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*Guidance on Developing REDCap E-Consent: Minimal risk  
or Exempt Research Not Requiring a Signature and Exempt  
Research that Includes HIPAA Authorization*

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## Background

This guidance will take you step-by-step to build your Exempt Information Sheet (and HIPAA authorization form if needed for your research) in REDCap. **This guidance is specifically intended for exempt research and for non-exempt studies with a waiver of documentation.** If your research is not exempt go to the CRRO website to access the [Guidance on Developing REDCap E-Consent: Non-Exempt Research Requiring a Signature](#).

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 [rhelp@bu.edu](mailto:rhelp@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 this guidance please contact Mary-Tara Roth at the CRRO ([mtroth@bu.edu](mailto:mtroth@bu.edu)).

## Creating your project in REDCap

1. Sign on to REDCap (<https://redcap.bumc.bu.edu/>) and go to “My Projects.”
2. 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 3.0.
  - 2.1 Complete Project title, Purpose (research), PI info, Project notes, etc.)
  - 2.2 At the end of the page, choose “e-Consent for Exempt Research” under “Choose a project template” and press the blue “Create Project” button.
    - 2.2.1 This template provides you with a default layout to help you get started. You will have to edit the fields and survey settings accordingly.

**+ 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)

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... <a href="#">Show more</a>

**Create Project** **Cancel**

## Enabling Survey mode for REDCap Project

3. At “My Projects” page, select the appropriate project that you are creating an e-consent for. This will bring you to the “Project Setup” tab.
  - 3.1 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  
Add / Edit Records  
Applications  
Calendar

**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**

Not started **Enable** Use surveys in this project? [?](#) [VIDEO: How to create and manage a survey](#)

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

**Design your data collection instruments**

Not started

Add or edit fields on your data collection instruments. This may be done by either using the Online Designer (online method) or by uploading a Data Dictionary (offline method). Quick

- 3.2 Select “Online Designer” button under “Design your data collection instruments & enable your surveys.”
- 3.3 Rename “My First Instrument” by selecting “Choose action” drop down button to “Rename.” Name the instrument (your Exempt Information Sheet 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.

## Creating the information sheet instrument

4. Click on your newly named instrument. First we're going to upload a link to the Information Sheet document so that the participant can download a copy at the start of the survey.

4.1 Click "Add field" button.

4.2 Under the Field Type drop down, choose "Descriptive Text." Complete the Field Label with the name of the document, i.e. Information Sheet or Information Sheet and HIPAA Authorization Form.

4.3 Click on "Upload document." Choose your document and upload the file.

4.4 Give it an appropriate variable name and click save.

4.5 For displaying your information sheet on the survey, you have two options. You may upload and display the image of the entire document (such as the information sheet template with

logos, etc. See “Option 1” below) or copy and paste the whole text directly into the REDCap field (see 4.8 below for details on this “Option 2”).

4.6 Option 1: Uploading the document. If you have AdobePro, you can easily convert the .pdf to .jpeg. If you do not have AdobePro, you can take a screenshot of the document and save it as a .jpeg.

4.6.1 NOTE: If your study is an exempt study with a waiver of documentation, you must go with option 1. So instead of uploading .jpeg files of the information sheet, upload the .jpeg files of your approved informed consent.

4.6.2 Click “Add field” button.

4.6.3 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.

4.6.4 Click on “Upload document.” Choose your jpeg format information sheet and upload the file. Then click on “In-line image.” Give the page a variable name (such as info\_sheet) and click save.

4.7 Follow the instructions in 4.6.1-4.6.4above for any additional pages.

**Add New Field**

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

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

**Question Number** (optional)   
Displayed only on the survey page

**Field Label**  Use the Rich Text Editor ?

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

**Variable Name** (utilized in logic, exports, and reports)  
info\_sheet.jpeg  Enable auto naming of variable based upon its Field Label?

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

Optional file attachment, image, audio, or video:

**Embed an external video** (provide video URL) ?  
  
e.g. <https://youtube.com/watch?v=E1cCuWMupz0>,  
<https://vimeo.com/62730281>,  
<http://example.com/movie.mp4>  
Display format of video:  Inline  Inside popup

**Attach an image, file, or embedded audio**  
[Fake Exempt information sheet.jpg](#) [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**

# Information Sheet

Resize font:



Please read the information sheet below carefully. If you have any questions regarding the study, please contact:

[Study Staff Name]

[phone number]

BOSTON MEDICAL CENTER AND THE  
BOSTON UNIVERSITY SCHOOLS OF MEDICINE,  
PUBLIC HEALTH AND DENTAL MEDICINE



## RESEARCH INFORMATION SHEET

Lorem ipsum dolor sit amet, consectetur adipiscing elit. Maecenas porttitor congue massa. Fusce posuere, magna sed pulvinar ultricies, purus lectus malesuada libero, sit amet commodo magna eros quis urna. Nunc viverra imperdiet enim. Fusce est. Vivamus a tellus. Pellentesque habitant morbi tristique senectus et netus et malesuada fames ac turpis egestas. Proin pharetra nonummy pede. Mauris et orci. Aenean nec lorem.

In porttitor. Donec laoreet nonummy augue. Suspendisse dui purus, scelerisque at, vulputate vitae, pretium mattis, nunc. Mauris eget neque at sem venenatis eleifend. Ut nonummy. Fusce aliquet pede non pede. Suspendisse dapibus lorem pellentesque magna. Integer nula. Donec blandit feugiat ligula. Donec hendrerit, felis et imperdiet euismod, purus ipsum pretium metus, in lacinia nulla nisi eget sapien. Donec ut est in lectus consequat consequat. Etiam eget dui. Aliquam erat volutpat. Sed at lorem in nunc porta tristique. Proin nec augue. Quisque aliquam tempor magna. Pellentesque habitant morbi tristique senectus et netus et malesuada fames ac turpis egestas. Nunc ac magna. Maecenas odio dolor, vulputate vel, auctor ac, accumsan id, felis. Pellentesque cursus sagittis felis.

Pellentesque porttitor, velit lacinia egestas auctor, diam eros tempus arcu, nec vulputate augue magna vel risus. Cras non magna vel ante adipiscing rhoncus. Vivamus a mi. Morbi neque. Aliquam erat volutpat. Integer ultrices lobortis eros. Pellentesque habitant morbi tristique senectus et netus et malesuada fames ac turpis egestas. Proin semper, ante vitae sollicitudin posuere, metus quam iaculis nibh, vitae scelerisque nunc massa eget pede. Sed velit urna, interdum vel, ultricies vel, faucibus at, quam. Donec elit est, consectetur eget, consequat quis, tempus quis, wisi.

In in nunc. Class aptent taciti sociosqu ad litora torquent per conubia nostra, per inceptos hymenaeos. Donec ullamcorper fringilla eros. Fusce in sapien eu purus dapibus commodo. Cum sociis natoque penatibus et magnis dis parturient montes, nascetur ridiculus mus. Cras faucibus condimentum odio. Sed ac ligula. Aliquam at eros. Etiam at ligula et tellus ullamcorper ultrices. In fermentum, lorem non cursus porttitor, diam urna accumsan lacus, sed interdum wisi nibh nec nisi.

If you have any questions, please contact MT Roth by email, [mtroth@bu.edu](mailto:mtroth@bu.edu) or phone 617-555-555.

4.8 Option 2: You can choose to copy and the paste the Information Sheet text right into the REDCap field. This option is ONLY for exempt studies.

4.8.1 Click “Add Field” and select “Descriptive Text.”

4.8.2 Copy and paste the content of your Information Sheet Form right into the text box under “Field Label.” Give it an appropriate variable name such as info\_sheet.

## Information Sheet

Resize font:  
+ | -

Please read the information sheet below carefully. If you have any questions regarding the study, please contact:

[Study Staff Name]

[phone number]

### RESEARCH INFORMATION SHEET

Lorem ipsum dolor sit amet, consectetur adipiscing elit. Maecenas porttitor congue massa. Fusce posuere, magna sed pulvinar ultricies, purus lectus malesuada libero, sit amet commodo magna eros quis urna. Nunc viverra imperdiet enim. Fusce est. Vivamus a tellus. Pellentesque habitant morbi tristique senectus et netus et malesuada fames ac turpis egestas. Proin pharetra nonummy pede. Mauris et orci. Aenean nec lorem.

In porttitor. Donec laoreet nonummy augue. Suspendisse dui purus, scelerisque at, vulputate vitae, pretium mattis, nunc. Mauris eget neque at sem venenatis eleifend. Ut nonummy. Fusce aliquet pede non pede. Suspendisse dapibus lorem pellentesque magna. Integer nulla. Donec blandit feugiat ligula. Donec hendrerit, felis et imperdiet euismod, purus ipsum pretium metus, in lacinia nulla nisi eget sapien.

Donec ut est in lectus consequat consequat. Etiam eget dui. Aliquam erat volutpat. Sed at lorem in nunc porta tristique. Proin nec augue. Quisque aliquam tempor magna. Pellentesque habitant morbi tristique senectus et netus et malesuada fames ac turpis egestas. Nunc ac magna. Maecenas odio dolor, vulputate vel, auctor ac, accumsan id, felis. Pellentesque cursus sagittis felis.

Pellentesque porttitor, velit lacinia egestas auctor, diam eros tempus arcu, nec vulputate augue magna vel risus. Cras non magna vel ante adipiscing rhoncus. Vivamus a mi. Morbi neque. Aliquam erat volutpat. Integer ultrices lobortis eros. Pellentesque habitant morbi tristique senectus et netus et malesuada fames ac turpis egestas. Proin semper, ante vitae sollicitudin posuere, metus quam iaculis nibh, vitae scelerisque nunc massa eget pede. Sed velit urna, interdum vel, ultricies vel, faucibus at, quam. Donec elit est, consectetur eget, consequat quis, tempus quis, wisi.

In in nunc. Class aptent taciti sociosqu ad litora torquent per conubia nostra, per inceptos hymenaeos. Donec ullamcorper fringilla eros. Fusce in sapien eu purus dapibus commodo. Cum sociis natoque penatibus et magnis dis parturient montes, nascetur ridiculus mus. Cras faucibus condimentum odio. Sed ac ligula. Aliquam at eros. Etiam at ligula et tellus ullamcorper ultrices. In fermentum, lorem non cursus porttitor, diam urna accumsan lacus, sed interdum wisi nibh nec nisi.

If you have any questions, please contact MT Roth by email, [mtroth@bu.edu](mailto:mtroth@bu.edu) or phone 617-555-555.

## Adding additional fields

5. Although you do not need to do so, you might decide that you want to add additional fields such as a check-off box that the individual affirms their agreement to participate in the study. Click “Add Field” and select “Single Answer (Radio Buttons).”
  - 5.1 In the text box under “Field Label,” .... Do you agree to participate in this research study?  
Yes/no
  - 5.2 Create text fields that will appear depending on participant’s response:
    - 5.2.1 If yes, display text such as “Thank you for agreeing to participate in our/[Insert study name] study.”
      - 5.2.1.1 If there is a survey that the participant will be completing directly after the information sheet, you can prompt the participant to continue to the next page to complete the survey.
      - 5.2.1.2 Another option is to create a separate survey instrument and utilize the “Survey Queue” feature, which will lead the participant to the next survey after they have read the information sheet and/or completed the HIPAA authorization form.
    - 5.2.2 If no, display text such as “Thank you for your time. You may close out of this web browser.”

## Adding electronic signature fields for HIPAA authorization form

6. Some exempt research will require signed HIPAA authorization. You can add text box fields for the participant to type in his/her first and last name, and/or you can add a signature field, allowing the participant to provide an e-signature using a stylus, finger, or mouse. There is no requirement for the investigator to sign this form.
  - 6.1 Click the “Add Field” blue button.
  - 6.2 Select “Text Box...” from the dropdown menu.
  - 6.3 Under the field label type “First name.” Under “Variable Name” type “first\_name”.
  - 6.4 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, calcs, 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

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

**Save** **Cancel**

6.5 Continue and add Last Name field following steps 6.1-6.4.

6.6 Adding the Stylud 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 6.1-6.4.

6.6.1 If you are adding the signature field, complete the “Field Label” as follows: T “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 [Field Types video \(4 min\)](#).

**Field Type:** Signature (draw signature with mouse or fir)

**Field Label**  Use the Rich Text Editor ?  
Signature

**Variable Name** (utilized in logic, calcs, and exports)  
signature\_3  Enable auto naming of variable based upon its Field Label?  
ONLY letters, numbers, and underscores

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

**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

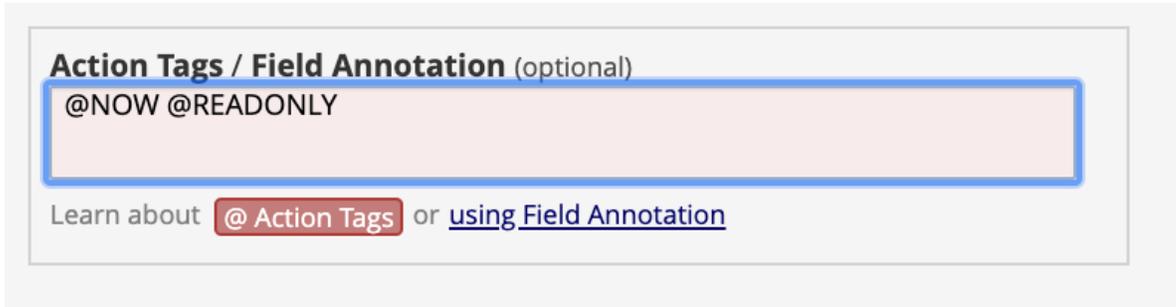
**Field Note** (optional)  
Small reminder text displayed underneath field

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

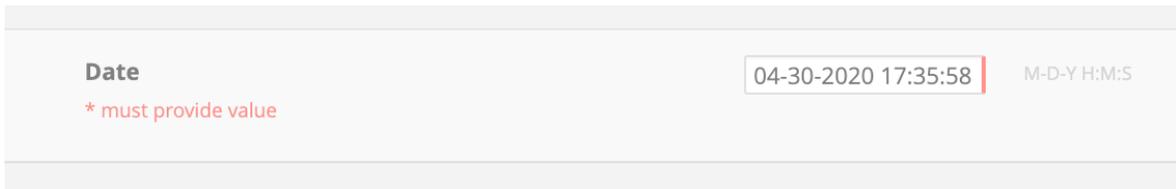
**Save** **Cancel**

6.7 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)).

6.7.1 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.

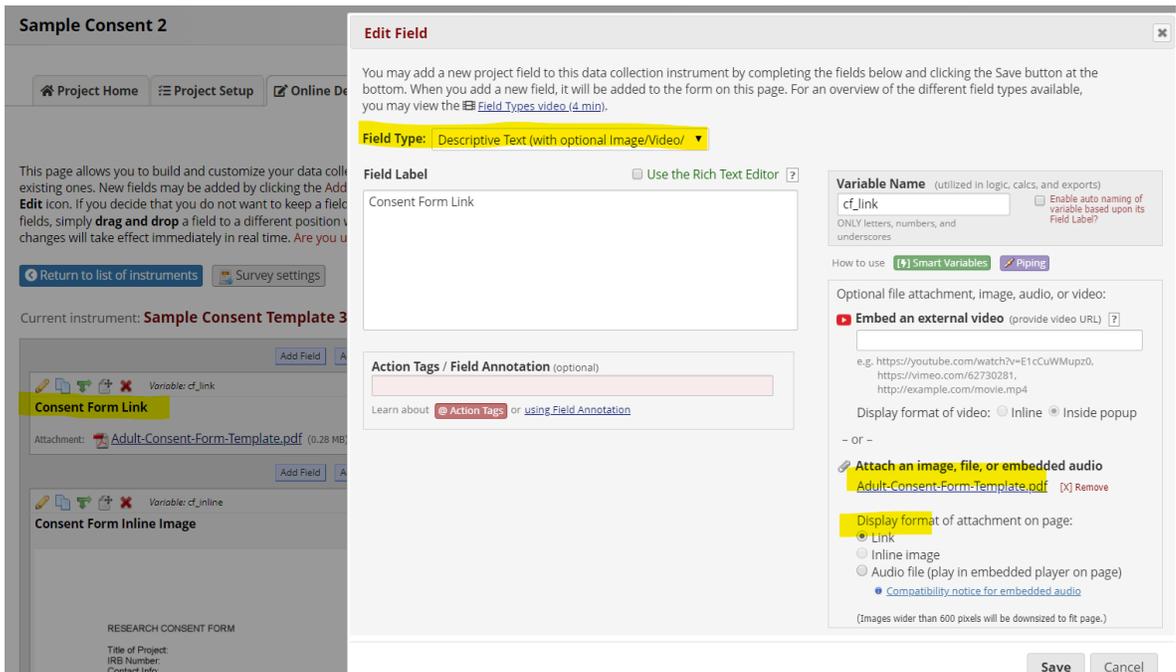


How it appears on the survey (it will be greyed out):



6.7.2 Complete additional fields as necessary.

6.8 You may also elect to set up a file download field, to allow the participant to download a hardcopy of the information sheet.



6.9 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 form below. When you add a new field, it will be added to the form on this page. For an example, you may view the [Field Types video \(4 min\)](#).

**Field Type:** Begin New Section (with optional text)

**Field Label:** Signature of Study Participant  Use the Rich Text Editor ?

How it will look:

**Signature of Study Participant**

**First Name**  
\* must provide value

**Last Name**  
\* must provide value

6.9.1 You may choose to add the following text that exists in your HIPAA Authorization Form:

**Signature of Study Participant:**

By signing this authorization form, you are indicating that

- you have read this form (or it has been read to you)
- your questions have been answered to your satisfaction
- you permit the use and release of health information that may identify you as described in this form.

**Edit Field** ✕

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

Field Type:

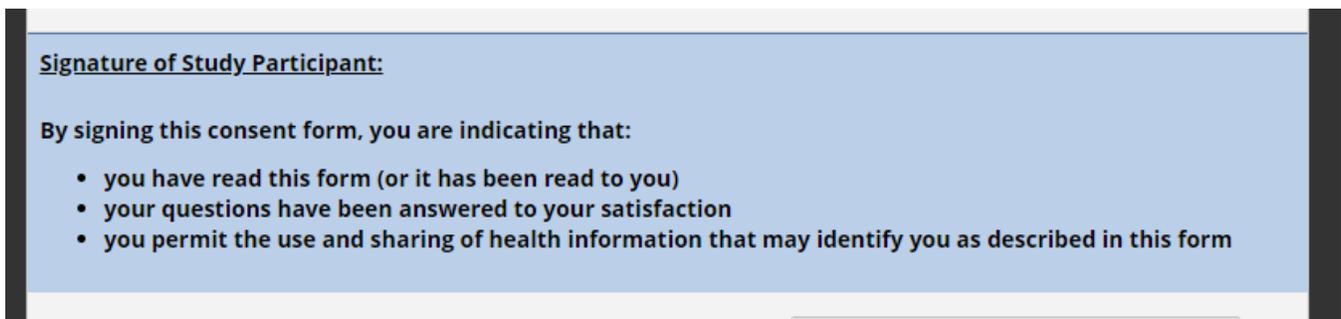
Field Label  Use the Rich Text Editor ?

Paragraph B I

**Signature of Study Participant:**

**By signing this consent form, you are indicating that:**

- You have read this form (or it has been read to you)



## Enabling survey feature and updating survey settings

7. When you have completed setting up your Exempt Information Sheet instrument, scroll to the top and click on the blue “Return to list of instruments” button. Then click on “Project Setup” tab.



- 7.1 Under the section “Design your data collection instruments & enable your surveys” click on the “Online Designer” button.
- 7.2 You will see your Information Sheet form under the “Data Collection Instruments” table. Click “Enable” under “Enabled as survey.” This brings you to the “Set Up My Survey” tab (or if it is already set up, the tab is called “Modify survey settings”).

**Sample Consent 2**

Project Home | Project Setup | Online Designer | Data Dictionary | Codebook

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

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

**Data Collection Instruments**

Survey options: Survey Queue | Survey Login | Survey Notifications | Upload or download Auto Invitations

Add new instrument: Create | Import | Upload

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	

7.3 Under “Basic Survey Options” fill in “Survey Title” and “Survey Instructions.” This information will appear at the top of your electronic consent survey page. The instructions can be some simple instruction that makes sense within your consent process, such as: “Please review this research information sheet 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 (if the signature applies to your study). 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 a copy of your Information Sheet and signed HIPAA Authorization Form. (You can prompt the participant to download a copy of the signed HIPAA form here since the option to allow participants to download a pdf of their completed survey is turned on in the survey settings and so the button to download will appear below this survey completion text)

7.4.1 If your study does not require an electronic signature (i.e. no HIPAA authorization form), please edit this “Survey Completion Text” section accordingly.

7.4.2 Click the “Save Changes” blue button on the bottom of this webpage.

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

Vs.

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

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

Close survey

**Thank you for your participation in this research study!**

Download your survey response (PDF):

 Download

- 7.5.3 You may choose to not enable this 'download' feature if you are not collecting electronic signatures. But, please remember to add a field with a link to the Information Sheet (described in Step 3.0) so that the participant does have the option to download a copy at the start of the survey. s

## Additional survey settings if using HIPAA authorization form

8. If collecting electronic signatures, you must enable the e-consent framework option under the survey settings. Scroll to near the end of the survey settings page.
  - 8.1 To the right of the "PDF Auto-archiver" choose the third option: "Auto-Archiver + e-Consent Framework."
  - 8.2 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."
  - 8.3 IMPORTANT: The "Allow e-Consent responses to be edited by users?" should NOT be checked off.
  - 8.4 Next to "e-Consent version" provide a version number.

**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)

▼

8.5 Enable signature erasing feature: under the “Force signature field(s) to be erased...,” select the fields “First Name” and “Last Name.” Click on the “+Select another signature field” to add the 2<sup>nd</sup> signature field. This feature will erase the signature if the participant returns to the consent after viewing the confirmation page. That way, in case any the participant makes any changes when s/he returns to the consent page, the most up-to-date form is signed.

8.5.1 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 here.

## 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).

**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

## Enabling Twilio in REDCap

- 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 follow this link to request the Twilio Module in REDCap:  
<https://redcap.bumc.bu.edu/surveys/?s=HJPXWCME7H>
  - IRB approval is required to use Twilio.

## Checking project and moving to production status

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

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

11.1 Move your project to production status.

11.1.1 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 email [rchelp@bu.edu](mailto:rchelp@bu.edu) 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 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](https://redcap.bumc.bu.edu/redcap_v9.3.0/ExternalModules/?prefix=multilingual&page=README.md)

12. 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: Non-Exempt Research Requiring a Signature](#)

Resources for REDCap:

[REDCap FAQ](#)

[REDCap Training Videos](#)

REDCap email support: [rchelp@bu.edu](mailto:rchelp@bu.edu)