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]().

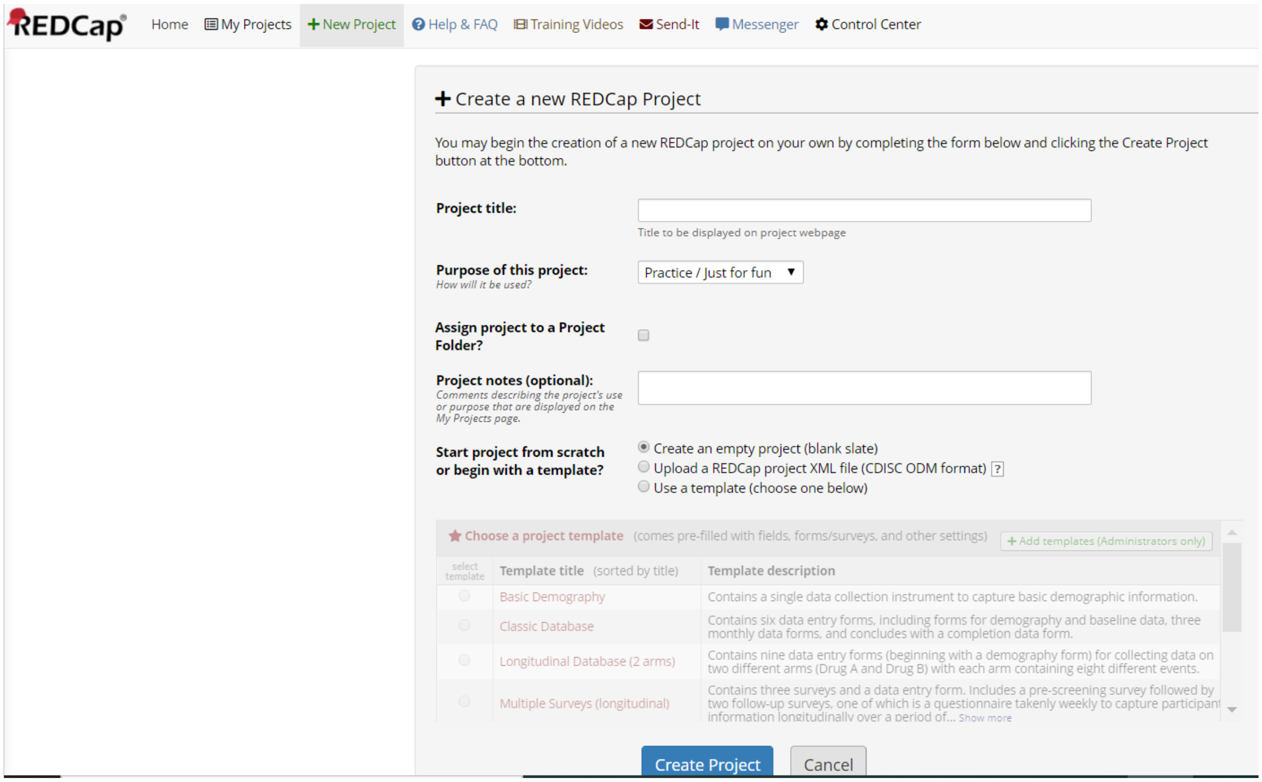
Please note that though this guidance that has been created with best study practices in mind, you may need or want to change certain features or functionalities to match your own unique study needs and workflow. If you have any questions regarding how to make certain changes, please contact rchelp@bu.edu.

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 this guidance please contact Mary-Tara Roth at the CRRO (mtroth@bu.edu).

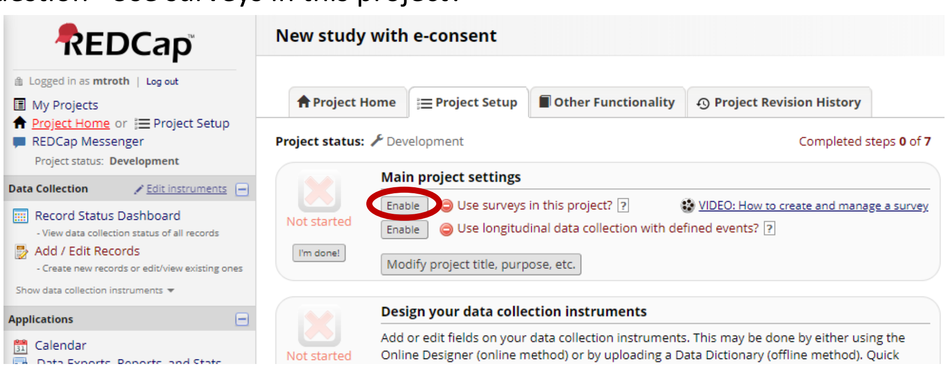
Creating your project in REDCap

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.



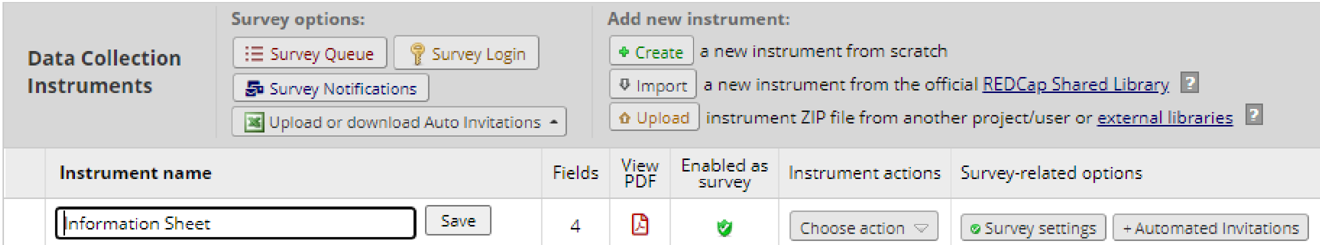
Enabling Survey mode for REDCap Project

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?"



   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.

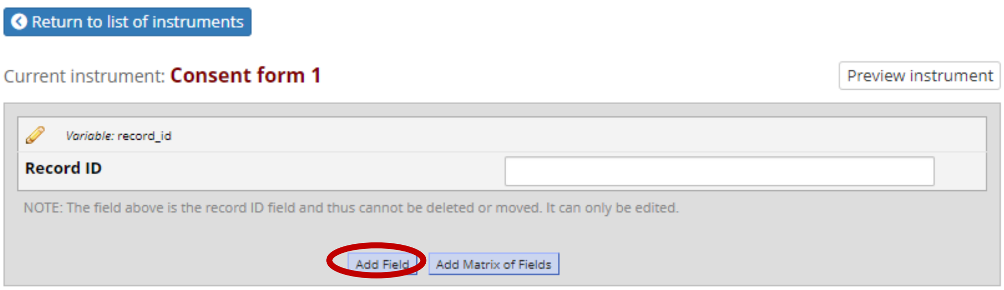
The Online Designer will allow you to make project modifications to fields and data collection instruments very easily using only your web browser. NOTE: While in development status, all field changes will take effect immediately in real time.



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.

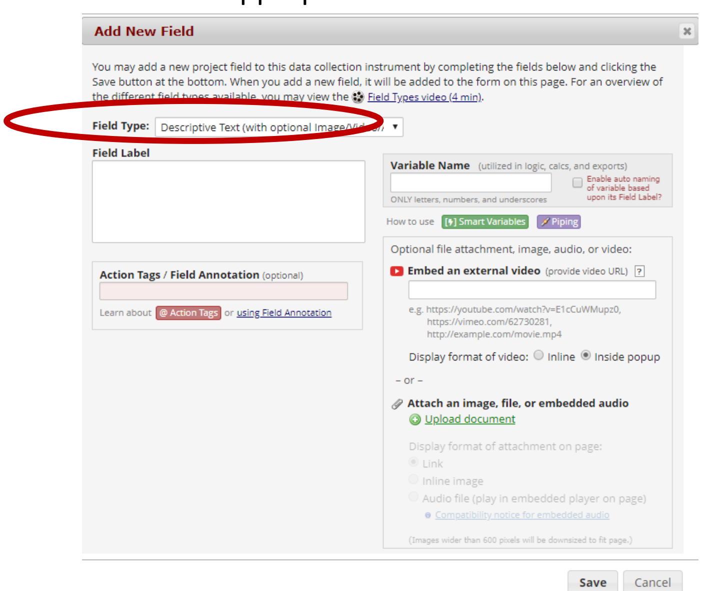
   4.1 Click "Add field" button.

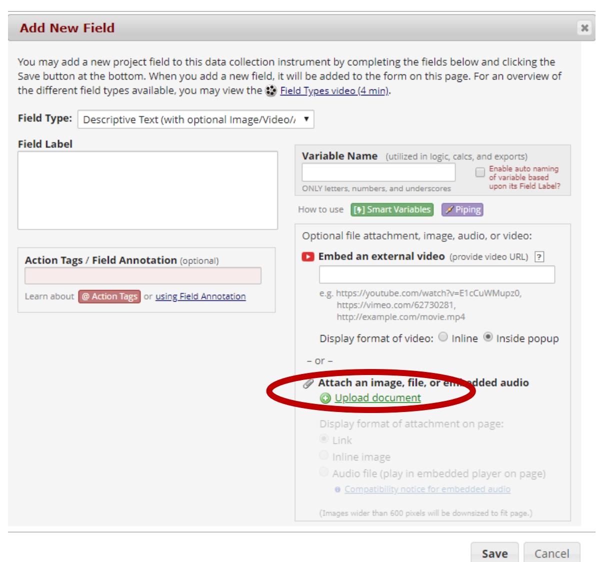


   4.2 Under the Field Type drop down, choose "Descriptive Text." Complete theField Label"with the name of the document, i.e. Information Sheet or Information Sheet and HIPAA Authorization Form.

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

   4.4 Give it an appropriate variabile 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.

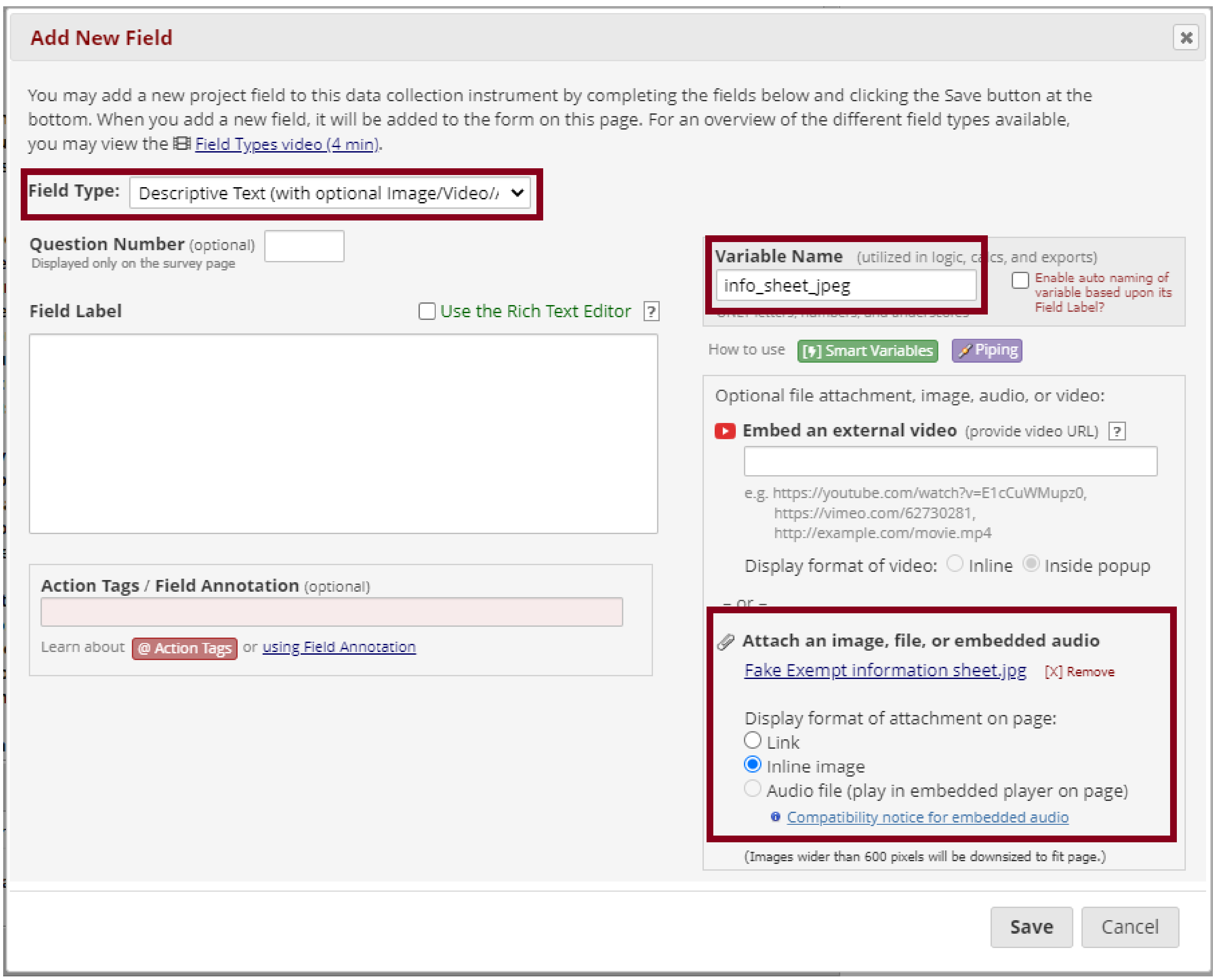
4.6.1 NOTE: If your study is an exempt study with a waiver of documentation, you must go with option 1. So instead of uploading .jpeg files of the information sheet, upload the .jpeg files of your approved informed consent.

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.



Resize font:

Information Sheet

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

Boston Medical Center
Exceptional care. Without exception.

Boston University

RESEARCH INFORMATION SHEET

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If you have any questions, please contact MT Roth by email, mtroth@bu.edu or phone 617-555-555.

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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.

Resize font:

Information Sheet

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

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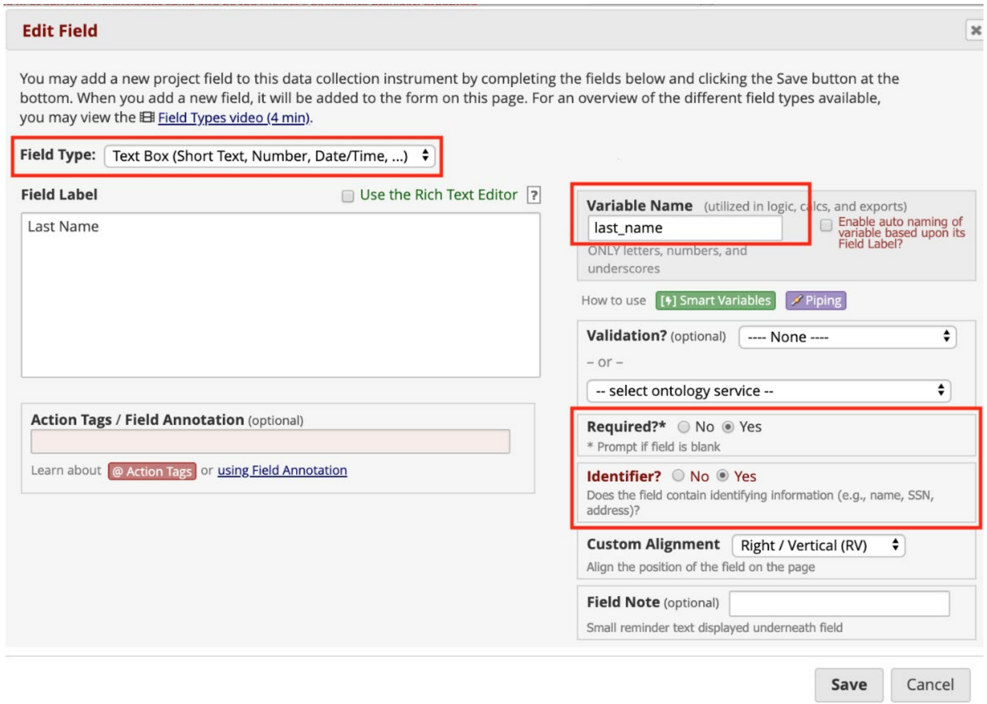
If you have any questions, please contact MT Roth by email, mtroth@bu.edu or phone 617-555-555.

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

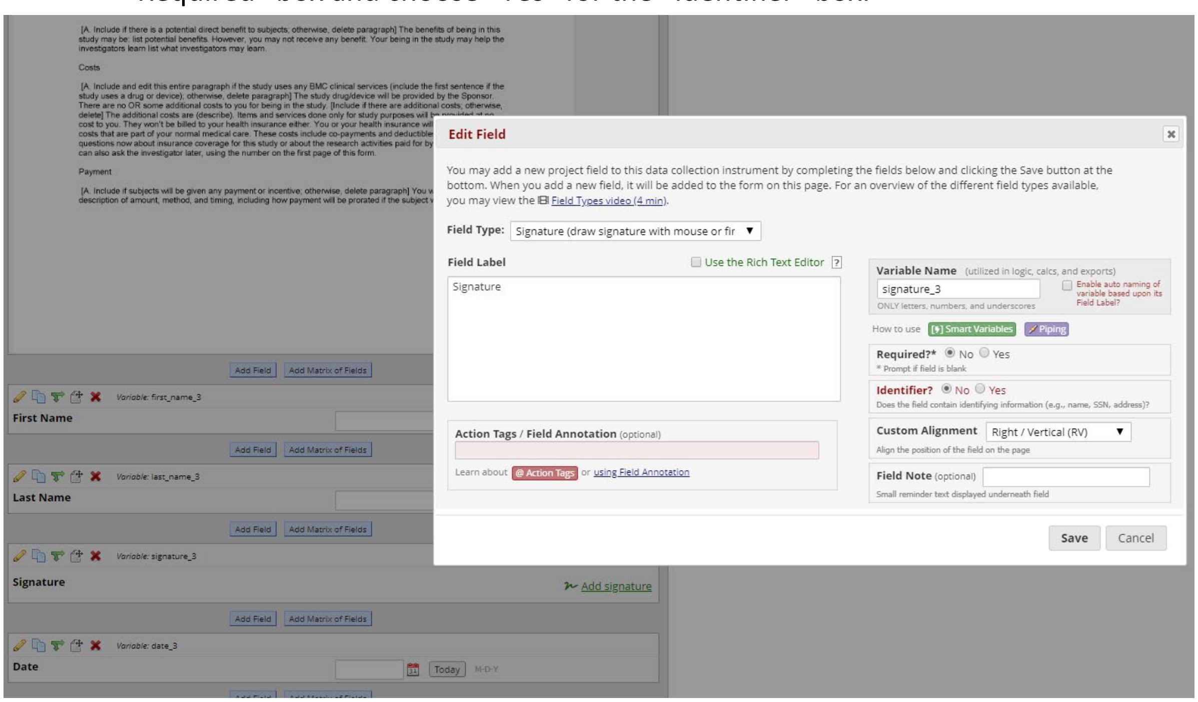
6. Some exempt research will require signed HIPAA authorization. You can add text box fields for the participant to type in his/her first and last name, and/or you can add a signature field, allowing the participant to provide an e-signature using a stylus, finger, or mouse. There is no requirement for 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.”



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

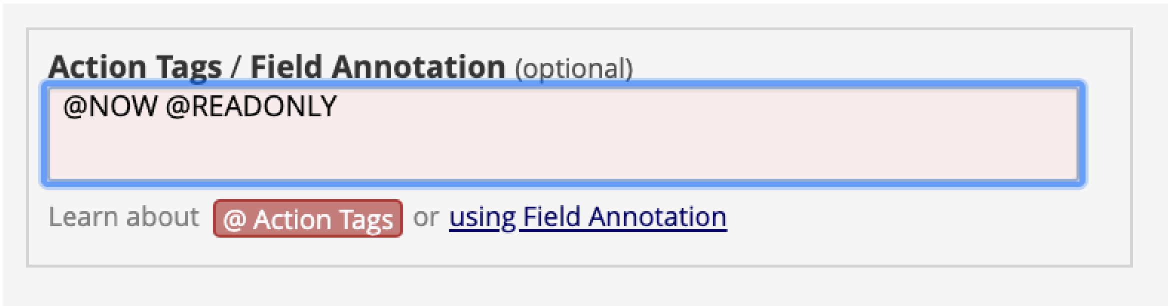
6.6 Adding the Stylud Signature field is optional but is recommended as it offers an experience simmilar to providing a physical signature. In Field type, choose “Signature…” from the dropdown menu. Proceed as before with steps 6.1-6.4.

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.

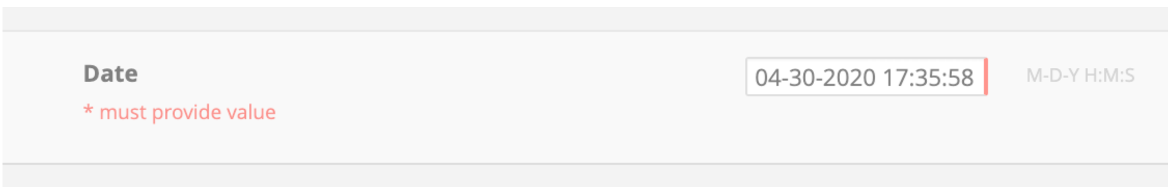


6.7 Add a date field. Choose “Add field” blue button. Under “Field Type” choose “Text Box.” Complete “Field Label” and “Variable Name.” Under “Validation?” choose a date option from the dropdown menu. We recommend that you use the “Datetime w/ seconds” option (e.g. “Datetime w/ seconds (M-D-Y H:M:S)).

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 be generated and un-editable, reducing the potential for error.

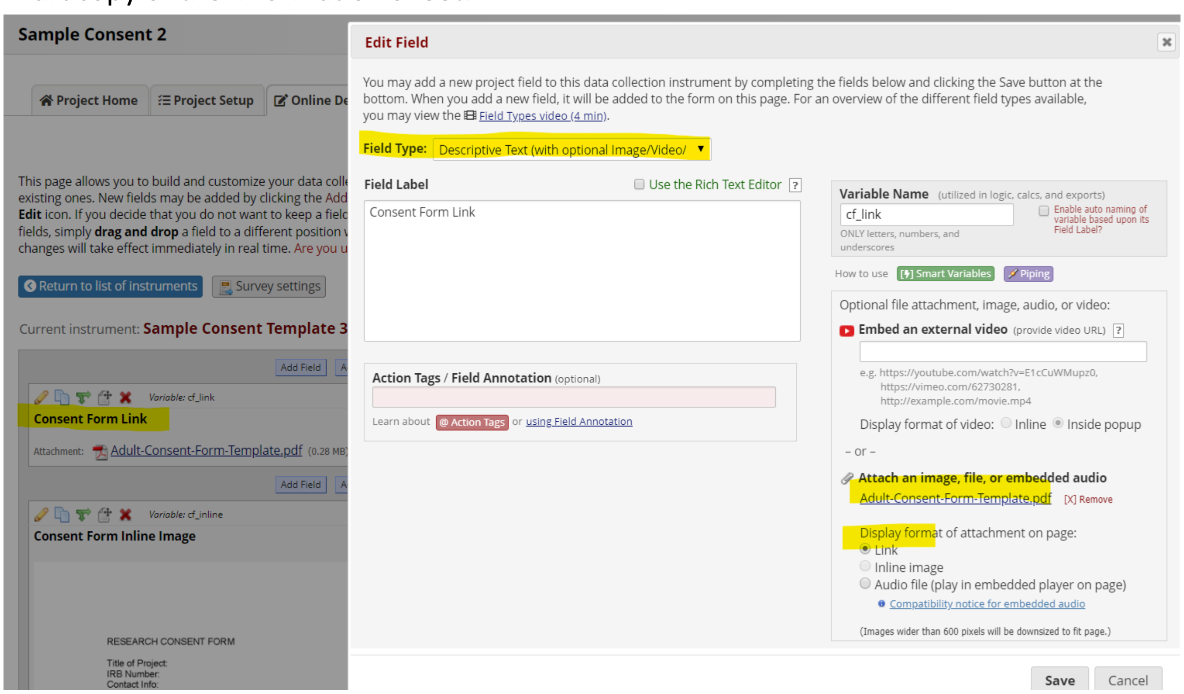


How it appears on the survey (it will be greyed out):

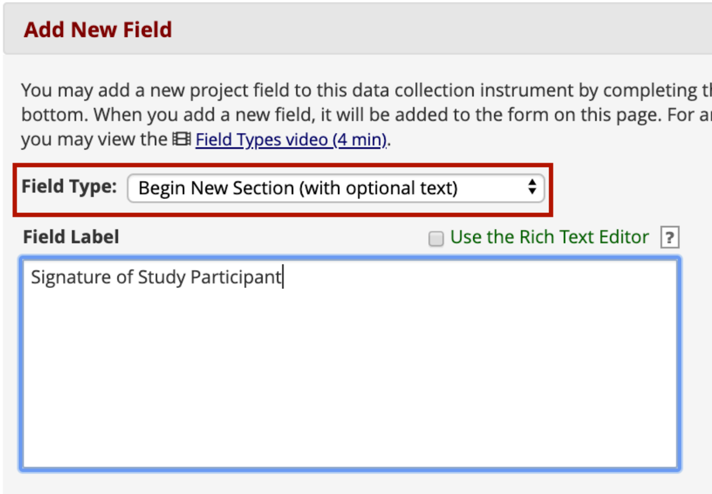


6.7.2 Complete additional fields as necessary.

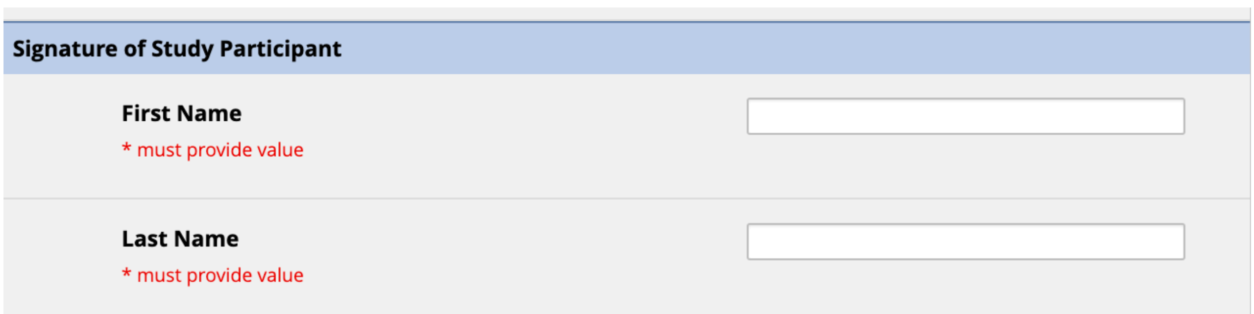
6.8 You may also elect to set up a file download field, to allow the participant to download a hardcopy of the information sheet.



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)"



How it will look:

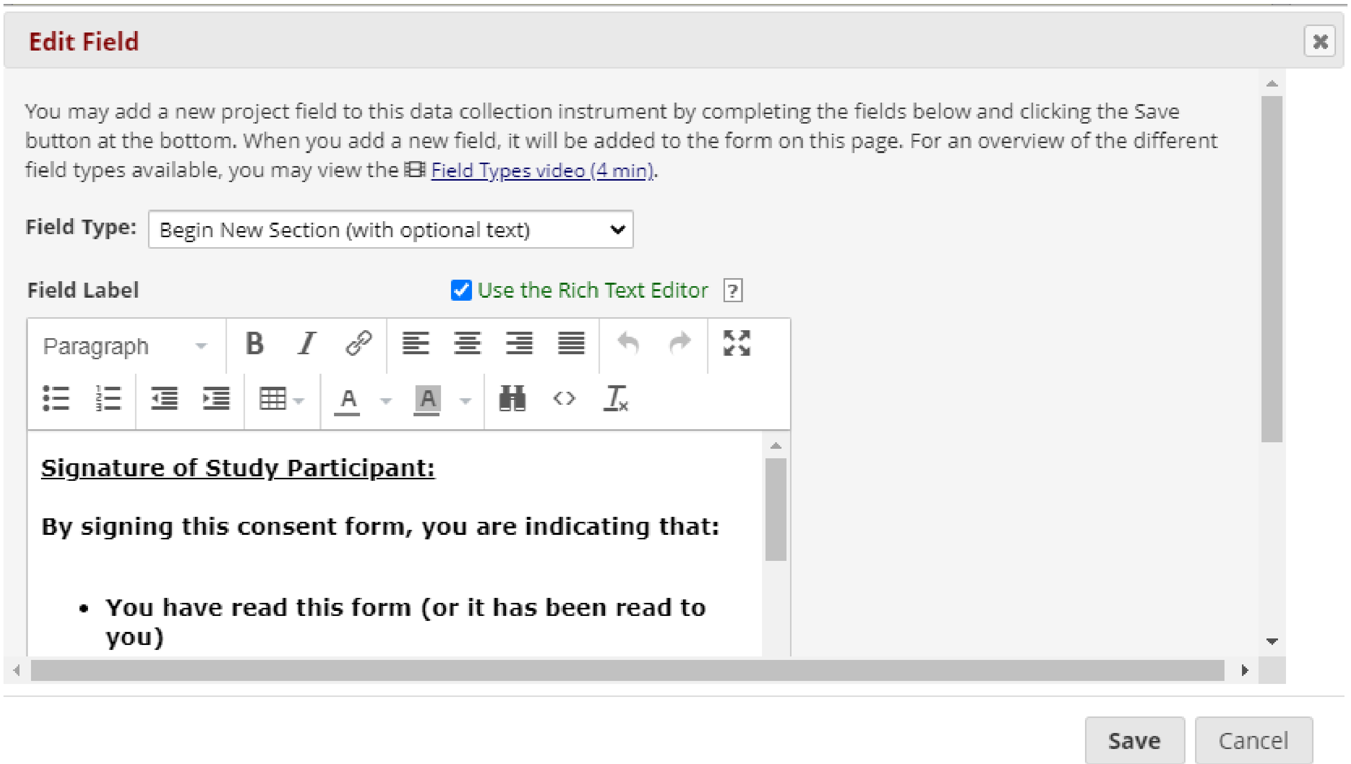


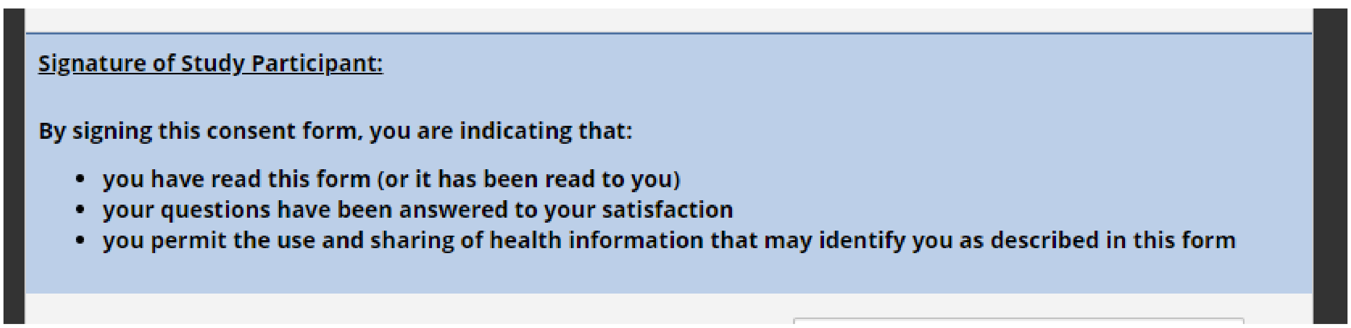
6.9.1 You may choose to add the following text that exists in your HIPAA Authorization Form:

<u>Signature of Study Participant:</u>

By signing this authorization form, you are indicating that

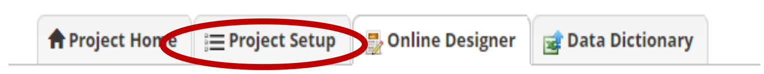
- you have read this form (or it has been read to you)
- your questions have been answered to your satisfaction
- you permit the use and release of health information that may identify you as described in this form.





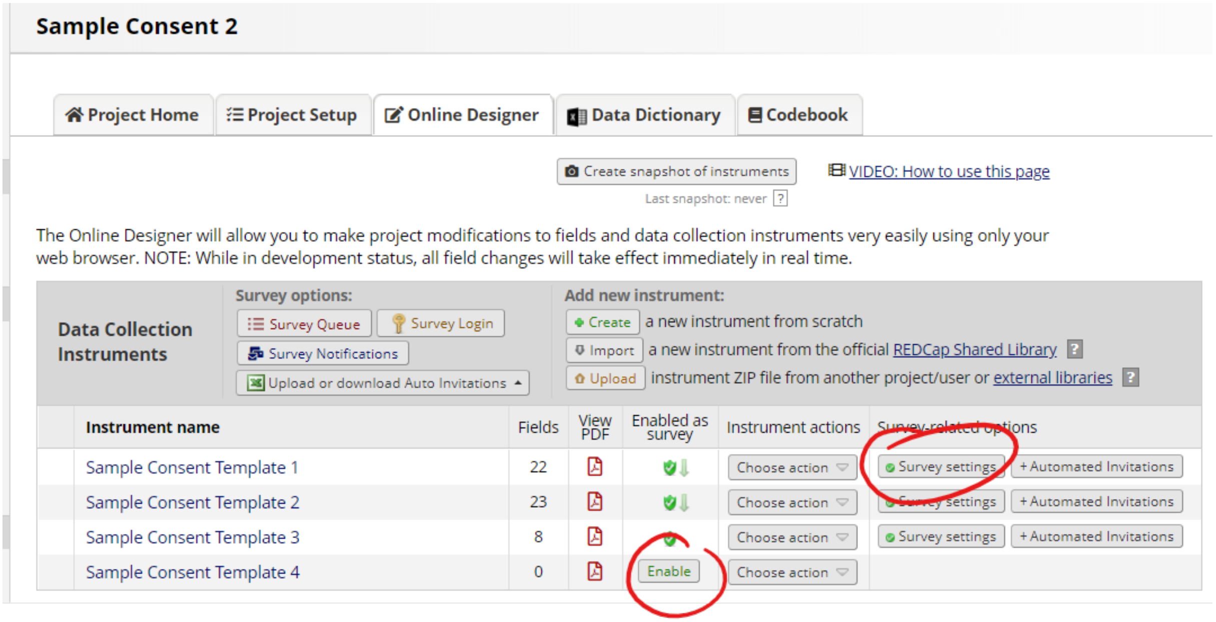
Enabling survey feature and updating survey settings

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").



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.

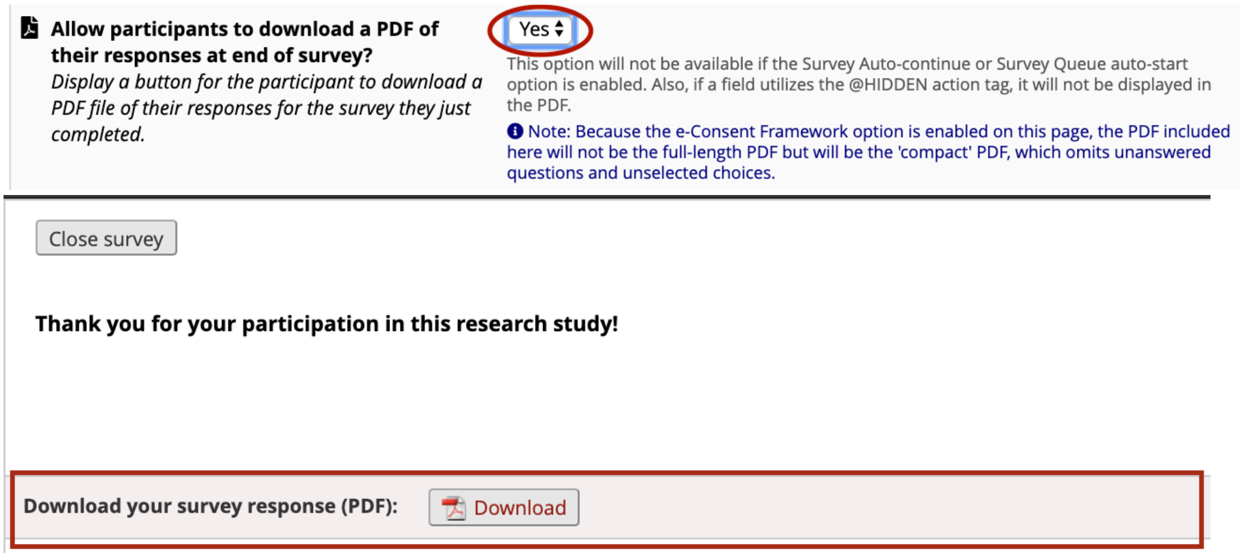
7.4.2 Click the "Save Changes" blue button on the bottom of this webpage.

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:

Vs.

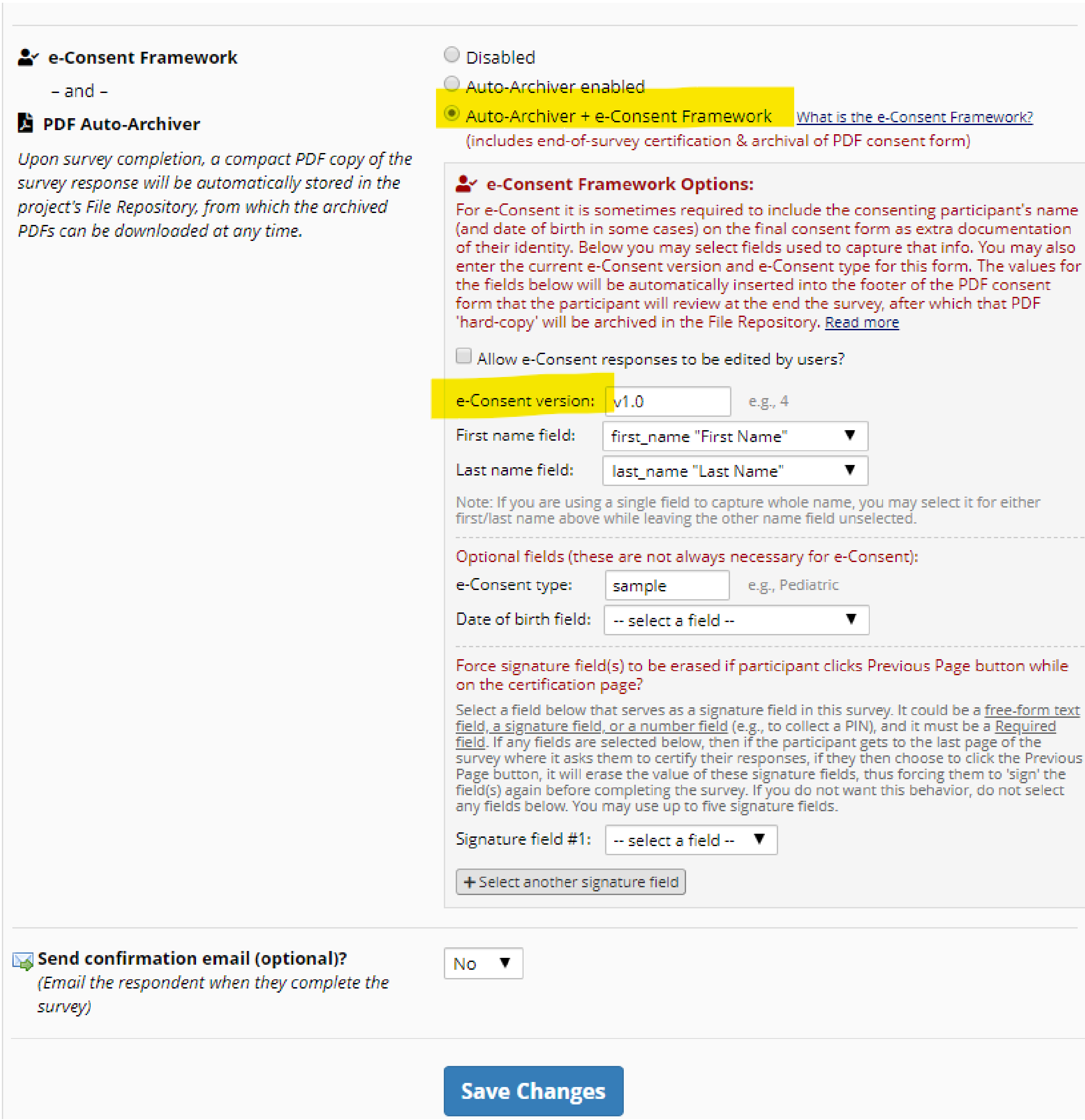
7.5.2 To allow for the participant to download their completed HIPAA Authorization form, change the option to “Yes” for the question “Allow participants to download a PDF of their responses at end of survey?” So when the participant completes and submits the HIPAA Authorization form a button will show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



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

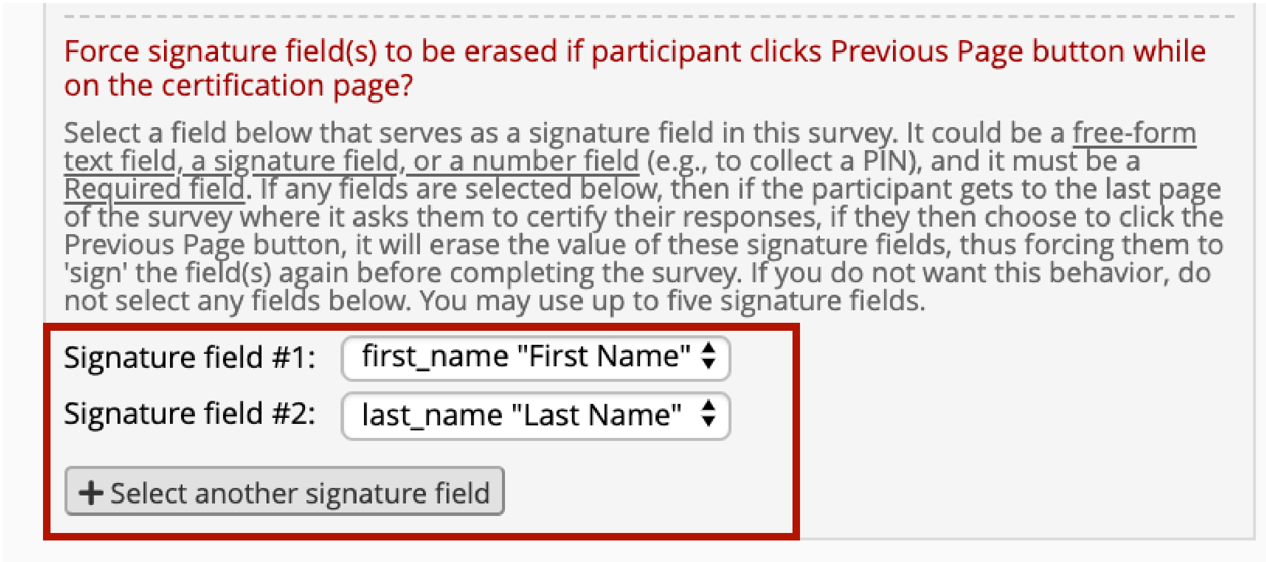
Additional survey settings if using HIPAA authorization form

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.



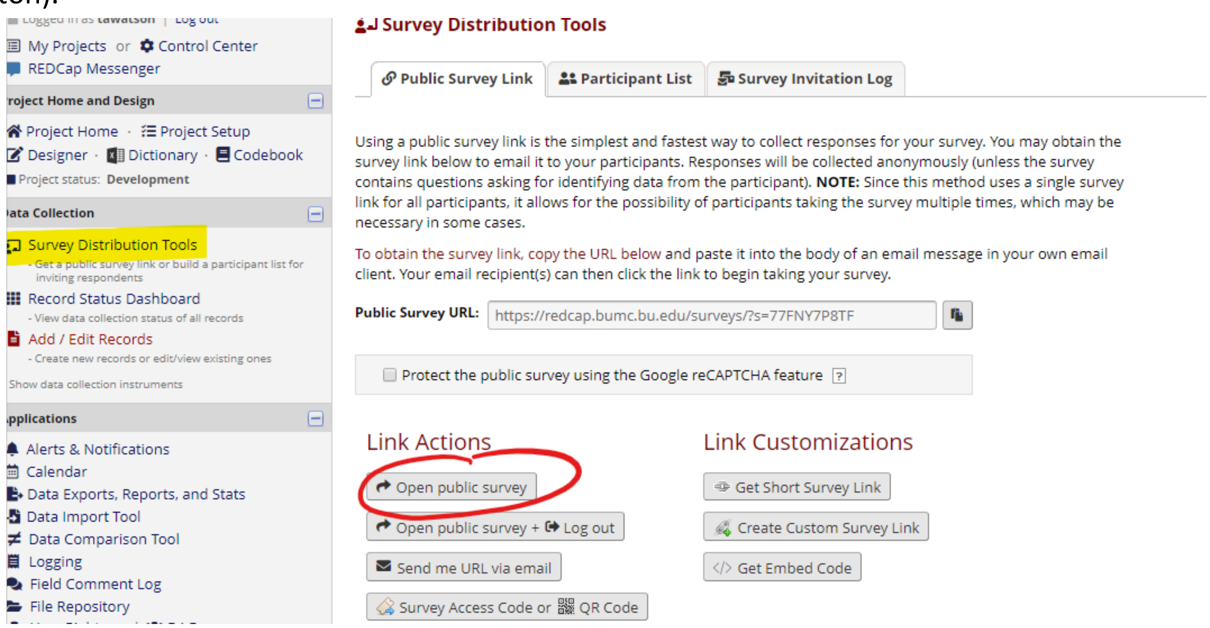
8.5 Enable signature erasing feature: under the "Force signature field(s) to be erased…," select the fields "First Name" and "Last Name." Click on the "+Select another signature field" to add the 2nd signature field. This feature will erase the signature if the participant returns to the consent after 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.



How to test out the Consent link during Development Mode

9. 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).



Enabling Twilio in REDCap

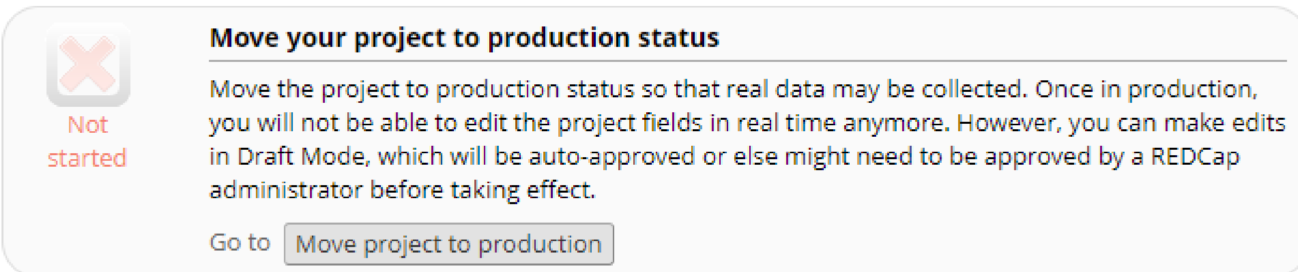
10. REDCap has the capability to send SMS text messages to survey respondents by using a third-party web service named Twilio. Costs associated with this service are managed from your Twilio account. For more information about Twilio in REDCap, please visit the request link below,
    10.1 Please follow this link to request the Twilio Module in REDCap: https://redcap.bumc.bu.edu/surveys/?s=HJPXWCME7H
    10.2 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."



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 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

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