19 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.

6.19.1 Prior to the "Signature of Study Personnel" section heading, click "Add Field" and under "Field Type" choose "Descriptive Text."

- 6.19.2 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.
- 6.19.3 Name the variable name accordingly. For example, “pf_info.” Then click “Save.”

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

- 6.20 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.
- 6.20.1 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.”
- 6.21 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.
- 6.21.1 The below image is just an example. Edit the wording as you see fit.

Variable: confirm

I confirmed the participant's identify by asking for their DOB.

* must provide value

click the checkbox to confirm

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

6.22.1 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.

6.22.2 On instructions for setting up Survey Settings, please go to step 7.

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:

[+ Select another signature field](#)

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

6.23.1 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.

Variable: survey

Remember to open as a survey.

Add Field Add Matrix of Fields

6.23.2 Go to step 14 for instructions on how to complete the study personnel form as a survey.

6.24 The overall survey for the Study Peronnel Consent Form will look like this:

Study Personnel Consent Form v1.0 Resize font: [icon] [icon]

Participant Name:
John Smith

Date of signature:
07-21-2020 11:56:06

I confirmed the participant's identify by asking for their DOB. ☐
* must provide value click the checkbox to confirm

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.

First Name
* must provide value Printed name of person conducting consent discussion

Last Name
* must provide value Printed name of person conducting consent discussion

Signature (if possible sign with finger, stylus or mouse) [Add signature](#)
Signature of person conducting consent discussion

Date M-D-Y H:M:S
* must provide value

Comments:
Expand

[Next Page >>](#)

Enabling survey feature and updating survey settings

7. When you have 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.

The screenshot shows the REDCap Project Setup interface. At the top, there is a navigation bar with buttons: "Return to list of instruments" (blue), "Project Home", "Project Setup" (circled in red), "Online Designer", and "Data Dictionary". Below this, the "Sample Consent 2" section is visible. It includes a sub-navigation bar with "Project Home", "Project Setup", "Online Designer", "Data Dictionary", and "Codebook". The main content area shows the "Data Collection Instruments" section. On the left, there are "Survey options" like "Survey Queue", "Survey Login", "Survey Notifications", and "Upload or download Auto Invitations". On the right, there are "Add new instrument" options: "Create" (new instrument from scratch), "Import" (new instrument from the official REDCap Shared Library), and "Upload" (instrument ZIP file from another project/user or external libraries). The main table lists instruments with columns: Instrument name, Fields, View PDF, Enabled as survey, Instrument actions, and Survey-related options. The table has four rows for "Sample Consent Template 1" through "Sample Consent Template 4". The "Enabled as survey" column for the last row has a green "Enable" button circled in red. The "Survey-related options" column for each row has a "Survey settings" button circled in red.

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	Survey settings + Automated Invitations

- 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. Adapt the instructions to suit your consent process, for instance: “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. Then click the “Save Changes” blue button on the bottom of this webpage.
- 7.4.1 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)*

7.5 For further changes to the survey settings, scroll to the section “Survey Customization”

7.5.1 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 * must provide value	
2) Last Name * must provide value	
3) Signature (if possible sign with finger, stylus or mouse)	 Add signature
4) Date * must provide value	  Now M-D-Y H:M:S

Vs.

Signature of Study Participant	
First Name * must provide value	
Last Name * must provide value	
Signature (if possible sign with finger, stylus or mouse)	 Add signature
Date * must provide value	  Now M-D-Y H:M:S

7.5.2 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?** Yes

Display a button for the participant to download a PDF file of their responses for the survey they just completed.

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.

[Close survey](#)

Thank you for your participation in this research study!

Download your survey response (PDF): [Download](#)

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

7.6.1 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.”

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

7.8 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.

[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*                           

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)

- 7.9 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.
- 7.9.1 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

How to test out the Consent link during Development Mode

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).

8. Please note that if you proceed to step 9 and enable the Survey Login feature and create 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.

8.1 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.

Logged in as **lawson** | Log Out

My Projects or Control Center

REDCap Messenger

Project Home and Design

Project Home · Project Setup

Designer · Dictionary · Codebook

Project status: Development

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

Applications

Alerts & Notifications

Calendar

Data Exports, Reports, and Stats

Data Import Tool

Data Comparison Tool

Logging

Field Comment Log

File Repository

Survey Distribution Tools

Public Survey Link Participant List Survey Invitation Log

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

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

Public Survey URL:

☐ Protect the public survey using the Google reCAPTCHA feature ?

Link Actions

Open public survey

Open public survey + Log out

Send me URL via email

Survey Access Code or QR Code

Link Customizations

Get Short Survey Link

Create Custom Survey Link

Get Embed Code

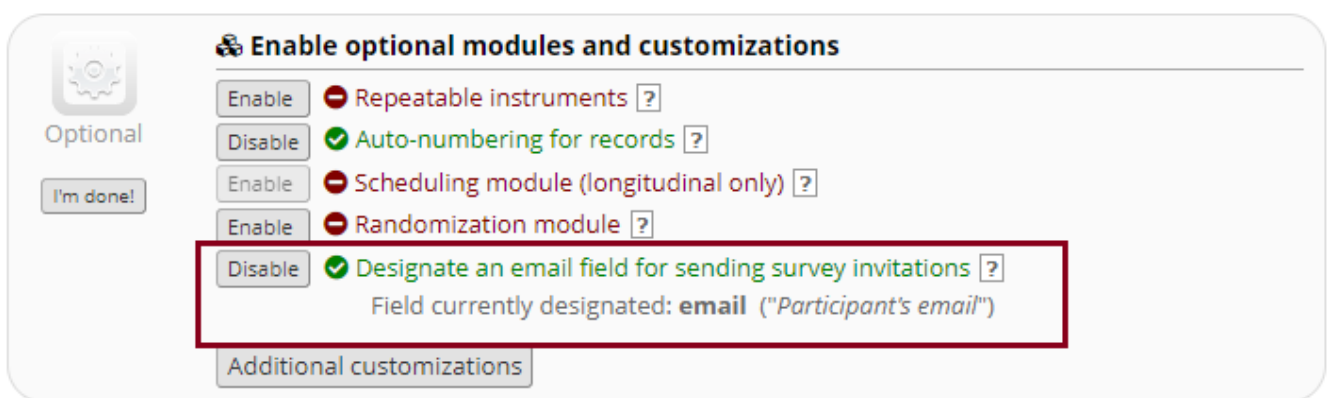
Creating passwords for consent link

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.

Creating the Participant Information Instrument (Using Survey Log-in feature)

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



Enable optional modules and customizations

Optional

I'm done!

Enable ☐ Repeatable instruments ?

Disable ☒ Auto-numbering for records ?

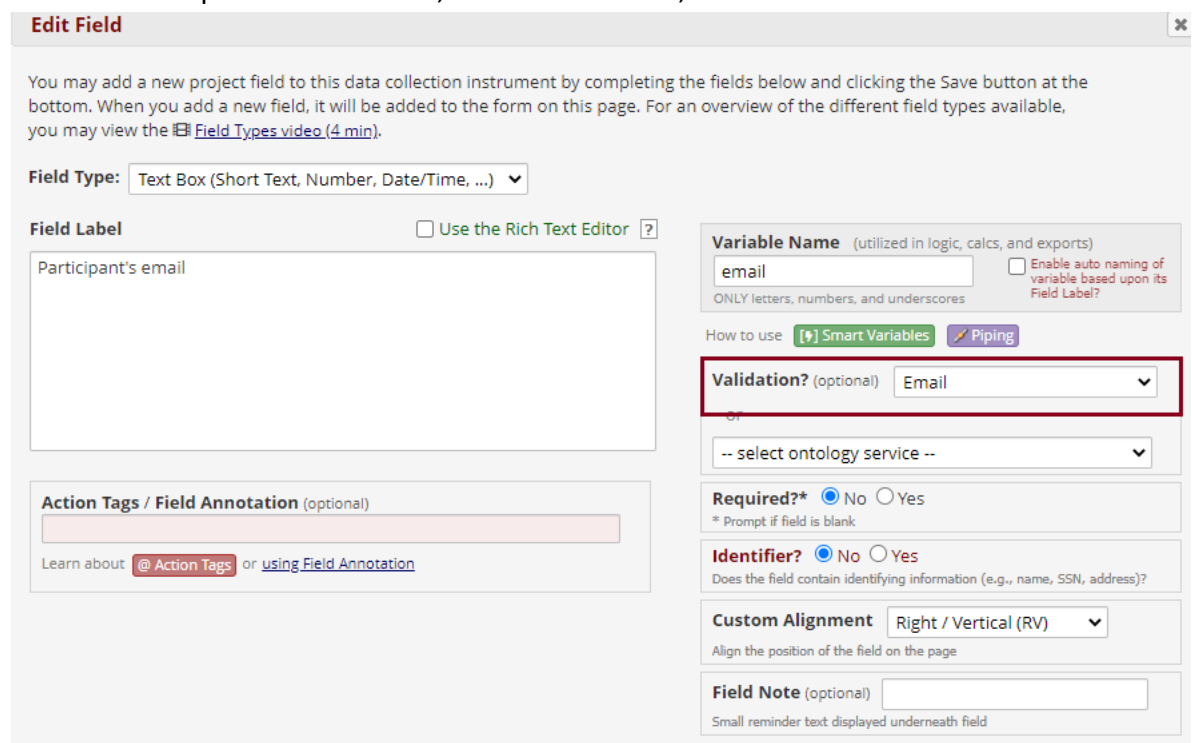
Enable ☐ Scheduling module (longitudinal only) ?

Enable ☐ Randomization module ?

Disable ☒ Designate an email field for sending survey invitations ?
Field currently designated: **email** ("Participant's email")

Additional customizations

- 9.1 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.
- 9.2 Open the newly created instrument.
- 9.3 Click add field and add the two fields, “Participant’s email” and “e-Consent Code.”
 - 9.3.1 For “Participant’s email” field, under “validation,” select “email.”



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 ?

Participant's email

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

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

Validation? (optional) Email ▼

-- select ontology service -- ▼

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

- 9.4 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](#)

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

9.5.1 The changes that must be made are marked in red.

9.5.1.1 Enable the Survey Login.

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

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

9.5.1.4 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 Add another login field	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. EXAMPLE: "If you have any trouble logging in to the survey, please contact survey_admin@myinstitution.edu for help."	If you have trouble logging in to the survey, please contact Jung at jung@bu.edu HTML may be used in order to add links or to add style to text.
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 0 = Disabled
Amount of time respondent will be locked out after having failed login attempts exceeding the limit set above.	0 Minutes, 0 = Disabled

Save

Cancel

9.5.1.4.1 To enable this, 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.)

Yes

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

What to do for updated approved informed consent forms

10. 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.

- 10.1 Replace the informed consent pdf link and the images of the informed consent form pages.
- 10.2 Go to the survey settings and update the settings accordingly. Please refer to step 7!

Creating Version Tracking instrument (to keep track of consent versions for ASI)

11. To keep track of informed consent versions, create a Version Tracking instrument. The fields in this instrument will be utilized to set up the Automated Survey Invitation (step 12).

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

11.1.1 It is recommended that you add a validation option for this field because if there's 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).

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

11.1.2.1 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

Action Tags / Field Annotation (optional)

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

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

version ☐ 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 –

-- select ontology service -- ▼

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**

11.2 Add a "Yes/No" field where the study staff will confirm whether or not to email the consent form.

11.3 Your instrument should look like this:

[Return to list of instruments](#)

Current instrument: **Version Tracking**

[Preview instrument](#)

The screenshot shows the configuration interface for the 'Version Tracking' instrument. It features two main sections. The first section is for the 'Version number' field, with a variable name of 'version' and a text input field. The second section is for the 'Email consent form' field, with a variable name of 'email_consent' and radio button options for 'Yes' and 'No'. Both sections have 'Add Field' and 'Add Matrix of Fields' buttons. A 'reset' button is located at the bottom right of the second section.

11.4 Go to Step 12 to enable this instrument as a repeatable instrument.

Enabling repeatable instruments for Version Tracking instrument

This is a useful module when you make changes to your approved consent form that necessitate reconsenting 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.

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

The screenshot shows the 'Enable optional modules and customizations' page. It features a list of optional modules with checkboxes and buttons to enable or disable them. The 'Repeatable instruments' option is highlighted with a red box. Other options include 'Auto-numbering for records', 'Scheduling module (longitudinal only)', 'Randomization module', and 'Designate an email field for sending survey invitations'. There is also an 'Additional customizations' button at the bottom.

11.6 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)
☐	Participant Information	
☒	Version Tracking	[version]
☐	Participant Consent Form v1.0	
☐	Study Personnel Consent Form v1.0	
☐	Consent Form (participant and study personnel)	
☐	Participant Consent Form v2.0	

Save

Cancel

- 11.7 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		

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.

12. In Online Designer, under “Survey-related options,” click on the button “Automated invitations.”

12.1 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.

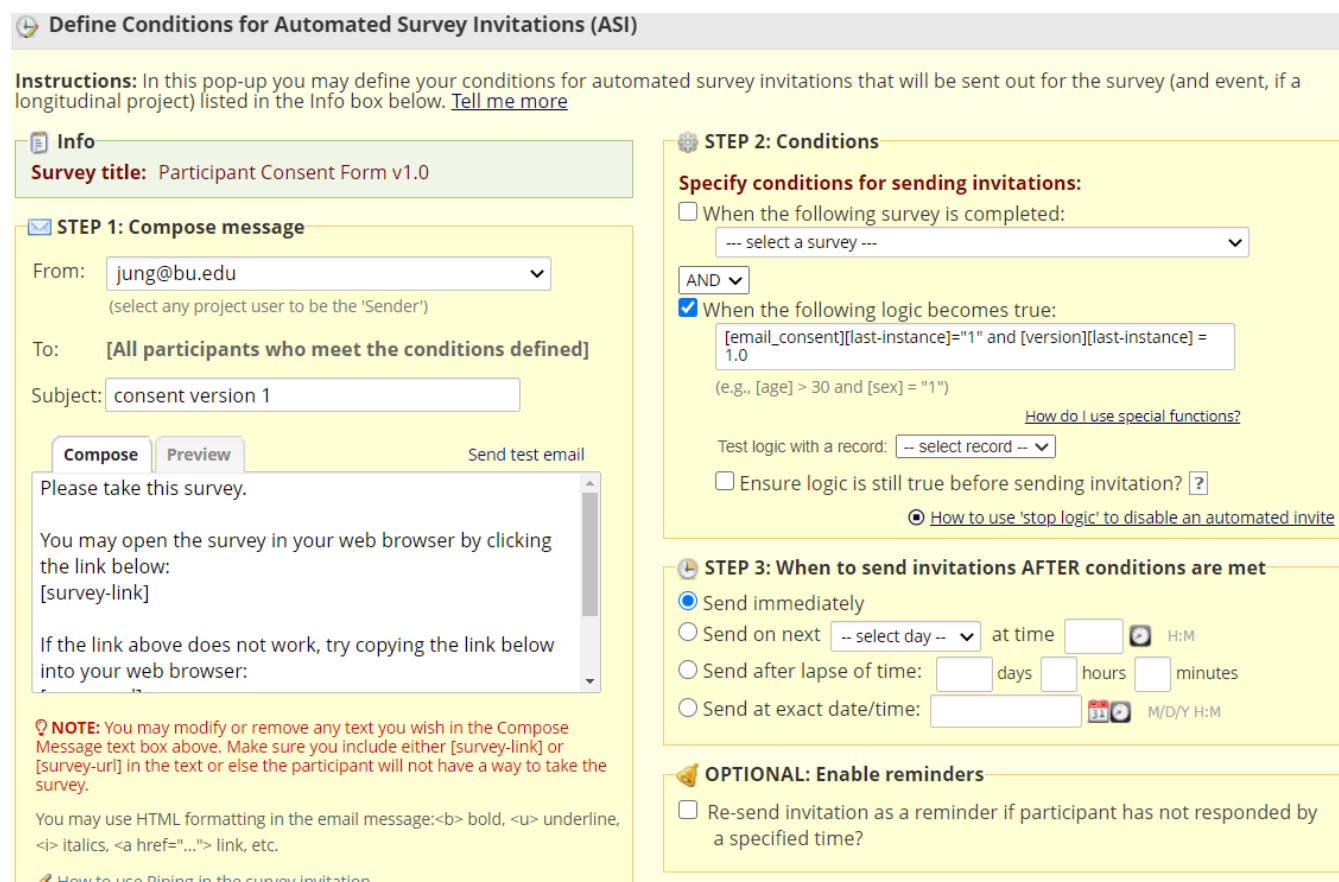
12.2 Step 2: Enter the following conditions (note that this matches the variable names shown in step 11.3):

12.2.1 [email_consent][last-instance] = “1” and [version][last-instance]= “#.##”

12.2.1.1 For #.##, enter the corresponding consent version number for that e-consent survey.

12.3 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.

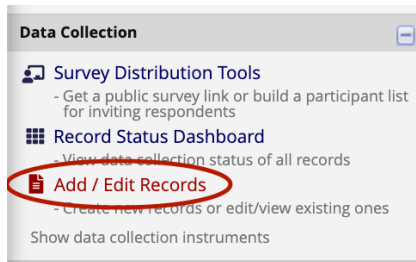
12.4 Step 4: Select “Active” to turn on automated invitations.

The image shows a screenshot of the 'Define Conditions for Automated Survey Invitations (ASI)' pop-up window in REDCap. The window is divided into several sections. At the top, there's a header 'Define Conditions for Automated Survey Invitations (ASI)'. Below it, an 'Info' box shows 'Survey title: Participant Consent Form v1.0'. The main area is split into two columns. The left column is 'STEP 1: Compose message', which includes fields for 'From' (jung@bu.edu), 'To' ([All participants who meet the conditions defined]), and 'Subject' (consent version 1). There are buttons for 'Compose', 'Preview', and 'Send test email'. Below these is a text area for the message body, containing a placeholder for a survey link. A 'NOTE' at the bottom explains that HTML formatting is allowed and that the survey link is essential. The right column is 'STEP 2: Conditions', which has a section 'Specify conditions for sending invitations:'. It includes a checkbox for 'When the following survey is completed:' (with a dropdown for 'select a survey'), an 'AND' dropdown, and a checked checkbox for 'When the following logic becomes true:'. The logic is set to '[email_consent][last-instance]='1' and [version][last-instance]= 1.0'. There are links for 'How do I use special functions?' and 'How to use stop logic to disable an automated invite'. Below this is 'STEP 3: When to send invitations AFTER conditions are met', with options for 'Send immediately' (selected), 'Send on next' (with day, time, and H:M dropdowns), 'Send after lapse of time' (with days, hours, and minutes dropdowns), and 'Send at exact date/time' (with a date/time dropdown). At the bottom is an 'OPTIONAL: Enable reminders' section with a checkbox for 'Re-send invitation as a reminder if participant has not responded by a specified time?'.
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: jung@bu.edu (select any project user to be the 'Sender')
To: [All participants who meet the conditions defined]
Subject: consent version 1
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](#)
STEP 2: Conditions
Specify conditions for sending invitations:
☐ When the following survey is completed:
--- select a survey ---
AND
☒ When the following logic becomes true:
[email_consent][last-instance]="1" and [version][last-instance]= 1.0
(e.g., [age] > 30 and [sex] = "1")
[How do I use special functions?](#)
Test logic with a record: -- select 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 -- select day -- 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?

Sending out the e-consent invitation email

13. 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.

- 13.1 From the left menu, under "Data Collection" click on "Add/Edit Record" to create a new record.



- 13.2 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.

A screenshot of a web form titled "Choose an existing Record ID". It features a dropdown menu labeled "-- select record --" and a green button labeled "+ Add new record". The button is circled in red.

- 13.3 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

A screenshot of a web form titled "Editing existing Record ID 1". The form contains several fields: "Record ID" with the value "1", "Participant's email" with the value "jung@bu.edu", "e-Consent Code" with the value "test123", and "Form Status" with a dropdown menu set to "Complete". At the bottom of the form, there are three buttons: "Save & Exit Form", "Save & ..." (with a dropdown arrow), and "-- Cancel --".

Re-sending the e-Consent invitation email

14. 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

Public Survey Link Participant List Survey Invitation Log

The Participant List option allows you to **send a customized email** to anyone in your list and **track who responds to your survey**. It is also possible to identify an individual's survey answers, if desired, by providing an Identifier for each participant (this feature must first be enabled by clicking the 'Enable' button in the table below). [More details](#)

Participant List belonging to "Participant e-Consent Form" ▼

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

Email	Record	Participant Identifier	Responded?	Invitation Scheduled?	Invitation Sent?	Link	Survey Access Code and QR Code
jung@bu.edu	1	Disabled		-			

14.1 Under "Compose message," edit the subject line and body of the email accordingly.

14.2 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?

Participant List Actions: -- check/uncheck participants -- ▼

(those who have not responded completely)

Email	Participant Identifier	Scheduled?	Sent?	Responded?
☐ jung@bu.edu (ID 1)		-		

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](#)

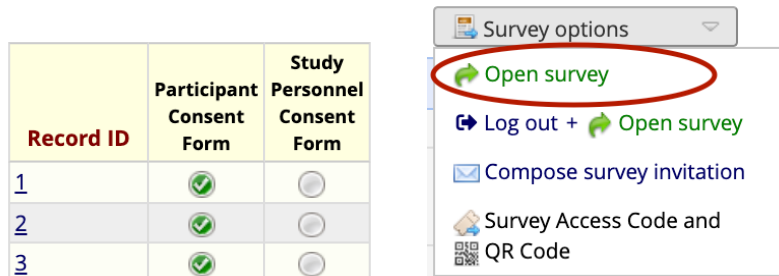
- Select a previously sent email to load it in the Compose box -

Send Invitations Cancel

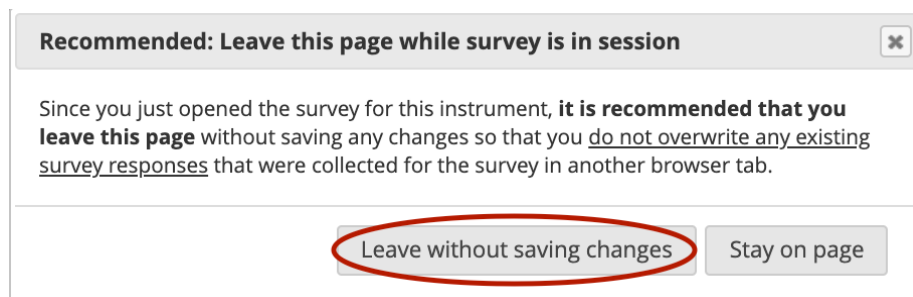
Completing the Study Personnel Consent Form – Reminder for Contactless Consent

15. Since the e-consent framework is turned on for the Study Personnel Consent Form, it must be completed as a survey. To access the consent link for study personnel, go to the participant's record and click on the "Study Personnel Consent Form" instrument.

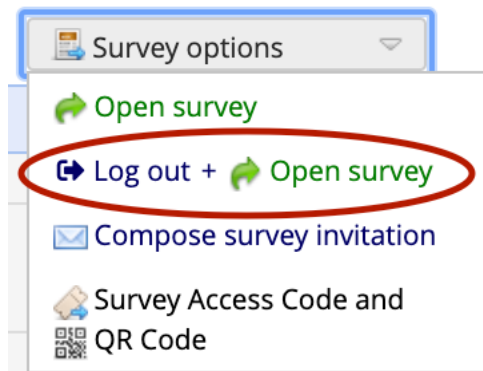
- 15.1 At the top of the form, find the "Survey Option" drop down and click on the "Open survey" option to access the consent link directly.



- 15.2 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." IMPORTANT: Make sure that you 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.



- 15.3 To ensure that the changes are made to the consent and to **avoid the risk mentioned in the previous step, 13.2**, the other option is to choose "Log out + Open survey" option from the drop-down menu. This will log you out of REDCap and direct you to the consent form to complete as a survey.



Enabling Twilio in REDCap

16. 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.

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

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

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

Checking project and moving to production status

17. 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>

17.1 Move your project to production status.

17.1.1 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](#)

Enabling the Multilingual External Module in REDCap

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. Please contact Tacha Coughlin, Coughlin, tawatson@bu.edu, with the name of your REDCap project to set this up.

The Multilingual EM allows surveys and data entry forms to be translated into multiple languages. The module and your language choices should be setup first, before building your instruments. To learn more visit

https://redcap.bumc.bu.edu/redcap_v9.3.0/ExternalModules/?prefix=multilingual&page=README.md

18. Please follow this link to request an External Module in REDCap:

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

Links to additional resources

Please visit the [CRRO website](#), for more information on e-Consent. You will find other useful guidances 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](#)

REDCap email support: rchelp@bu.edu