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

# Table of Contents

## Background

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

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

**This guidance is specifically intended for research that WILL require signatures on the consent form.** Under Massachusetts law, a person typing in their name on an electronic document constitutes a legally effective signature. REDCap will also allow an individual to sign their name using a stylus, a finger, or a mouse. If your study is non-exempt but IRB has approved a waiver of documentation of consent, please go to the CRRO website to access the Guidance on Developing REDCap E-Consent: Minimal risk or Exempt Research Not Requiring a Signature and Exempt Research that Includes HIPAA authorization.

(*Note that at this time this guidance is NOT applicable to consent for FDA-regulated research, as electronic systems used to create and maintain research records for FDA-regulated research must undergo validation procedures to be fully Part 11 compliant. Although REDCap has the components to be Part 11 compliant, this validation has not been completed.)*

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

If you do not have a REDCap account, complete the REDCap User Agreement survey: https://redcap.bumc.bu.edu/surveys/?s=RYKEW4N4RX

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

## Brief Overview

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

Below is a list of key terms to know before reading the guidance:
**Instrument** – A data collection tool that can be left as a form or enabled as a survey.

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

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

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

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

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

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

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

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

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

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

**Project Template** – pre-built REDCap project.

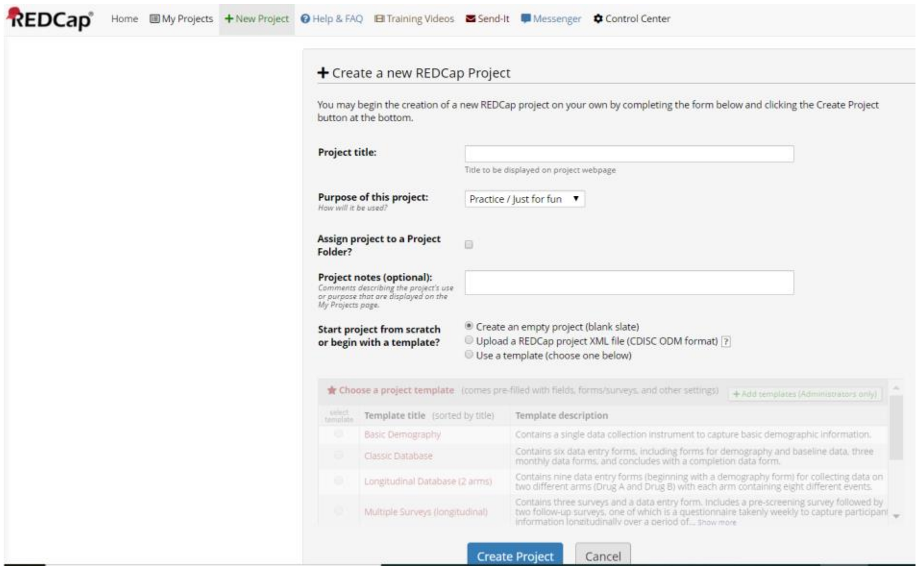
**External Module -** External Modules are add-on packages of software that can extend REDCap's current functionality, as well as provide customizations and enhancements for REDCap's existing behavior and appearance. Modules will need to be installed and enabled by a BUMC REDCap administrator. To request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

## Getting Started

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

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

4. Complete Project title, Purpose (research), PI info, Project notes, etc.
5. At the end of the page, choose “e-Consent for Non-Exempt Research” under “Choose a project template” and press the blue “Create Project” button.
   - 5.1.1 This template provides you with a default layout to help you get started. Please note that the default template provides you with examples for both in-person e-consent and contactless e-consent. Also, the automatic survey feature has been enabled in this template. If you are not going to utilize this feature, disable it.
   - 5.1.2 Edit the fields and survey settings accordingly for your study.

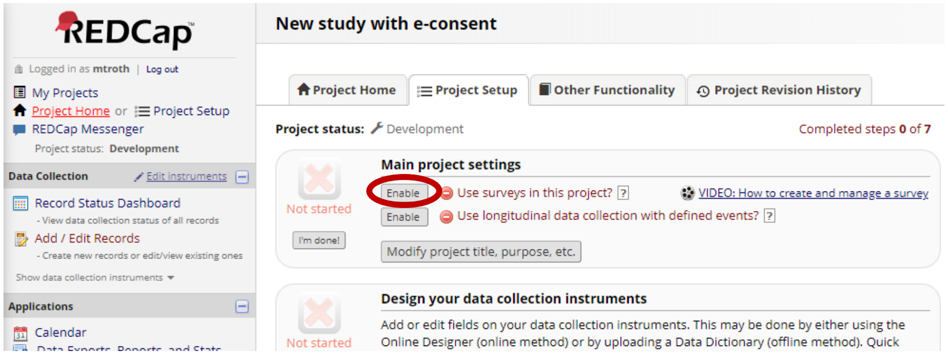



## Creating a Standard e-Consent

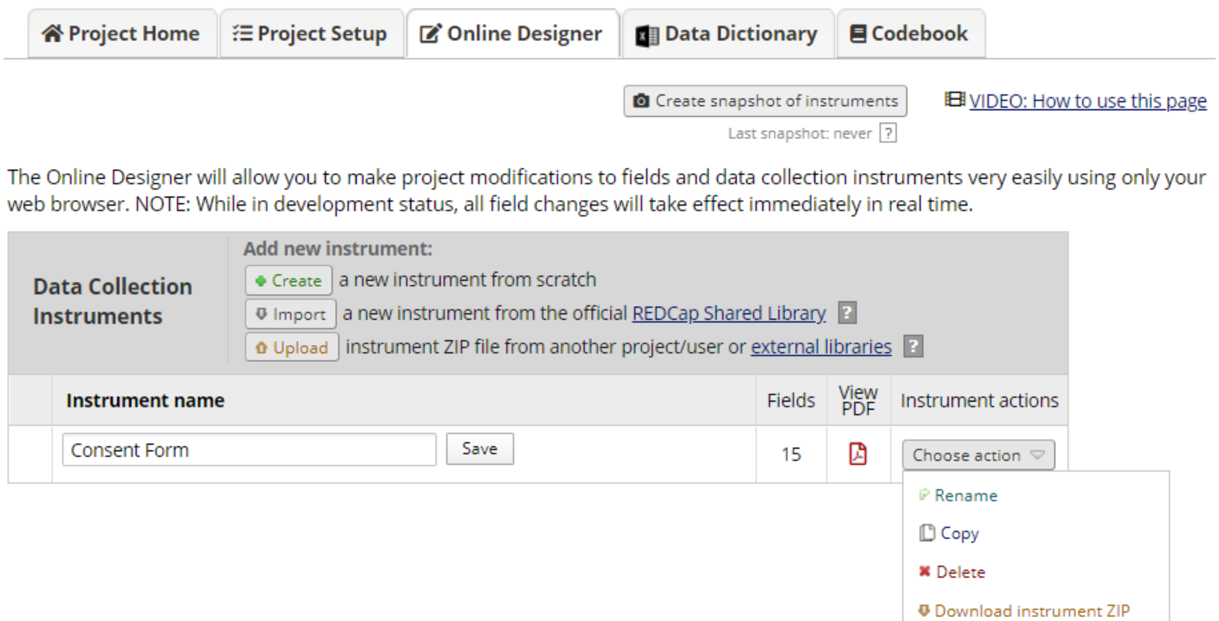
The section will incorporate signatures from both the participants and the study staff; this will go over in-person vs. contactless (remote) e-consent, include saving a PDF with both signatures in contactless e-consent setting.

### I. Project Settings

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

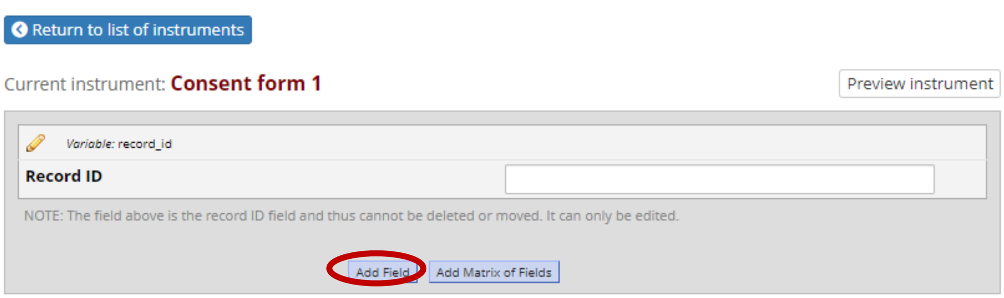



3. Select “Online Designer” button under “Design your data collection instruments & enable your surveys.”
4. Rename “My First Instrument” by selecting “Choose action” drop down button to “Rename.” Name the instrument (your consent document) and then click the “Save” button.



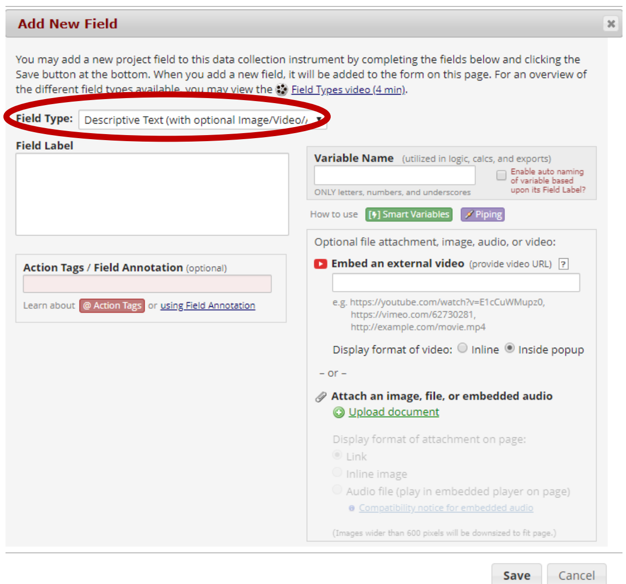

## II. Creating the e-Consent instrument

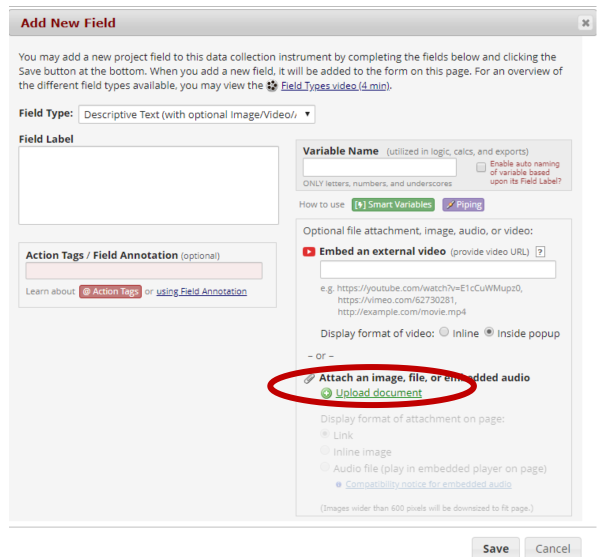
1. Now to build your consent form, click on your newly named instrument.
2. Click “Add field” button.



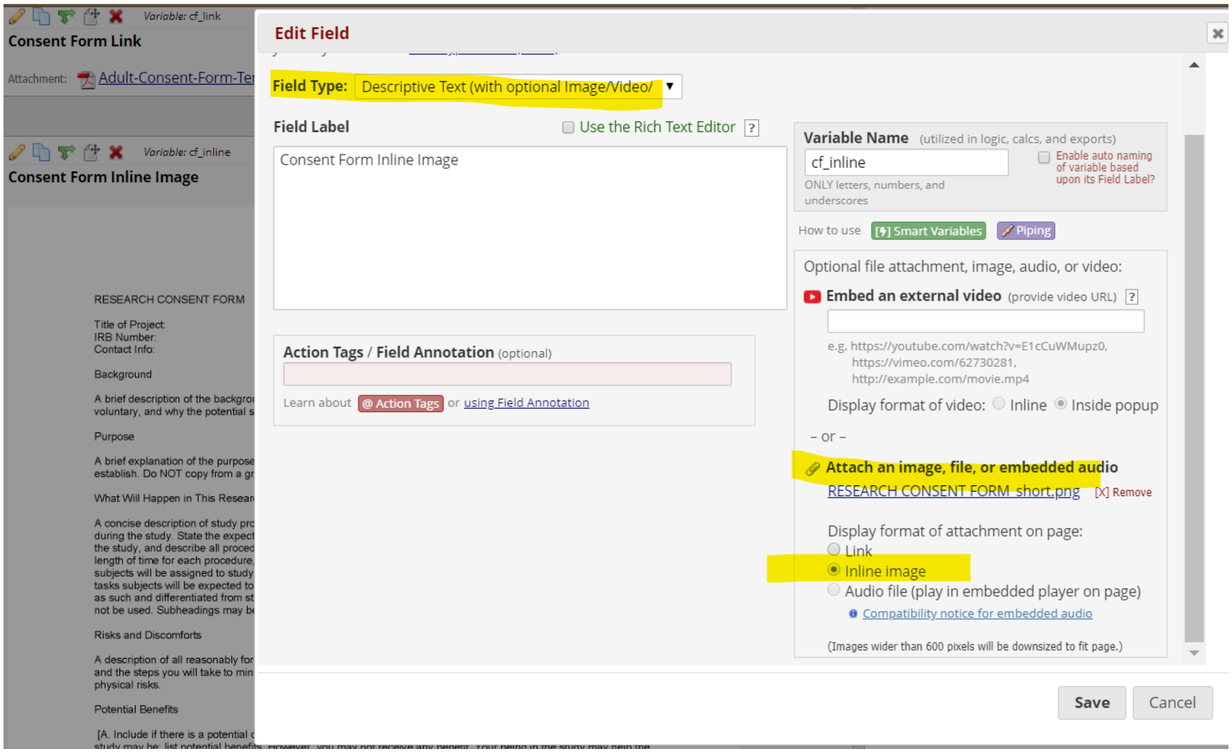

3. Under the Field Type drop down, choose “Descriptive Text.” You can keep the “Field Label” blank. It is not necessary to complete this field to upload the file.

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. At bottom of first consent form page (the jpeg image), click the “Add field” button.





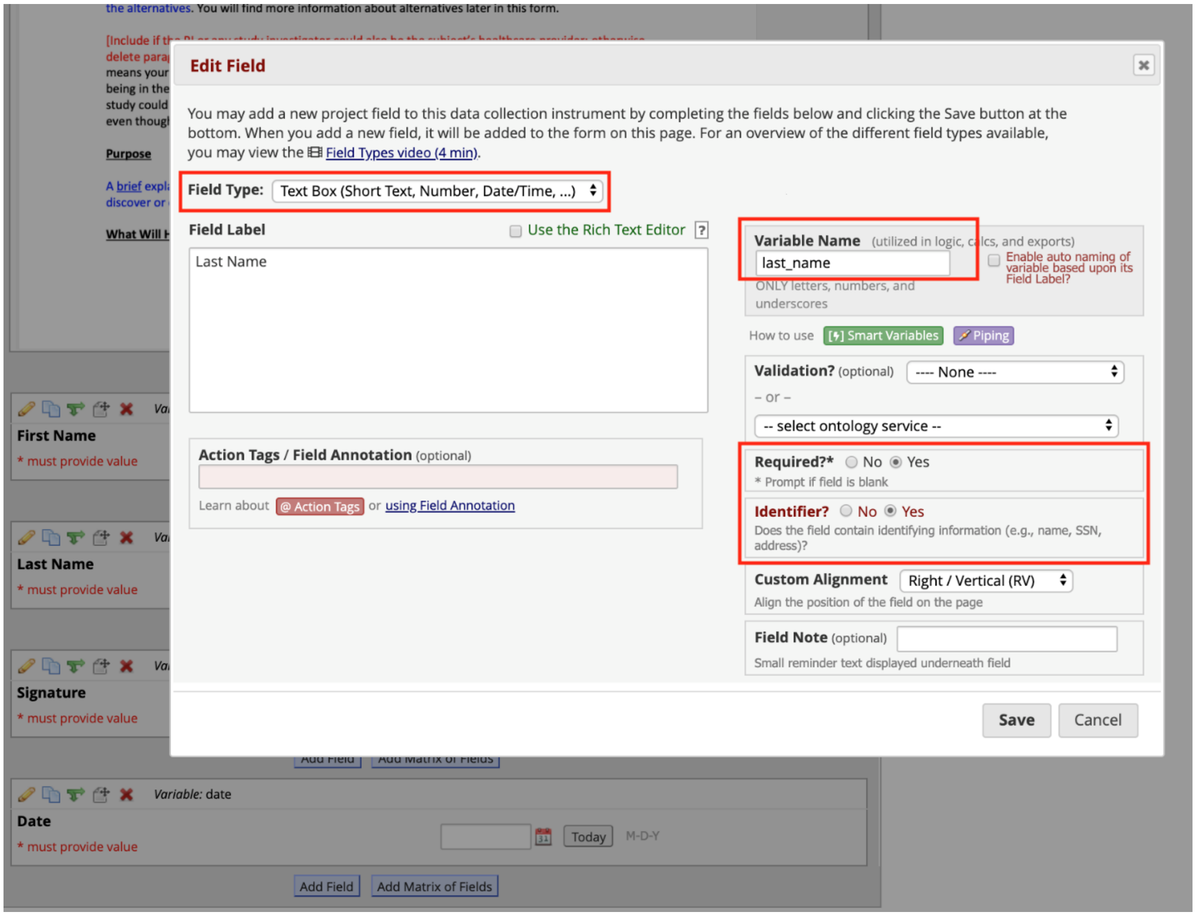

6. Follow the instructions in above to add all the consent form pages.



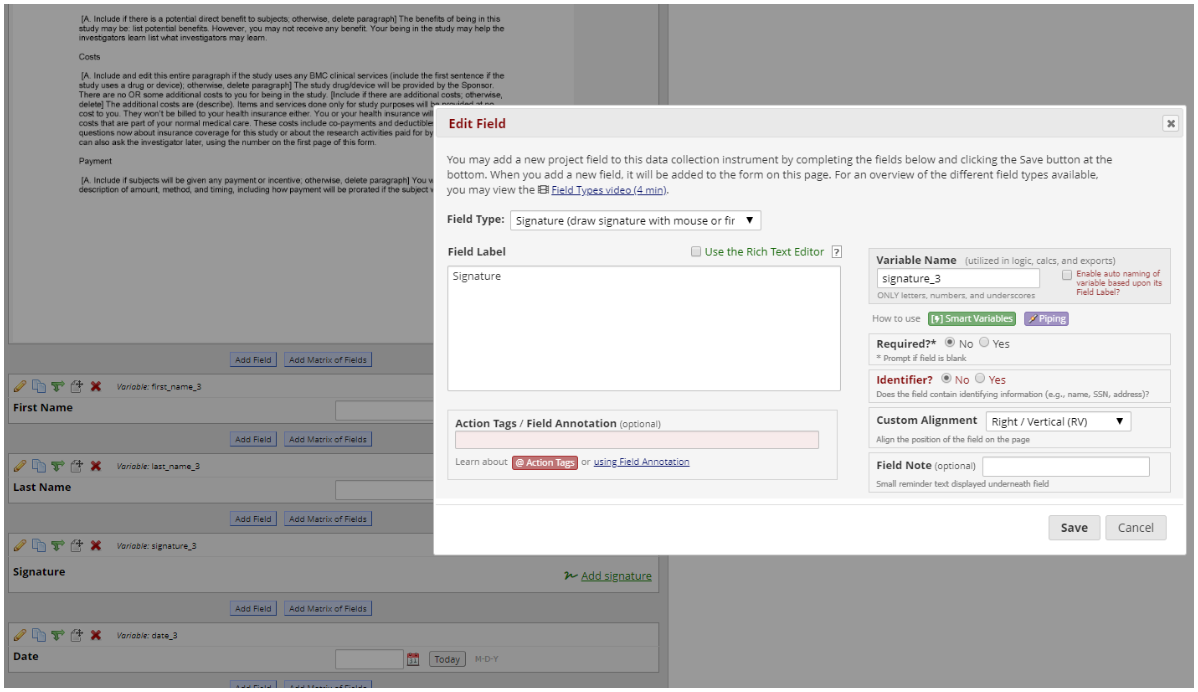
## III. Adding fields in e-Consent instrument

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

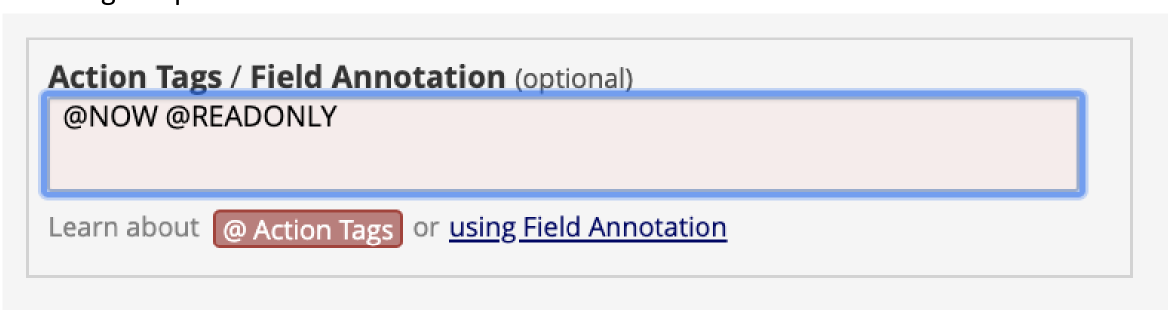
1. On the “Online Designer” tab, click on your consent form under the heading “Instrument name.”
2. Scroll down to the last page of your electronic consent form.
3. Click the “Add Field” blue button at the bottom of the page.
4. Select “Text Box…” from the dropdown menu.
5. Under the Field Label type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



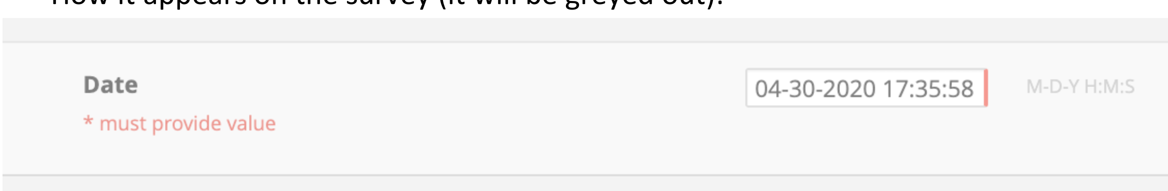

7. Continue and add Last name field following steps above.
8. Adding the Stylus Signature field is optional but is recommended as it offers an experience similar to providing a physical signature. In Field type, choose “Signature…” from the dropdown menu and proceed accordingly.
   8.1 If you are adding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



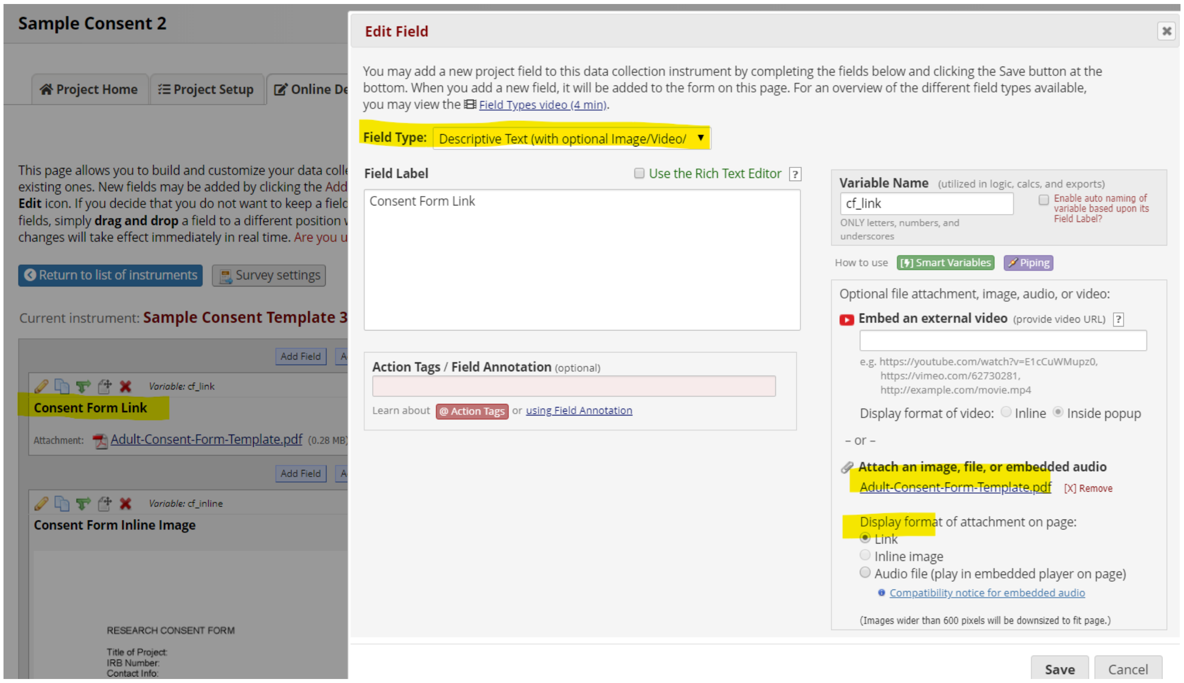

9. Now to add a date field, choose "Add field" blue button. Under "Field Type", choose "Text Box." Complete "Field Label" and "Variable Name." Under "Validation?" choose a date option from the dropdown menu. We recommend that you use the "Datetime w/ seconds" option (e.g "Datetime w/ seconds (M-D-Y H:M:S)).
   9.1 In addition, under "Action Tags/Field Annotation," add the following Action Tags: @NOW and @READONLY. This causes the date field to be automatically generated and un-editable, reducing the potential for error



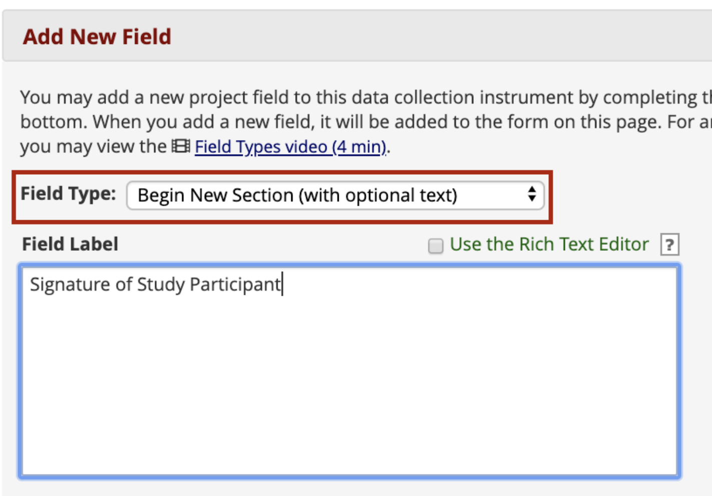

How it appears on the survey (it will be greyed out):




   9.2 Complete additional fields as necessary.
10. You may also elect to set up a file download field, to allow the participant to download a hardcopy of the blank consent form.



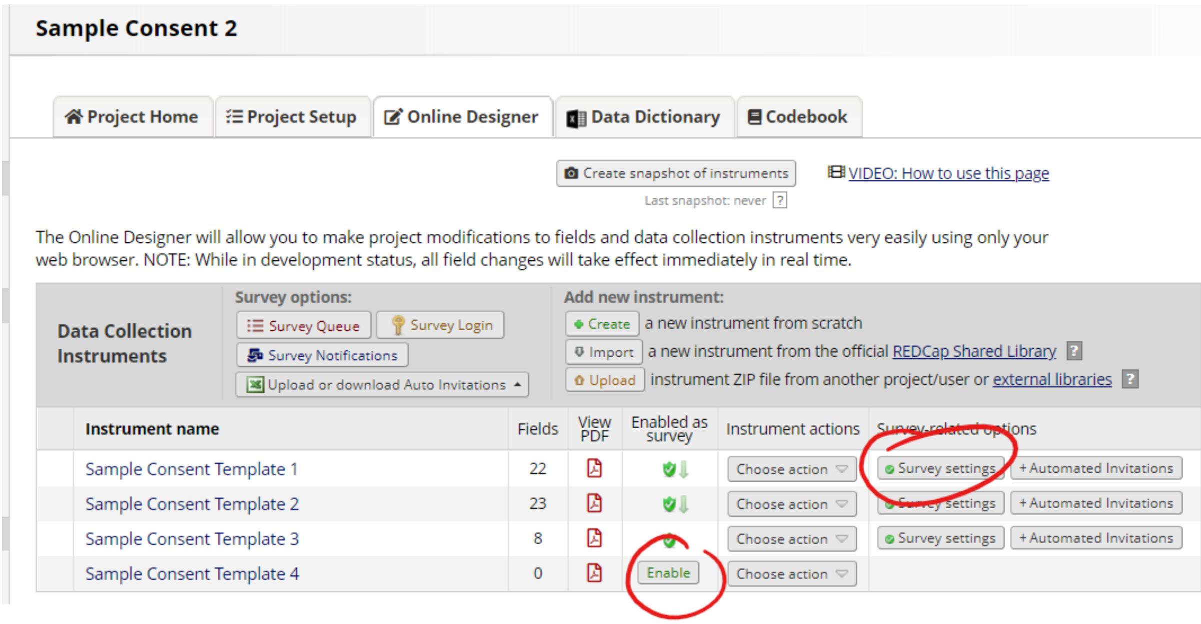

11. To break up the sections, add a heading prior to the participant's signature section. Click the "Add field" button and under "Field Type" choose "Begin New Section (with optional text)"



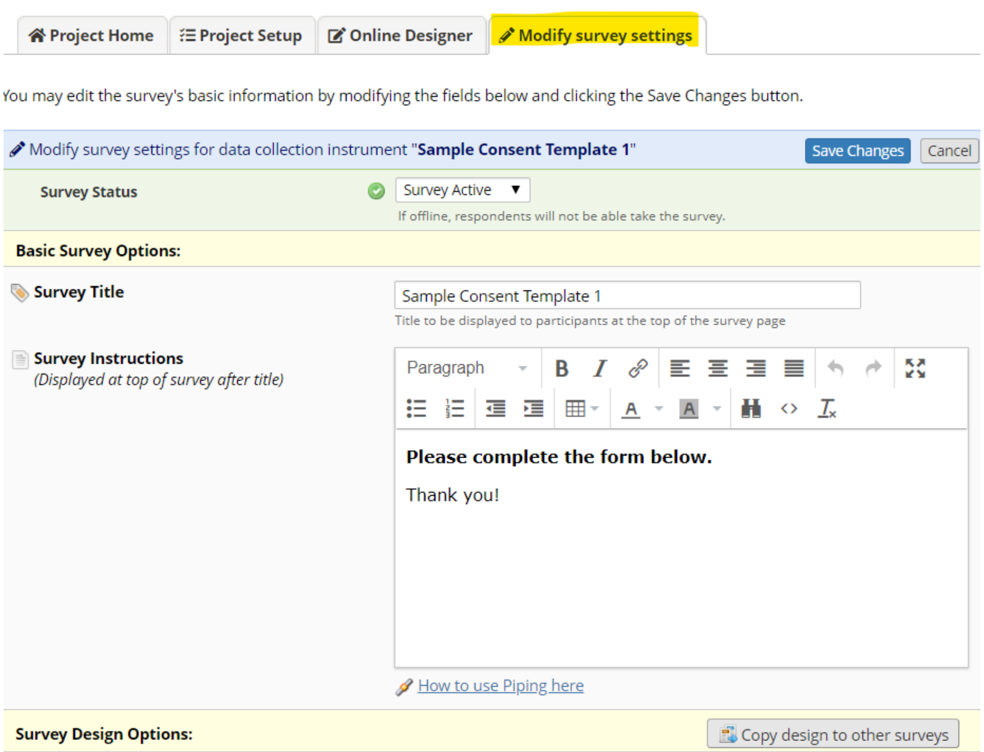

How it will look:

## IV. Enabling survey feature and updating survey settings

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




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




3. Scroll down to “Survey Termination Options” at the bottom of the survey settings page. Next to “Survey Completion Text”, provide the text you want to show to the participant after he/she

provides an electronic signature. Then click the "Save Changes" blue button on the bottom of this webpage.

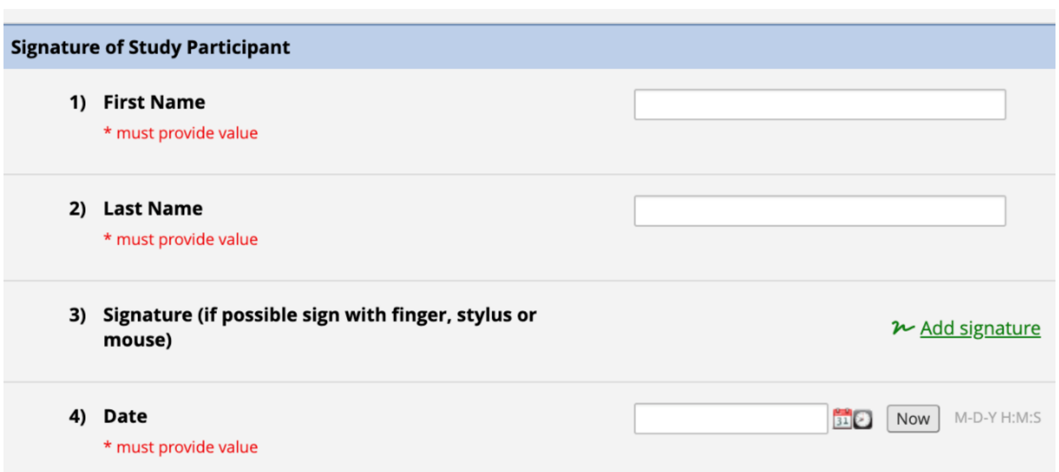
3.1 For example:

"Thank you for your participation in the research study:
[Name of Study]
If you have any questions, please contact:
[Study Contact Name]:
[insert phone number xxx-xxx-xxxx and/or email xxxx@bu.edu or xxxx@bmc.org]

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

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

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


**Signature of Study Participant**

1) **First Name**
* must provide value

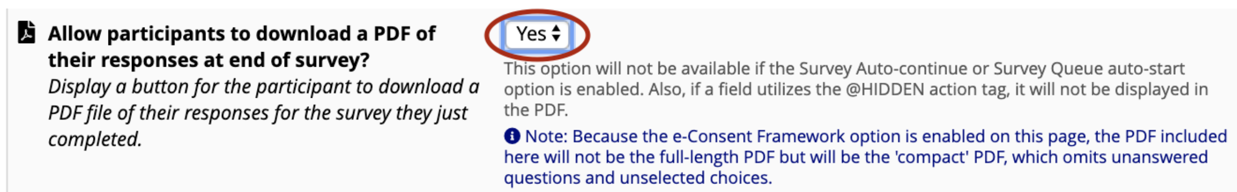
2) **Last Name**
* must provide value

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.


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





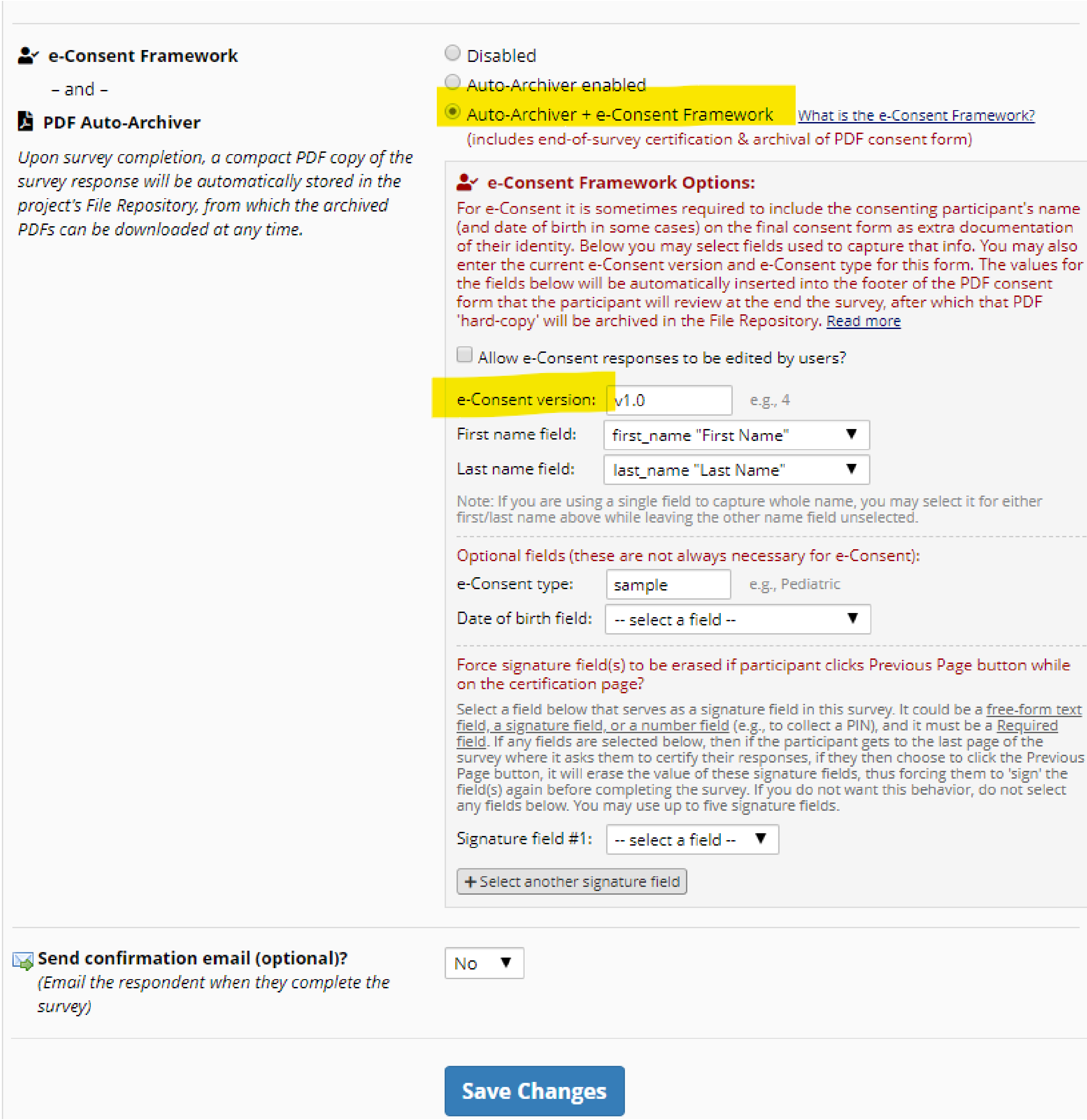
5. For e-consent instruments the e-Consent Framework must be turned on.

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

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

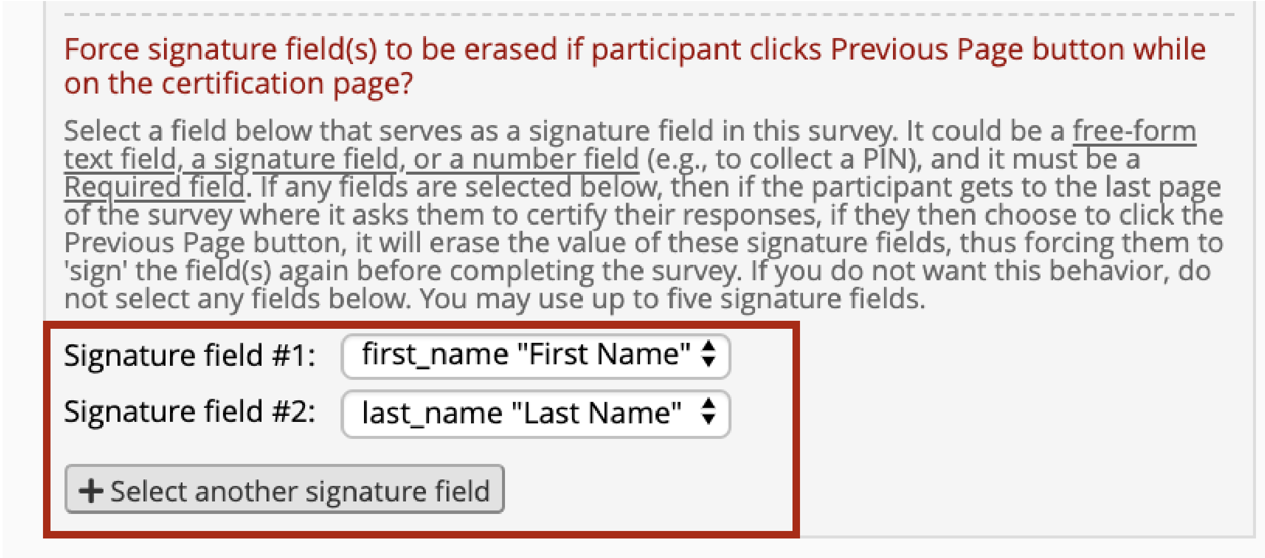
5.2 IMPORTANT: The "Allow e-Consent responses to be edited by users?" should NOT be checked off.

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



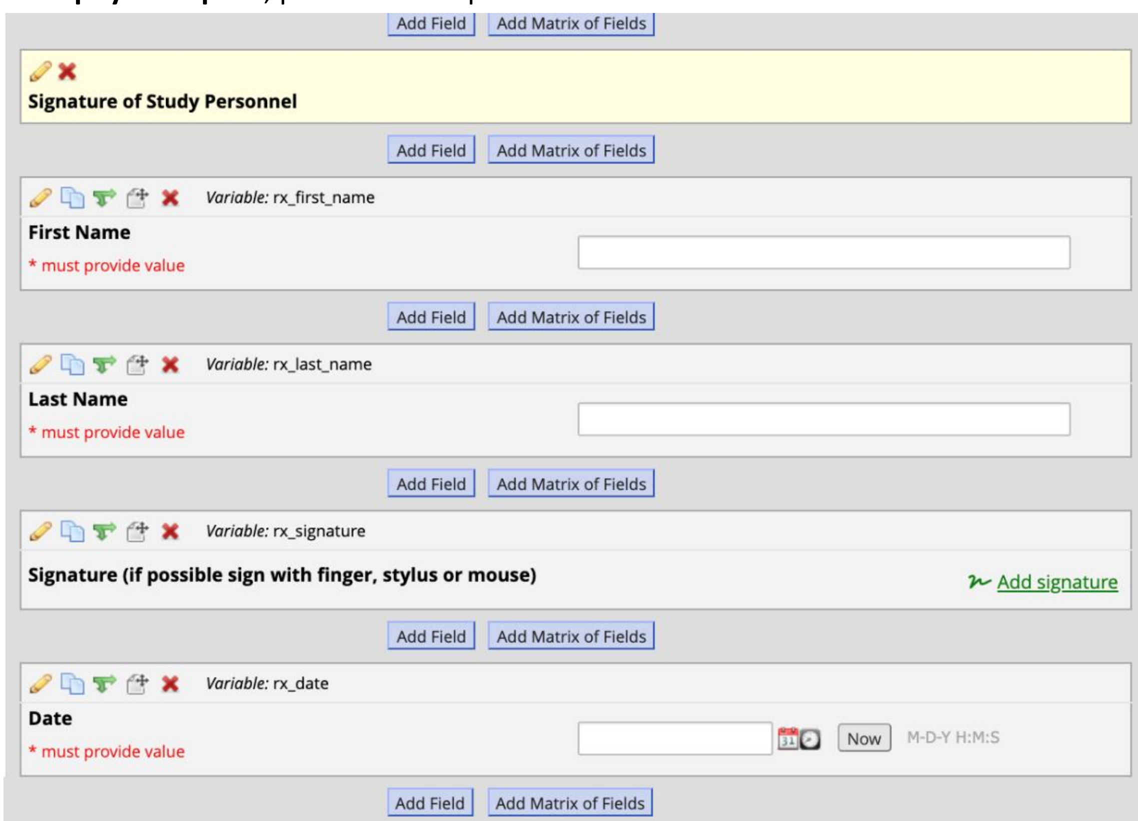

5.4 Enable signature erasing feature: under the "Force signature field(s) to be erased…," click on the "+Select another signature field" and then from the "select a field" dropdown menu, select the fields "First Name" and "Last Name." This feature will erase those two data entry fields if the participant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

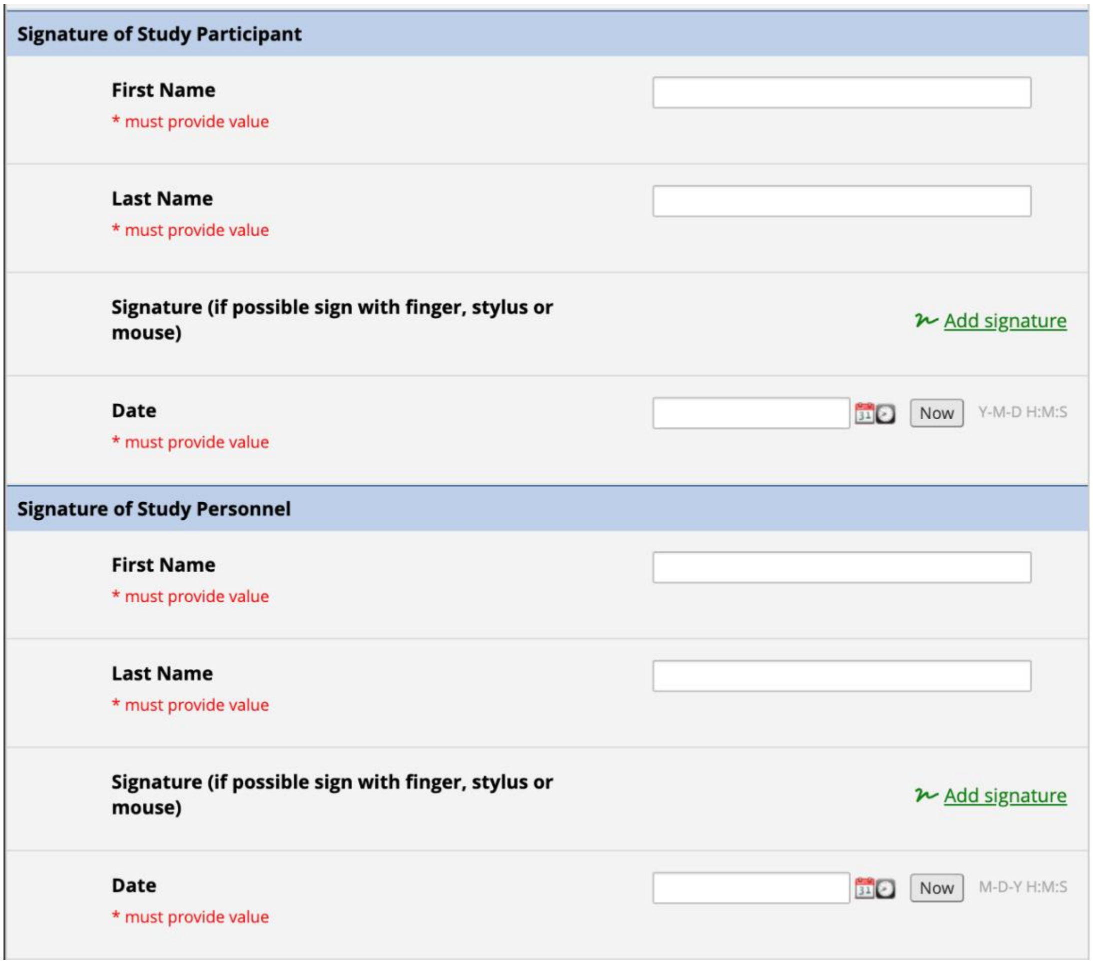
5.4.1 NOTE: Only required fields will appear as options in the drop-down menu. Therefore, since the "Signature" field (signature with finger/mouse/stylus) is an optional field, it will not be listed in the drop-down menu.




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

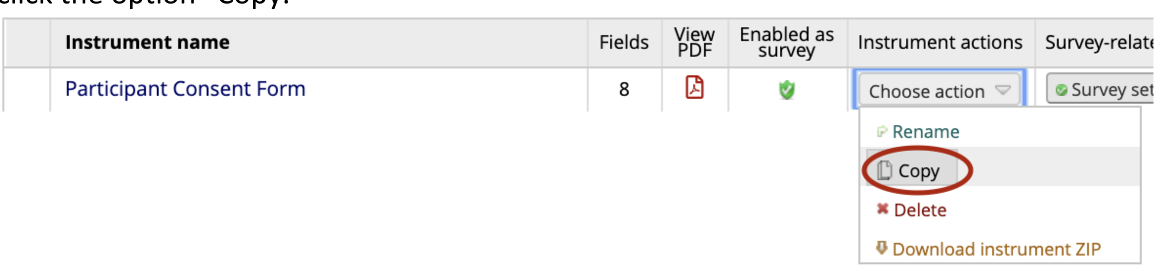
If you are conducting the consent discussion with the participant in-person, where you will each be in the **same physical space**, proceed as before, starting at section D.III, to create the section for "Signature of Study Personnel" within the same instrument (example images below). If you are conducting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



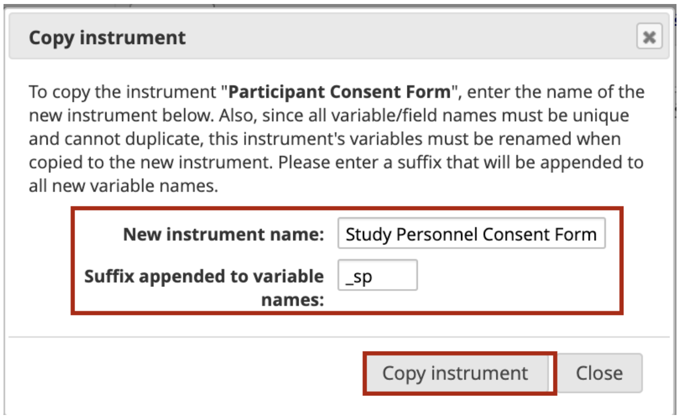



For contactless consenting, it is necessary to create two separate e-Consent instruments, one for the participant to sign and one for the study personnel to sign (these two consent instruments will both be tied to the same record ID). This can be easily done by just copying the first instrument and modifying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

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

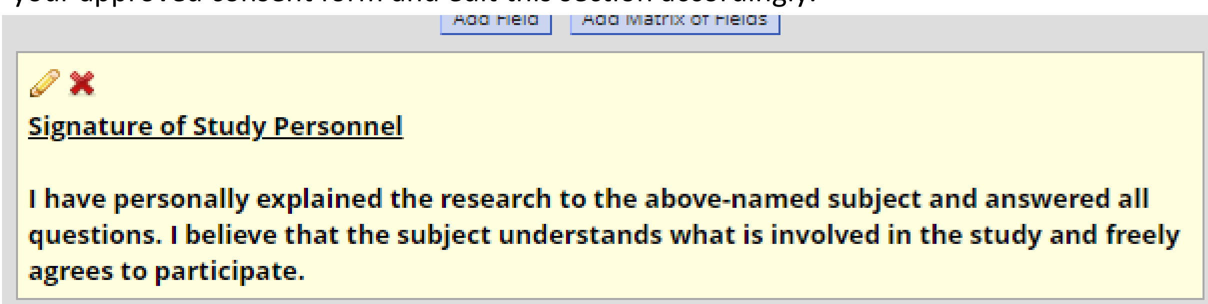



2. A window will pop-up. Update the fields accordingly and click the "Copy instrument" button.



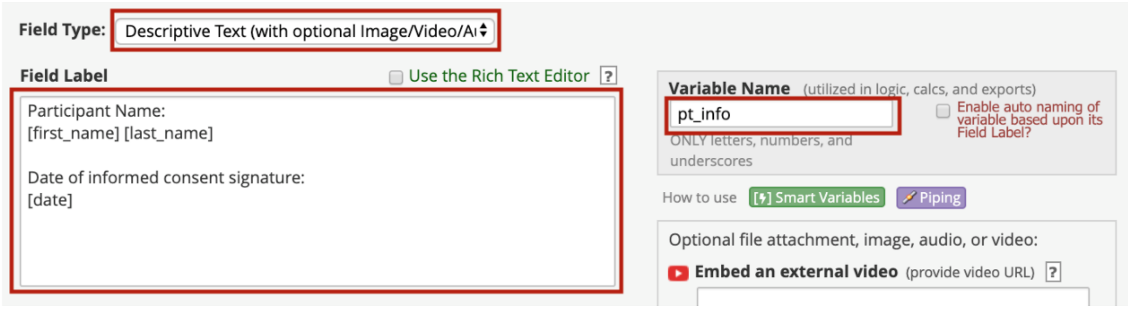


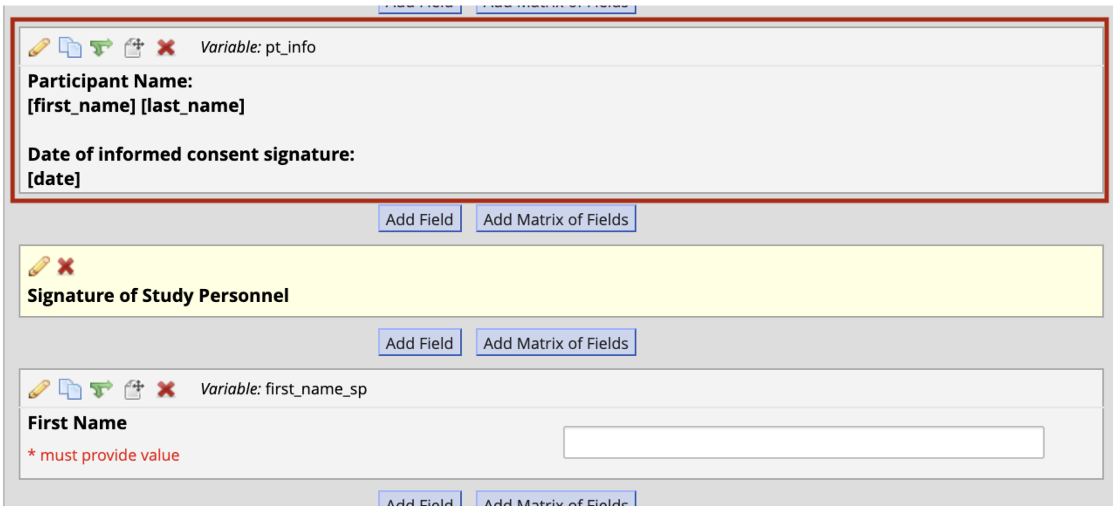
3. Click on the newly created “Study Personnel Consent Form” instrument to edit the fields accordingly. For example, the section title should be updated from “Signature of Study Participant” to “Signature of Study Personnel.”
4. If the study team chooses, they can remove the consent form pages and the copy of the pdf link of the consent for the Study Personnel Consent Form instrument. However, it is recommended that the following sentence, <u>as it is stated in your approved consent form</u>, 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.



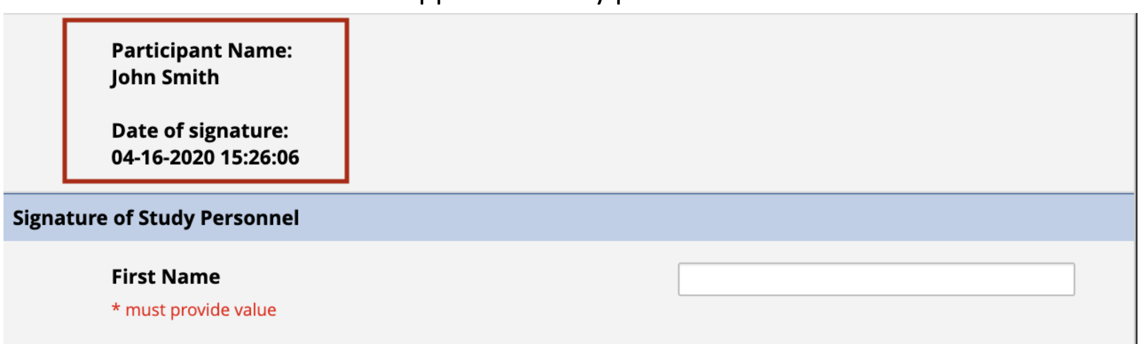

5. To ensure that the study personnel are signing the consent form for the correct participant, you can use the REDCap “piping” feature so that the participant’s information from the “Study Personnel Consent Form” instrument is auto-added. Piping pulls data from one instrument to another by referencing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

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

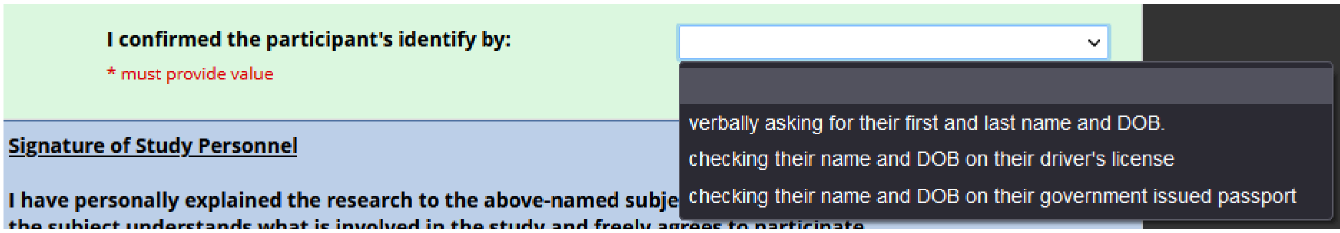



8. After the participant has completed the consent, study personnel should open their respective consent link. This is how it will appear to study personnel:



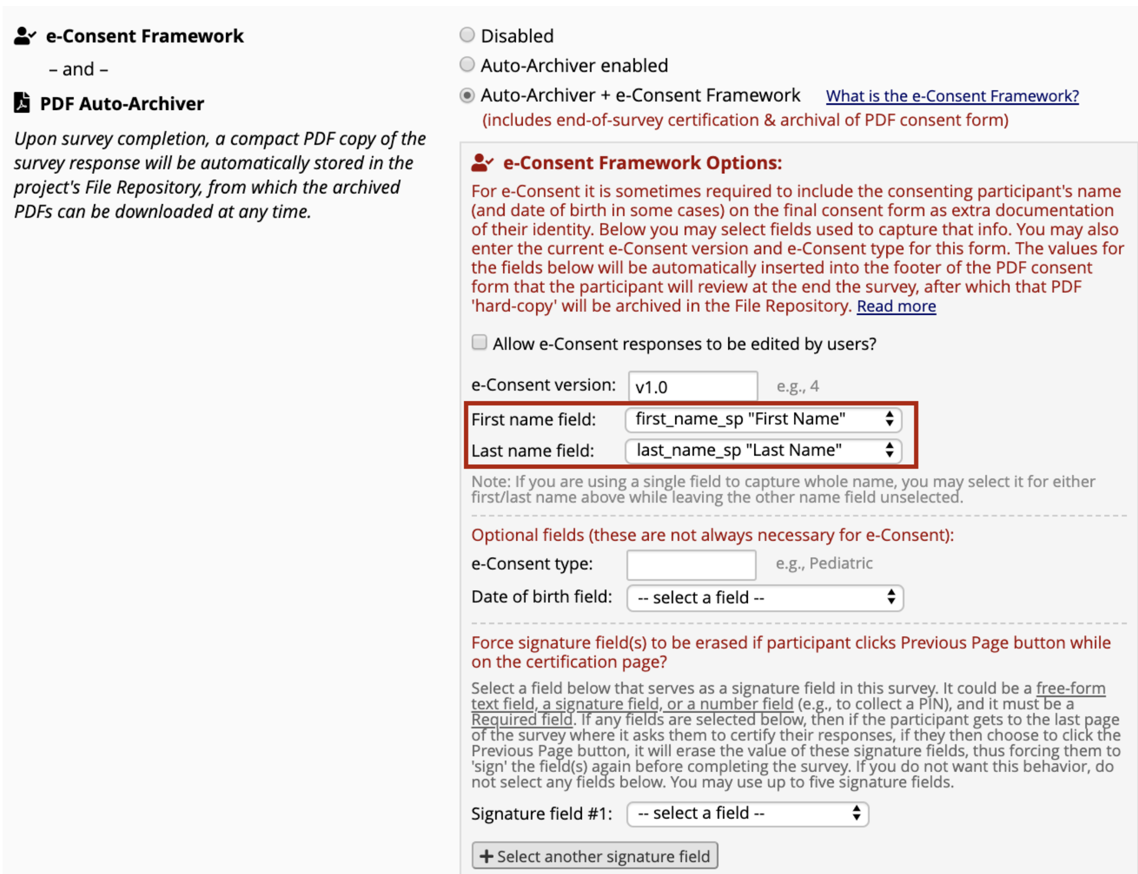

9. It is recommended that you add a field for “comments” or “notes,” where you can explain any situations that may come up during the consent process.
   9.1 Click “Add field.” Next to “Field Type” scroll through the options and select “Notes Box (Paragraph Text).” Give an appropriate variable name and click “Save.”
10. As part of consent documentation, it is recommended that you add a field where the study staff will document that they have confirmed the participant’s identity.
    10.1 The below image is just an example.




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

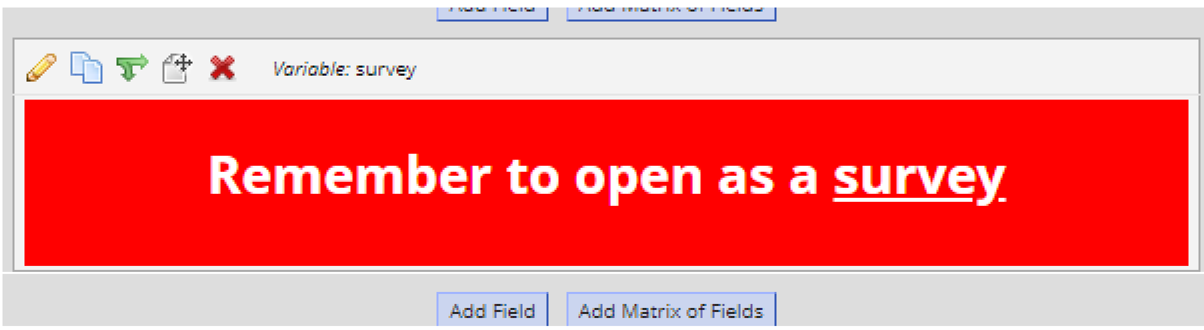
10.2.1 **MOST IMPORTANTLY**, you need to make sure to update the "First Name Field" and "Last Name Field" on the e-consent framework setting so that they refer to the variable names from the "Study Personnel Consent Form" instrument.

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



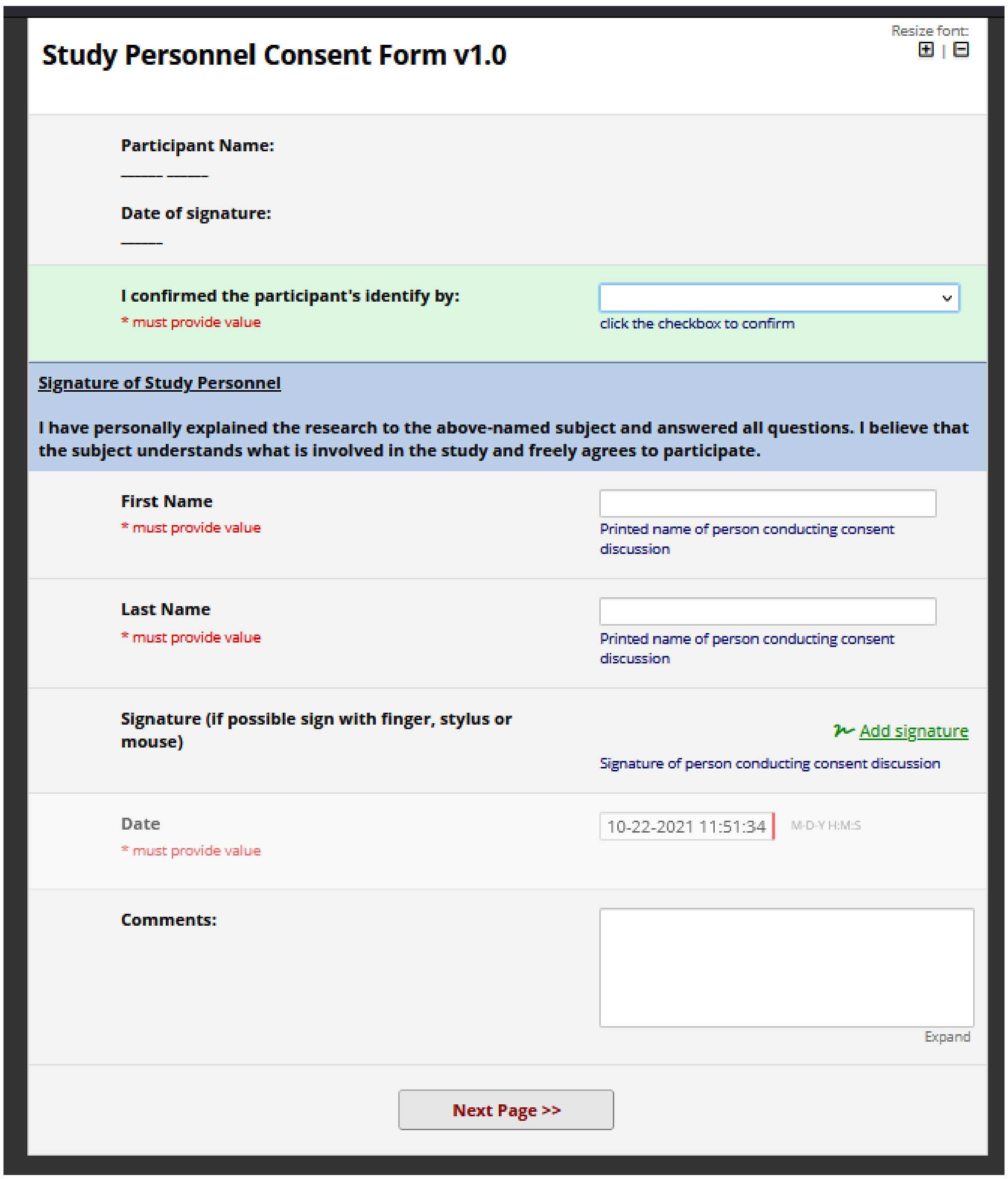

11. Since the e-consent framework is turned on, the study personnel consent form must be completed as a survey for the file to be appropriately archived once completed.

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




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

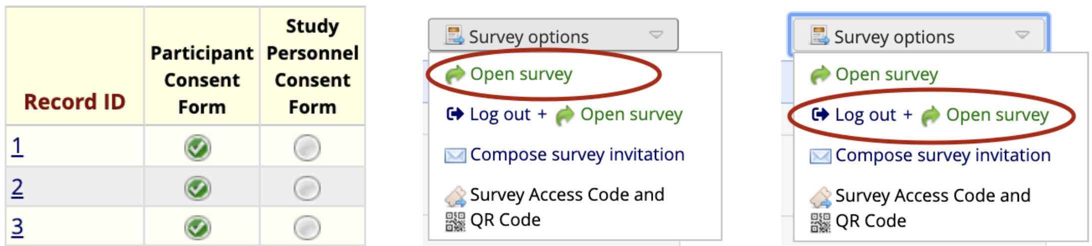
12. The overall survey for the Study Personnel Consent Form will look like this:



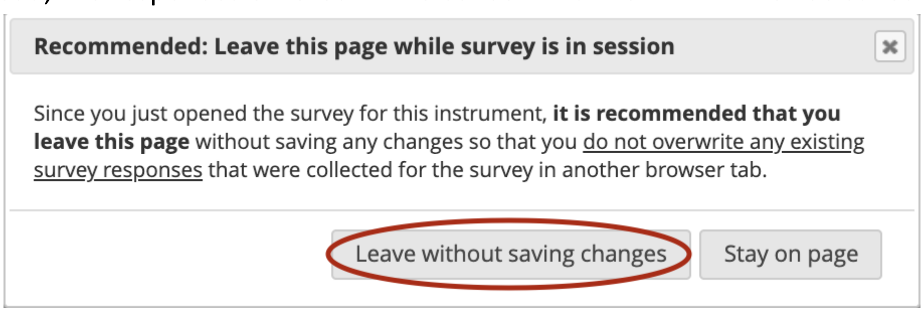
## VI. Completing the Study Personnel Consent Form – Reminder for Contactless Consent

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

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




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

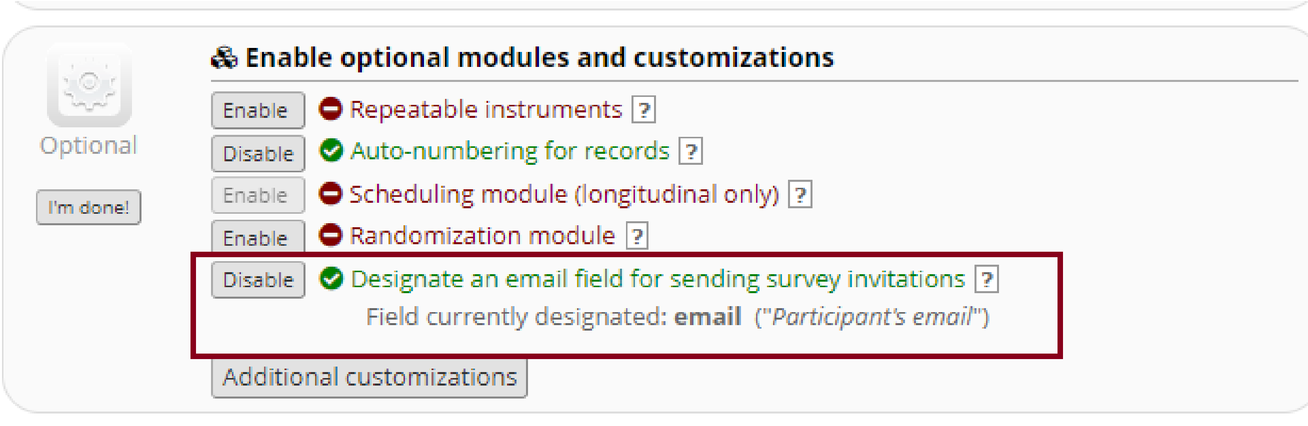



4. If you chose, "Log out + Open survey," **this will log you out of REDCap and direct you to the consent form to complete as a survey.** This is the safer method since it guarantees that changes made to the consent are saved and avoids the risk of not saving the changes unlike the other option noted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

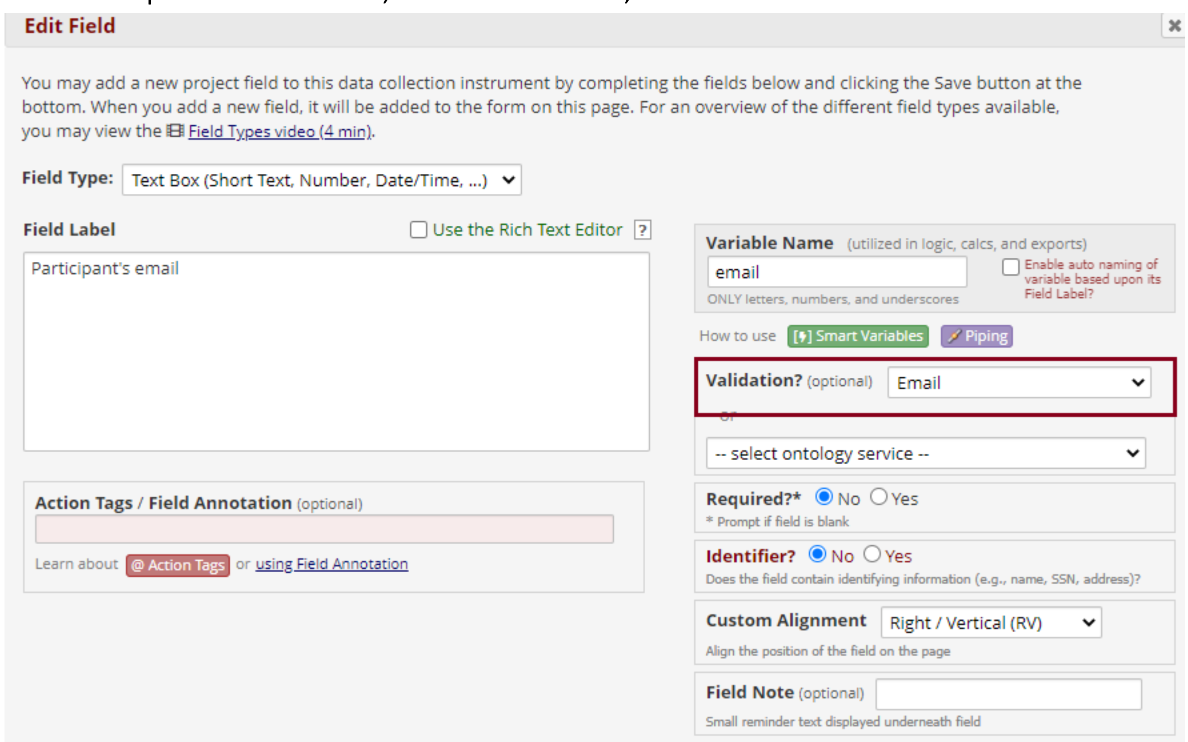
## VII. Creating the Participant Information Instrument (Creating password for consent link and Using Survey Log-in feature)

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

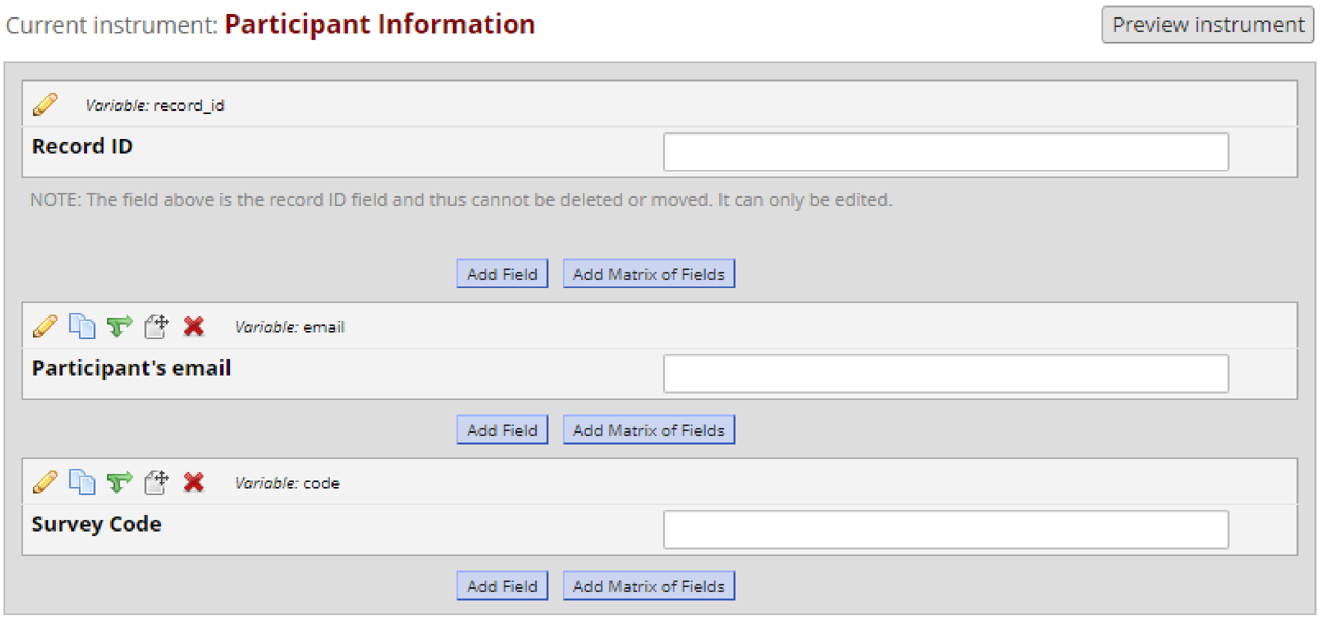
1. Under “Enable Optional modules and customizations” enable “Designate an email field for sending survey invitations.”



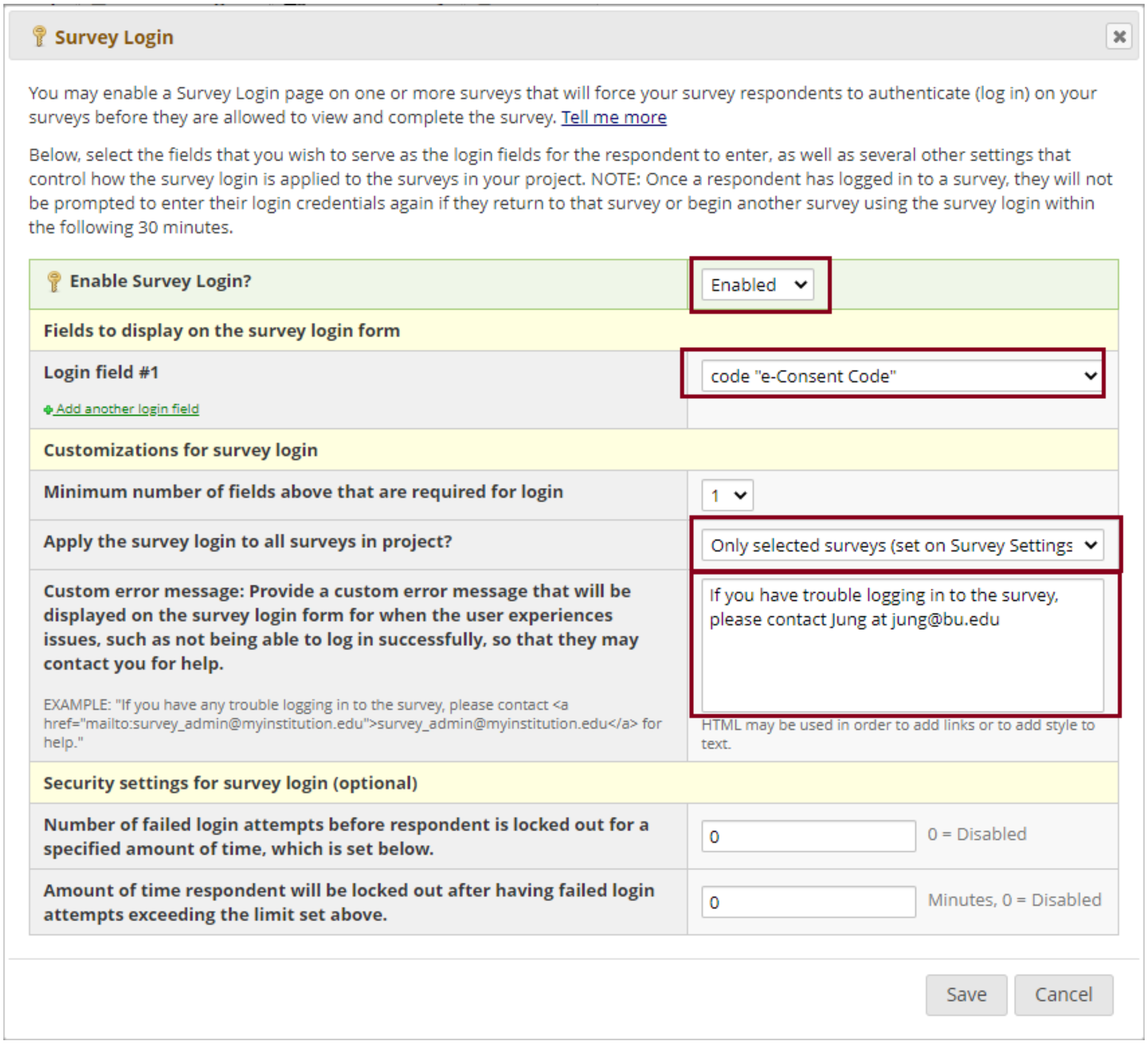

2. Go to “Online Designer” and click “create a new record.” Name this instrument something like “Participant Information.” This is where you will enter the participant’s email and code.
3. Open the newly created instrument.
4. Click add field and add the two fields, “Participant’s email” and “e-Consent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




6. The completed instrument should look like this:




7. In “Online Designer” under “Survey options,” select “Survey Login.”
    7.1 The changes that must be made are marked in red in the picture and listed below.
        7.1.1 Enable the Survey Login.
        7.1.2 For “Login field #1,” select “e-Consent Code” field.
        7.1.3 For “Custom error message,” what is provided in the image below is just an example. Customize the message accordingly.
            7.1.3.1 For “Apply the survey login to all surveys in project,” select “Only selected surveys.”




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


## VIII. Setting up the Multi Signature Consent External Module

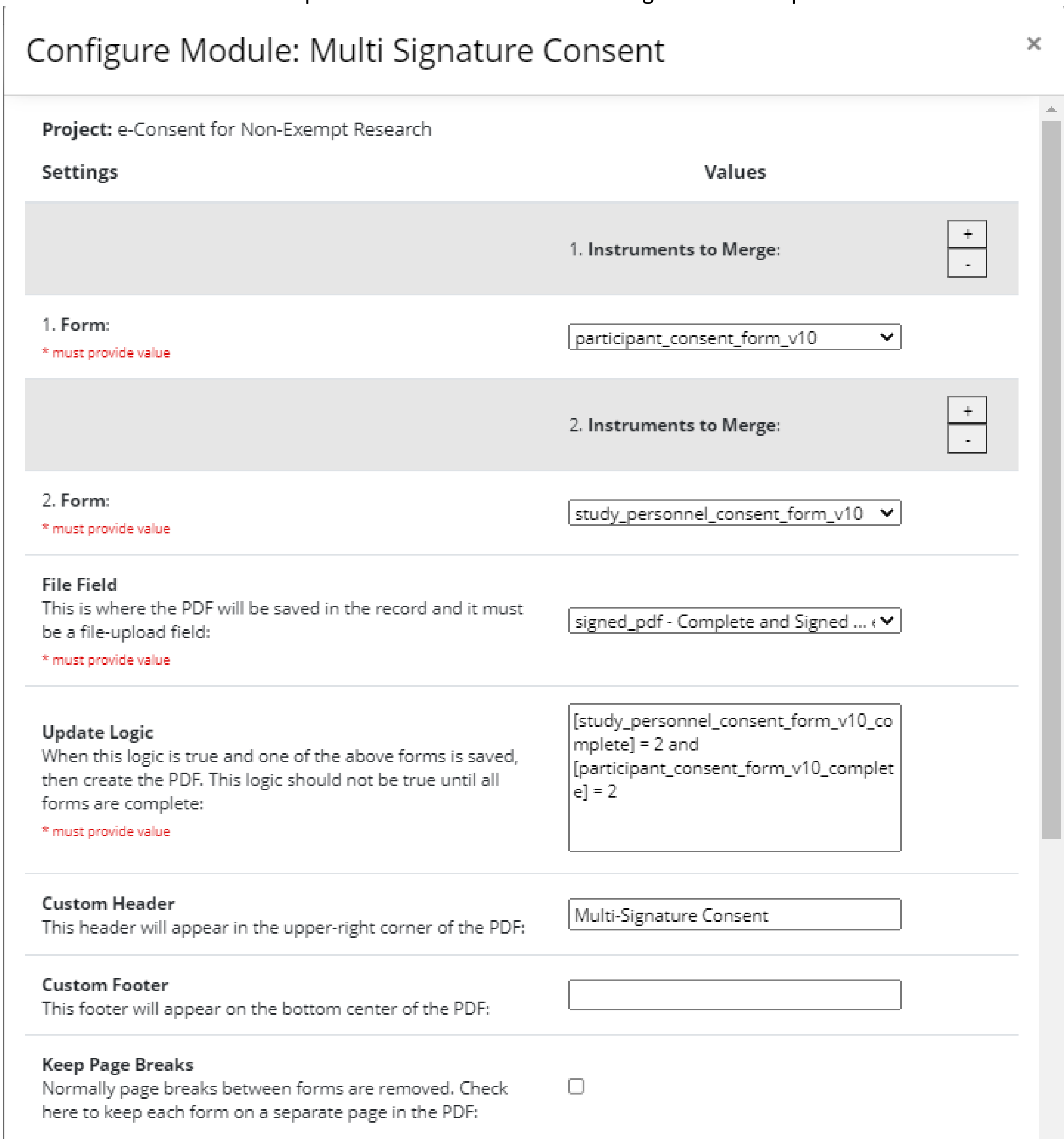
Multi Signature Consent module allows you to define one or more instruments to merge into one PDF file. When each defined instrument is complete, a combined PDF with signatures (and other fields) from those instruments is generated, saved to a file upload field in the project, and also to the file repository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

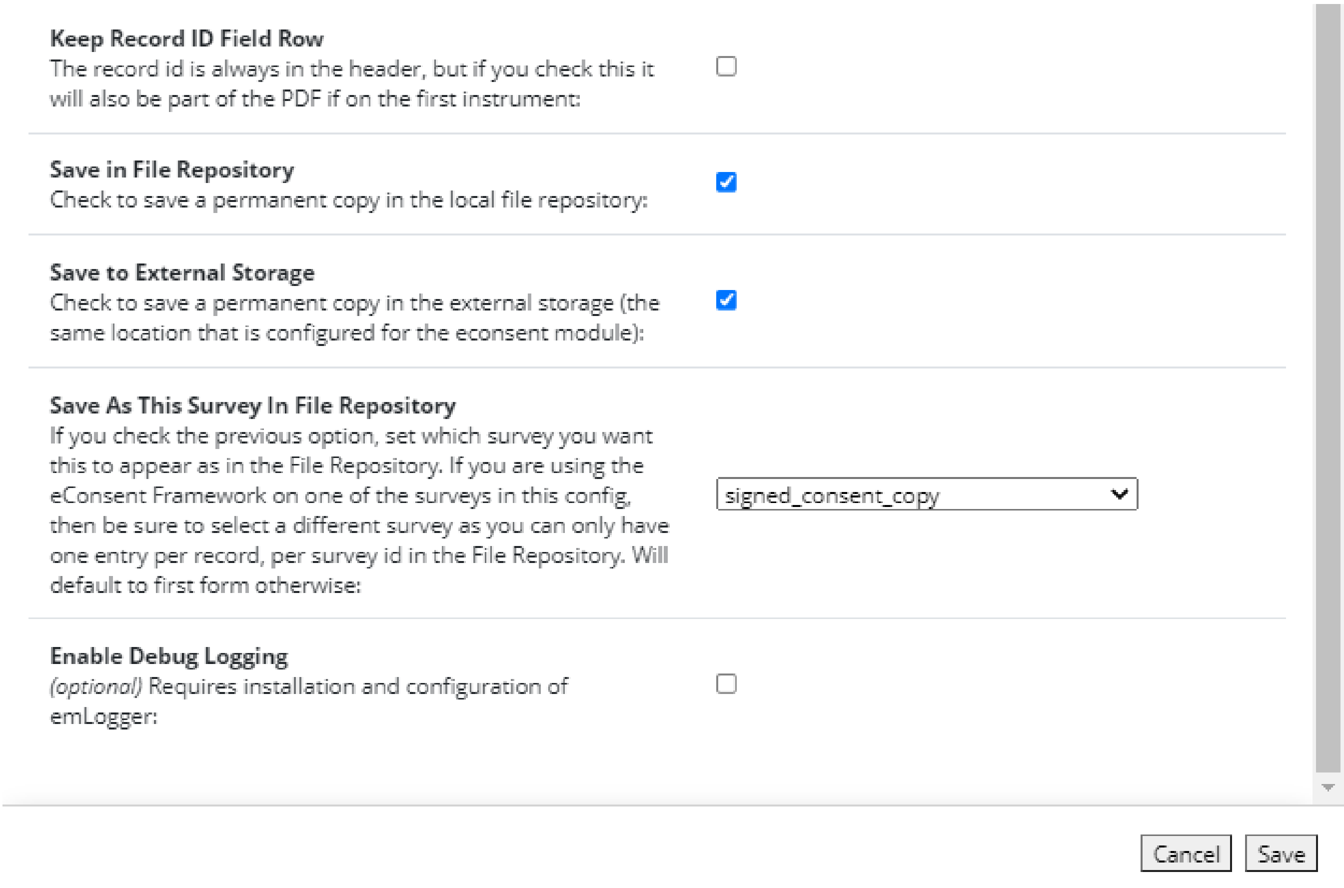
All modules need to be installed and enabled by a BUMC REDCap administrator. Please navigate to the External Modules, under the left Applications menu, and submit a request to have the Multi Signature Consent Module enabled or complete this form https://redcap.bumc.bu.edu/surveys/?s=F8W4LLXJRP.

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

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

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

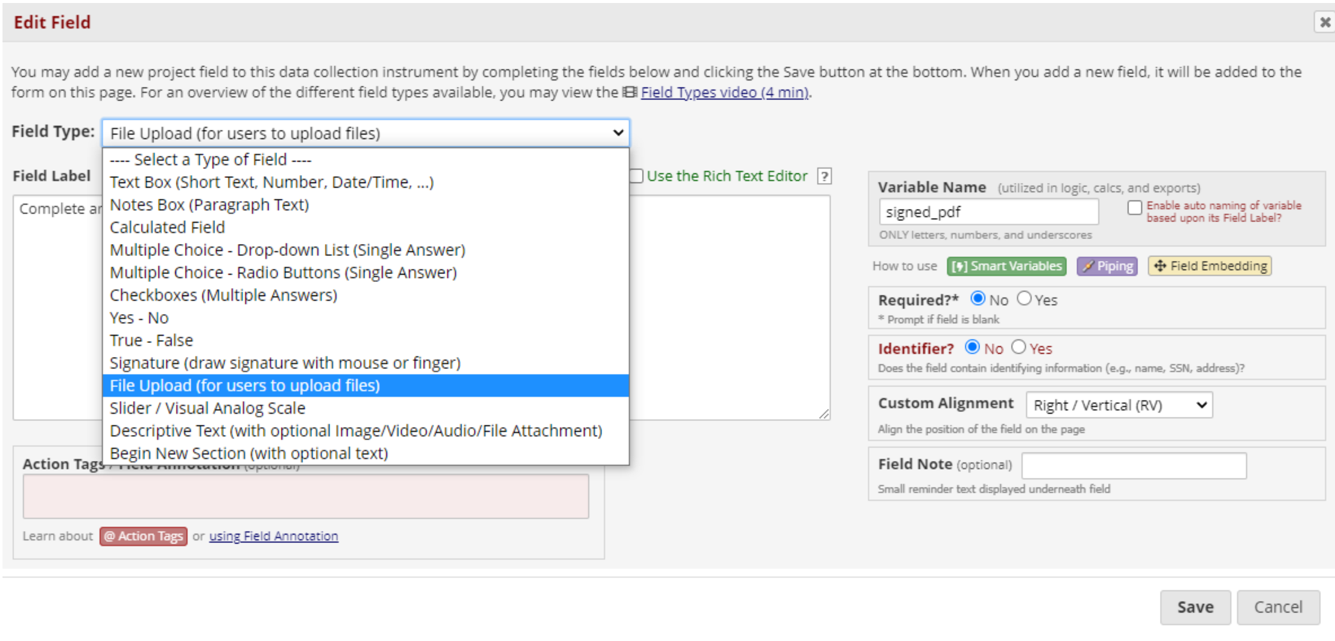


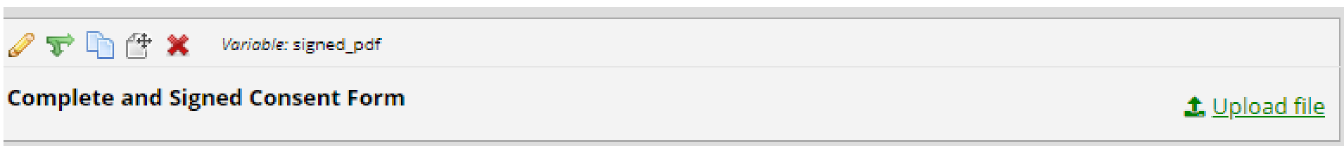



1. Create a new instrument and enable it as a survey. In the e-consent project template, we called it "Signed Consent Copy."

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

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



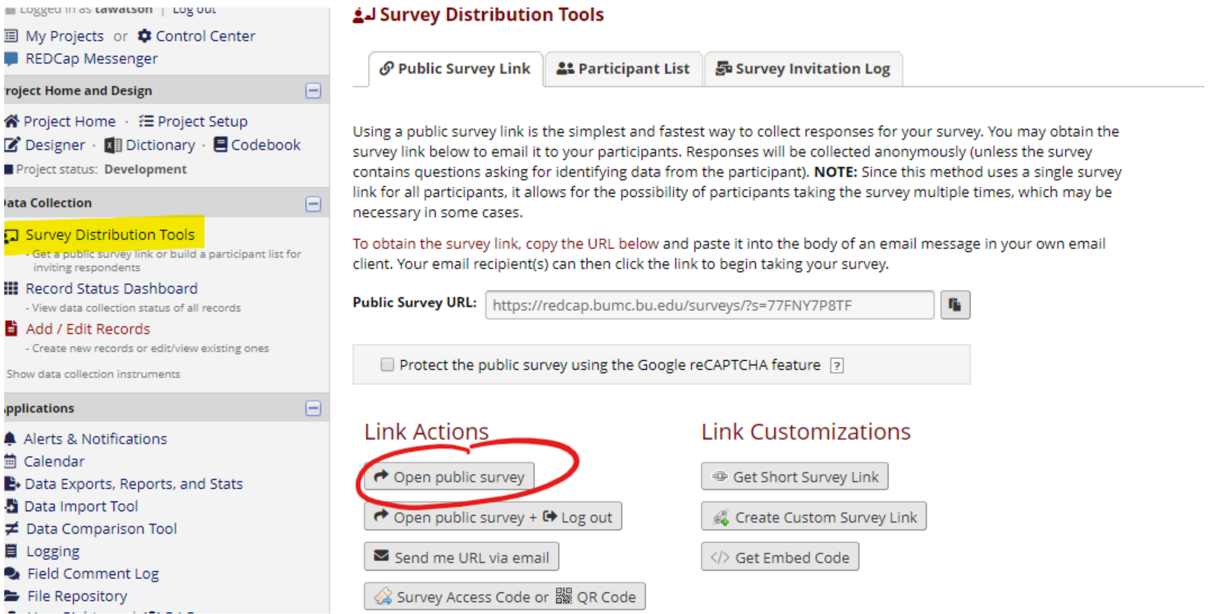




# Testing out your e-Consent

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

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

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



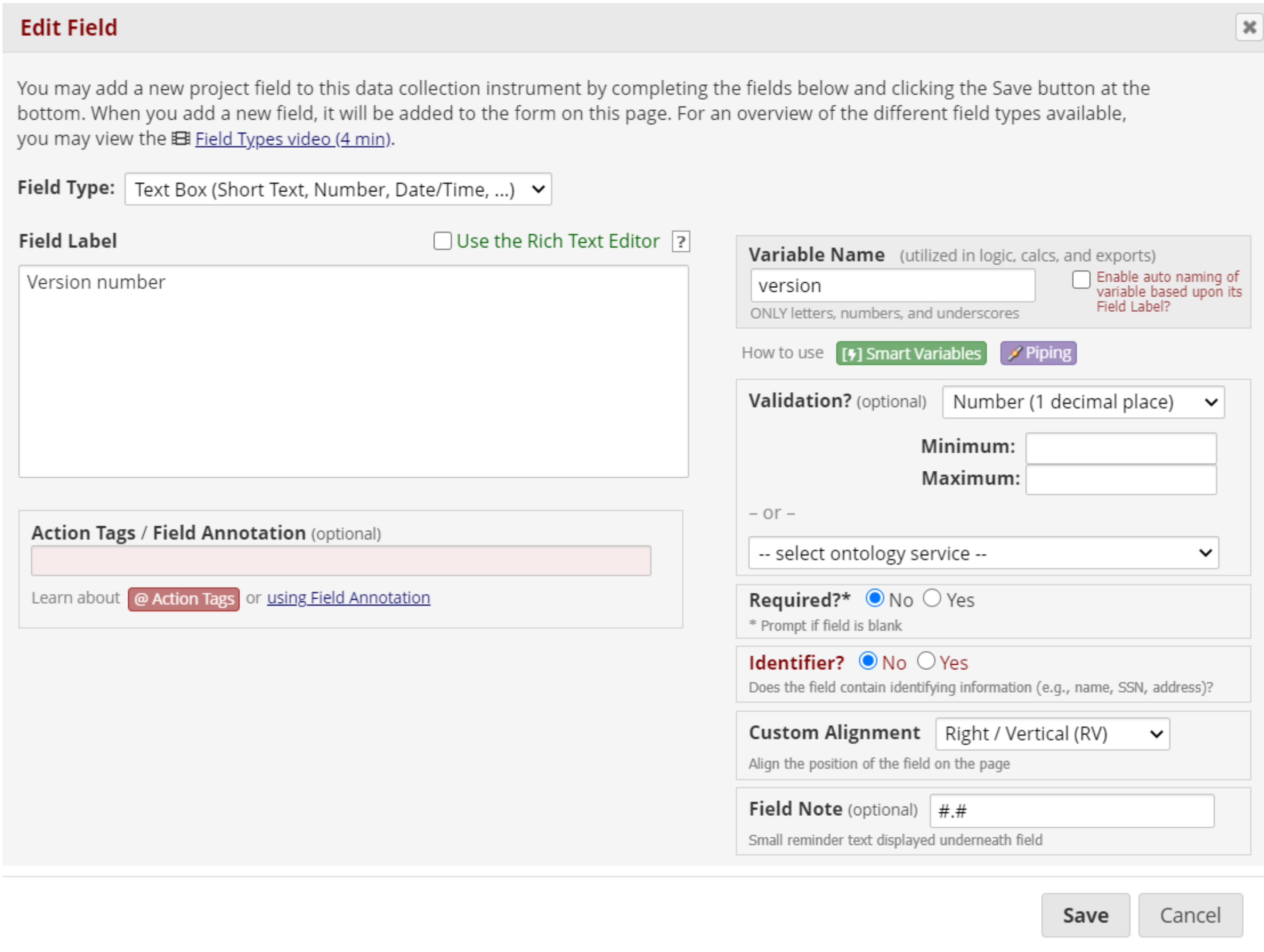

# Utilizing Automated Survey Invitation (ASI) to send out e-Consent survey

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

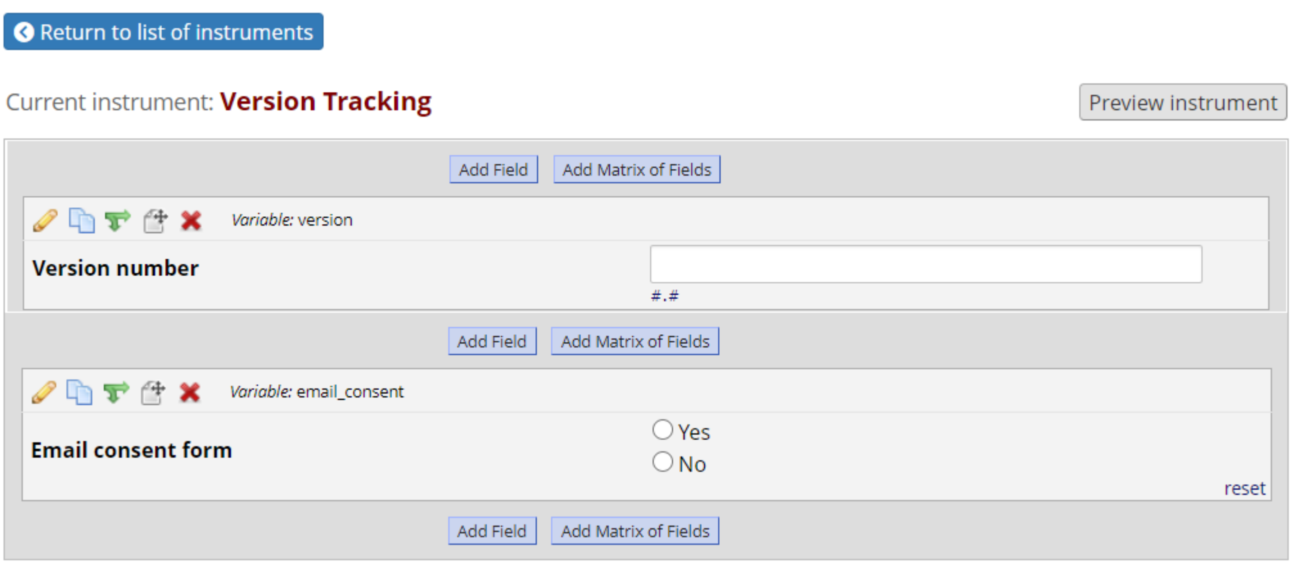
If you are utilizing Automated Survey Invitation (ASI), you need to set up a process to keep track of the informed consent versions. This is recommended in general even if you are not utilizing ASI in order to keep track of consent versions used.

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

1. Add a Text Box field to enter the informed consent version number.
   - 1.1 It is recommended that you add a validation option for this field because if there is a blank space next to the value entered, this space will be treated as a character. So the field value “1.0” is different from “1.0_” (the underscore represents the blank space).
     - 1.1.1 For the validation option, you can select “Number (1 decimal place).” So this field will have to be in the format “#.#”
       - 1.1.1.1 If this validation is not met, the user will get an error message.




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

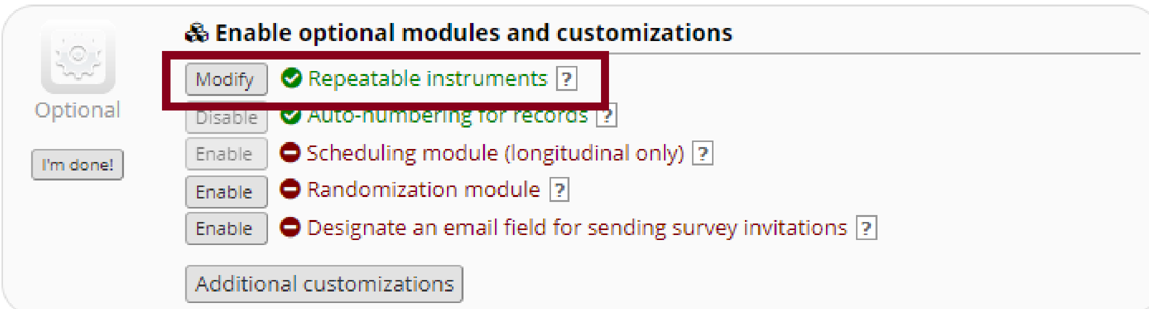



4. Proceed to the next section to enable this instrument as a repeatable instrument. This is a necessary step!

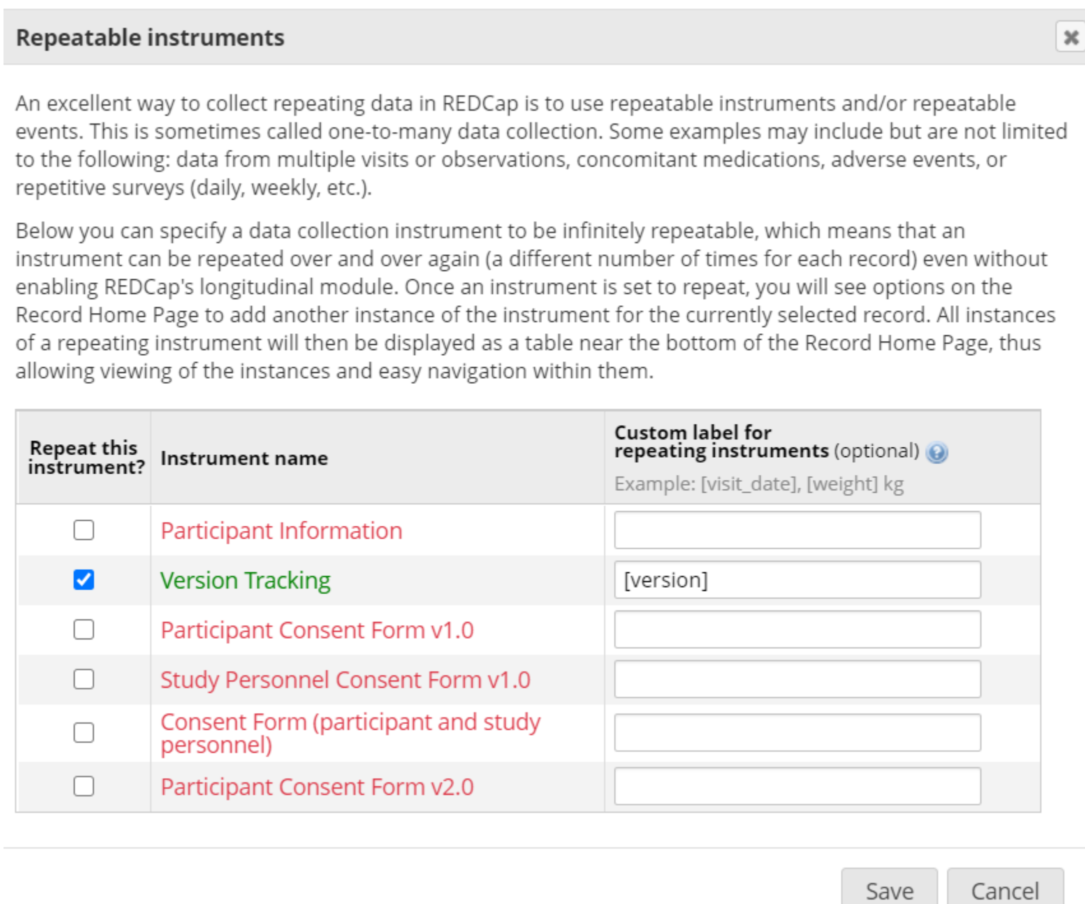
## II. Enabling repeatable instruments for Version Tracking instrument

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

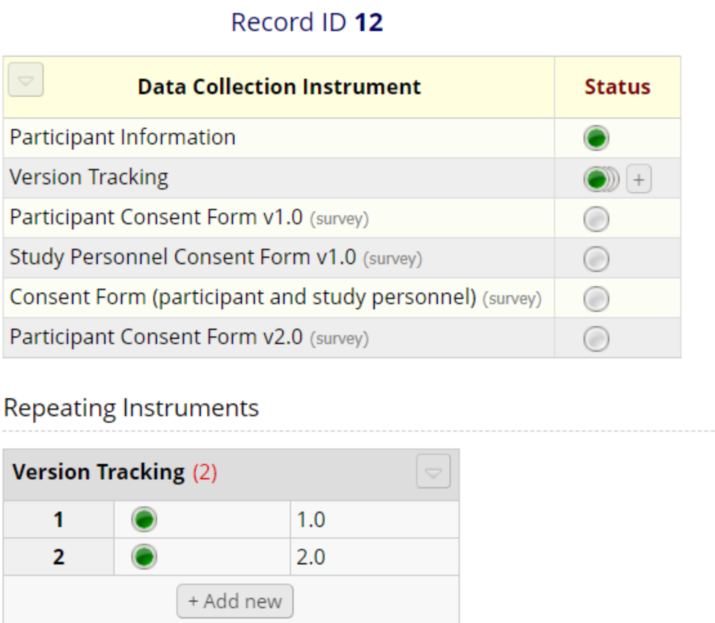
1. Go to the "Project Setup" page and under "Enable optional modules and customizations" click the "enable" button next to "Repeatable instruments."




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



3. 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]).

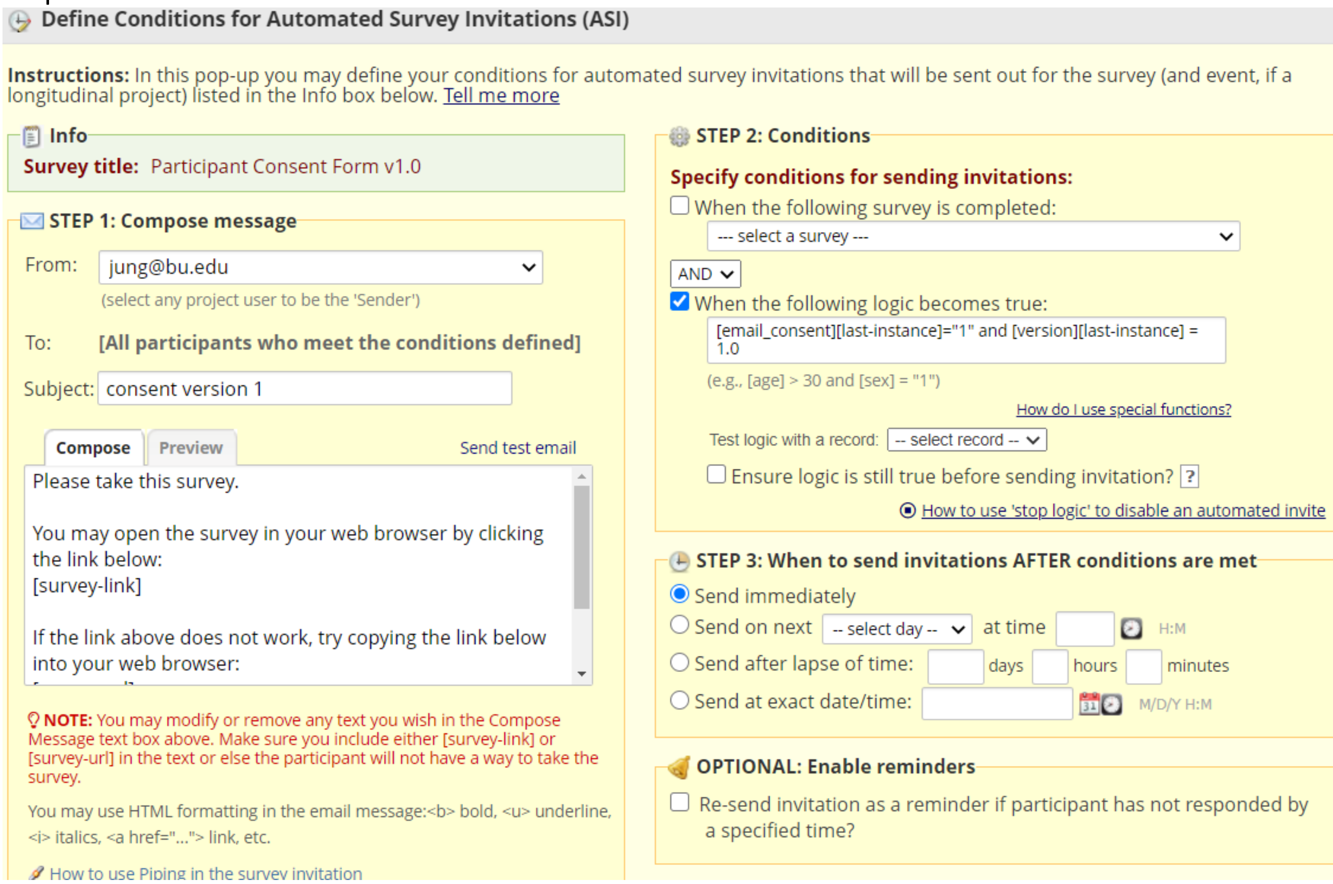



## III. Turning on Automated Survey Invitations (ASI)

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

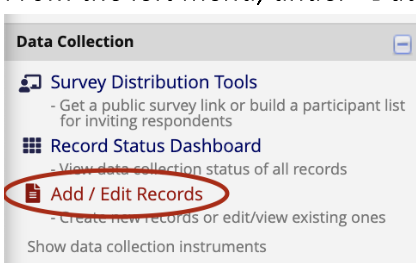
1. In Online Designer, under "Survey-related options," click on the button "Automated invitations."
2. Step 1: For the email subject line and body of the email, customize it for your study accordingly. Click on "Send test email" to see how the email will appear for the participant.
3. Step 2: Enter the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

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



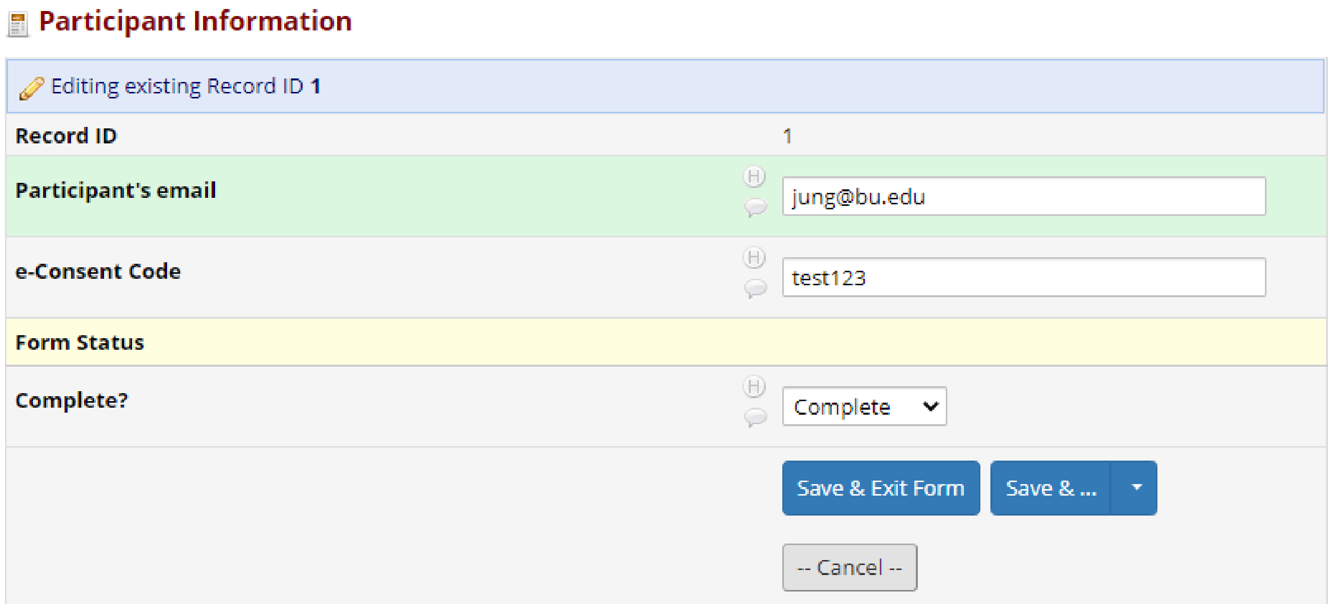

## IV. Sending out the e-consent invitation email

1. 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.
2. From the left menu, under "Data Collection" click on "Add/Edit Record" to create a new record.




3. 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.

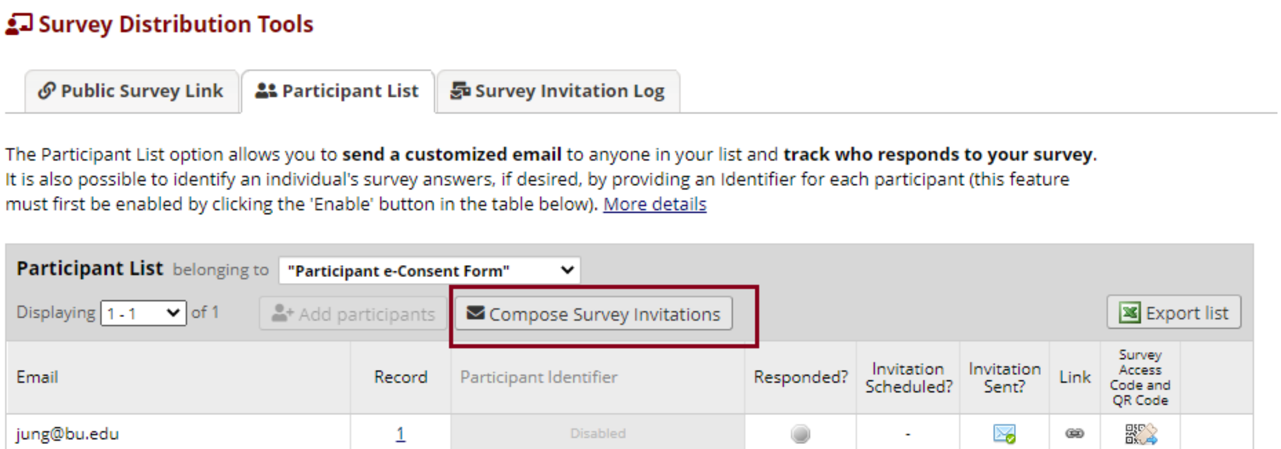

4. Click on the "Participant Information" instrument and enter the participant email and e-Consent code. Select "Complete" for form status and save the form.



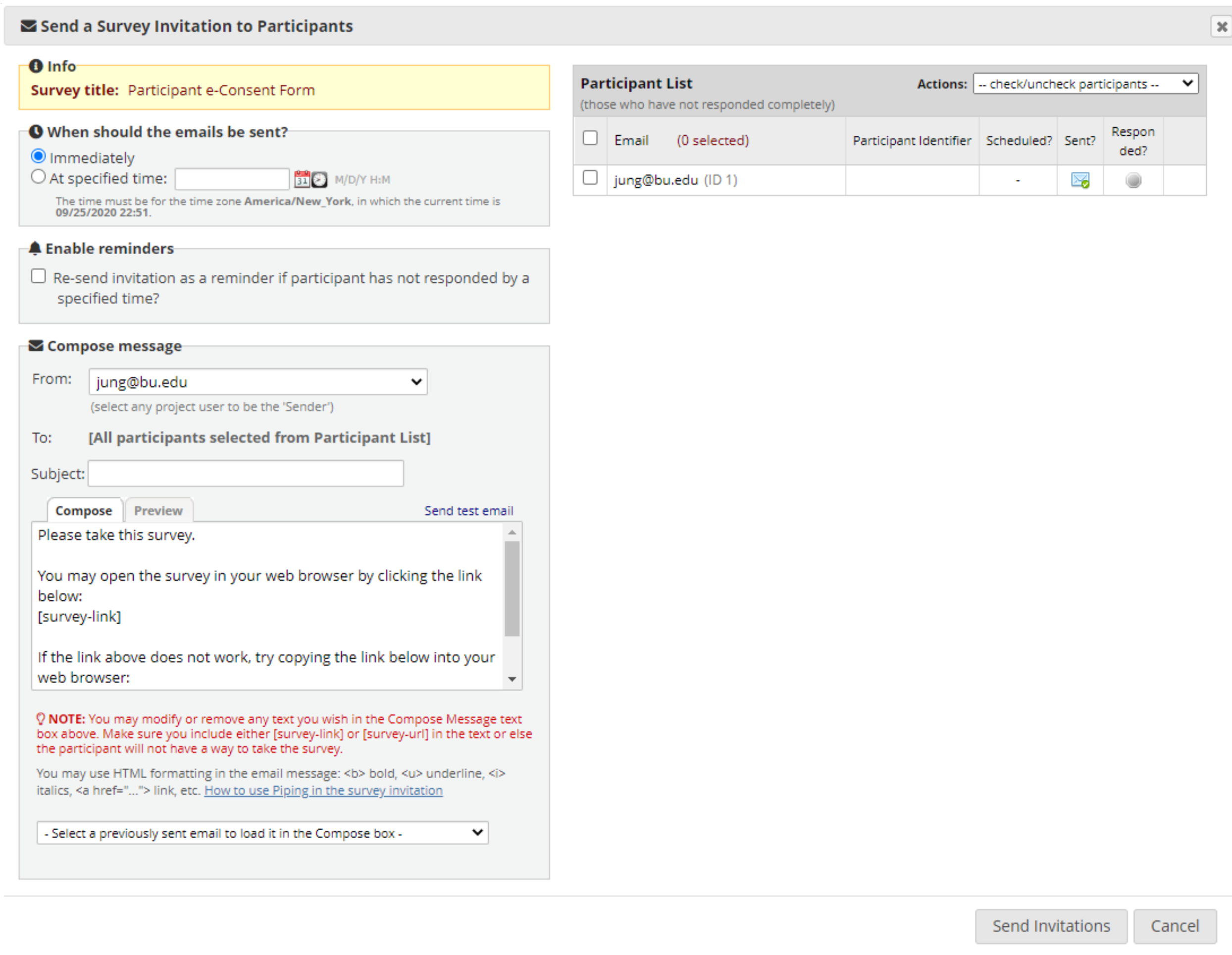

## Re-sending and troubleshooting survey invitation

### I. Re-sending the e-Consent invitation email

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

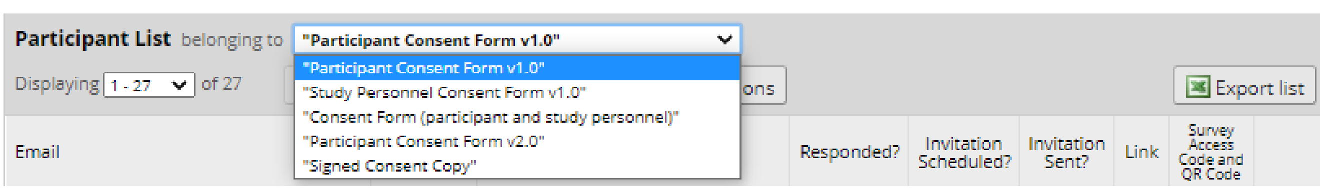



2. Under "Compose message," edit the subject line and body of the email accordingly. Do not delete the [survey-link] and [survey-url] smart variables.
3. Under "Participant List" select the record/email that needs the new invite and click "Send Invitations."

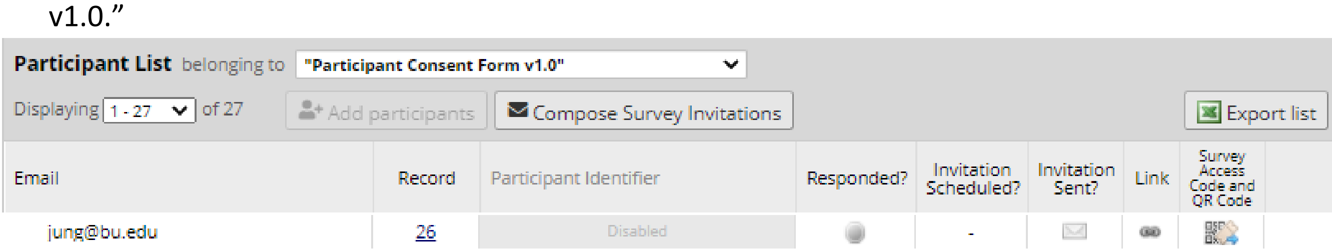



## II. Accessing survey (e-consent) link if having issue with survey invitation delay

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




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



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

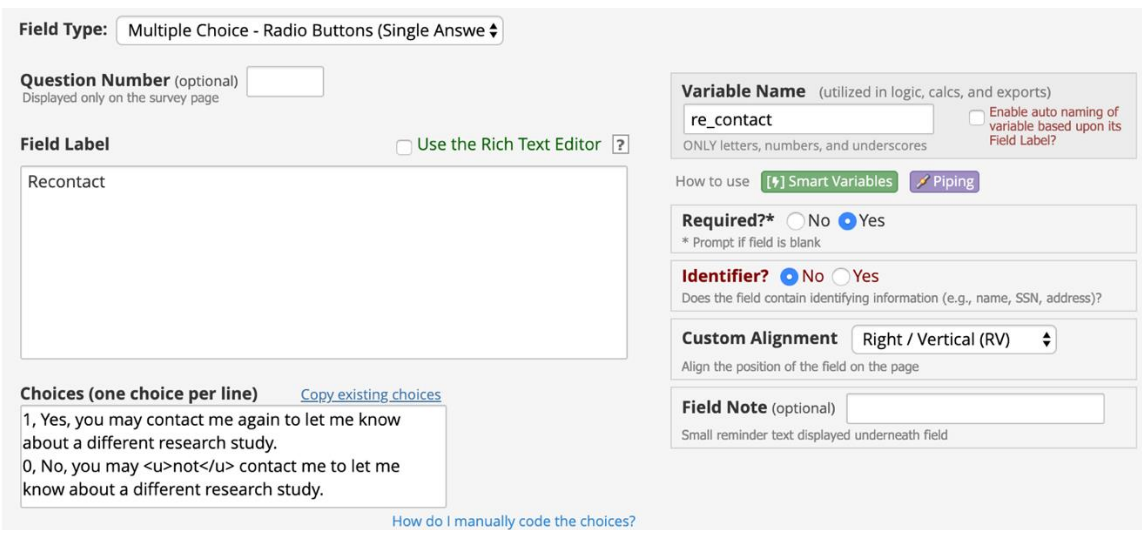
## What to do with updated/newly approved informed consent forms

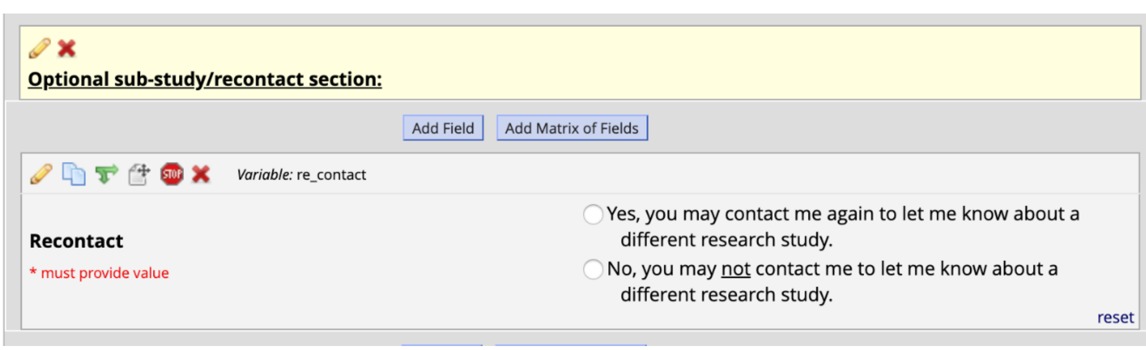
1. When you have an updated approved informed consent, create a NEW e-consent survey. This can easily be done by copying the original or previous e-consent instrument.
2. Replace the informed consent pdf link and the images of the informed consent form pages.
3. Go to the survey settings and update the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

## Additional Capabilities

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

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



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

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

____Yes ____No You may contact me again to ask for additional information related to this study

____Yes ____No You may contact me again to ask for additional biological samples related to this study

____Yes ____No You may contact me again to let me know about a different research study

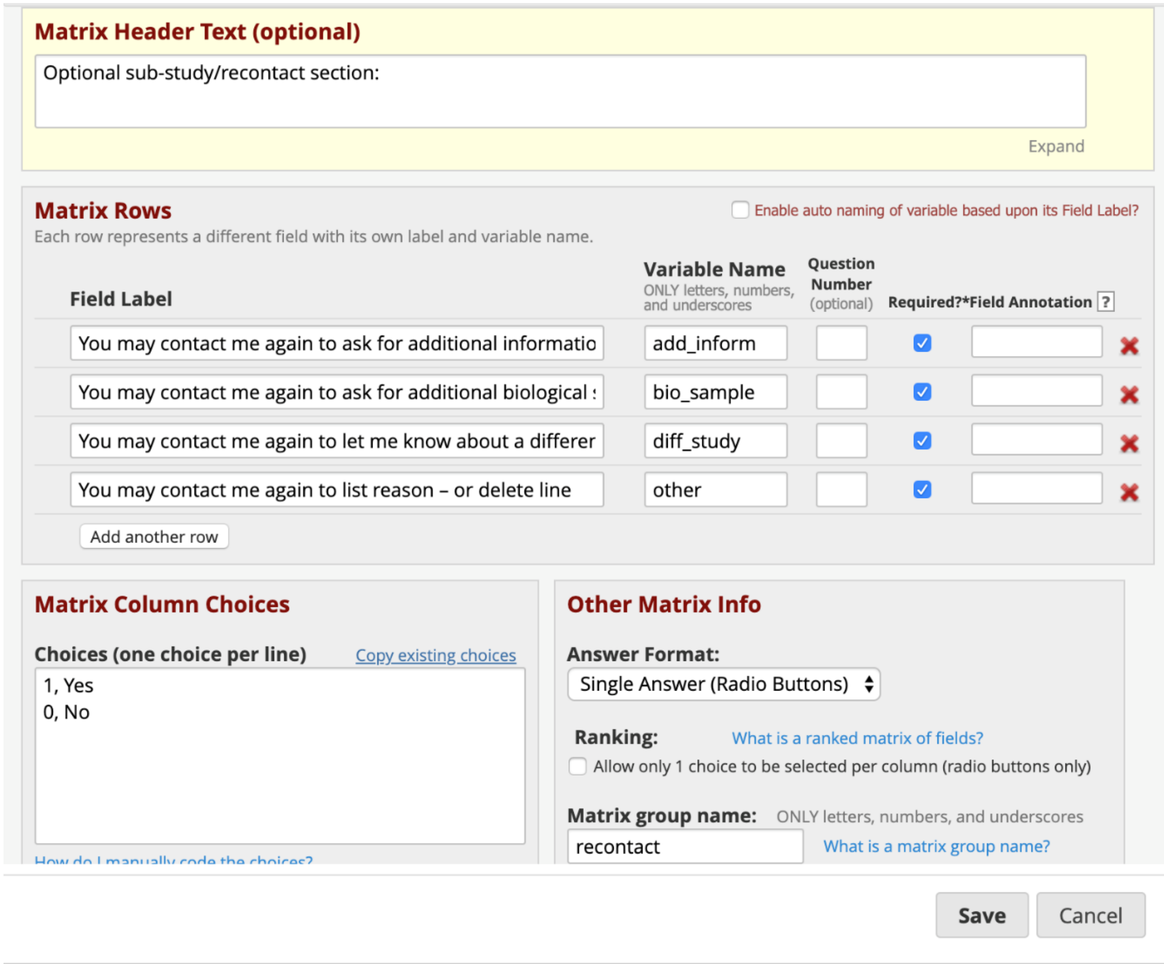
____Yes ____No You may contact me again to list reason – or delete line

15.1 Under "Matrix Header Text", enter the name of the optional section.

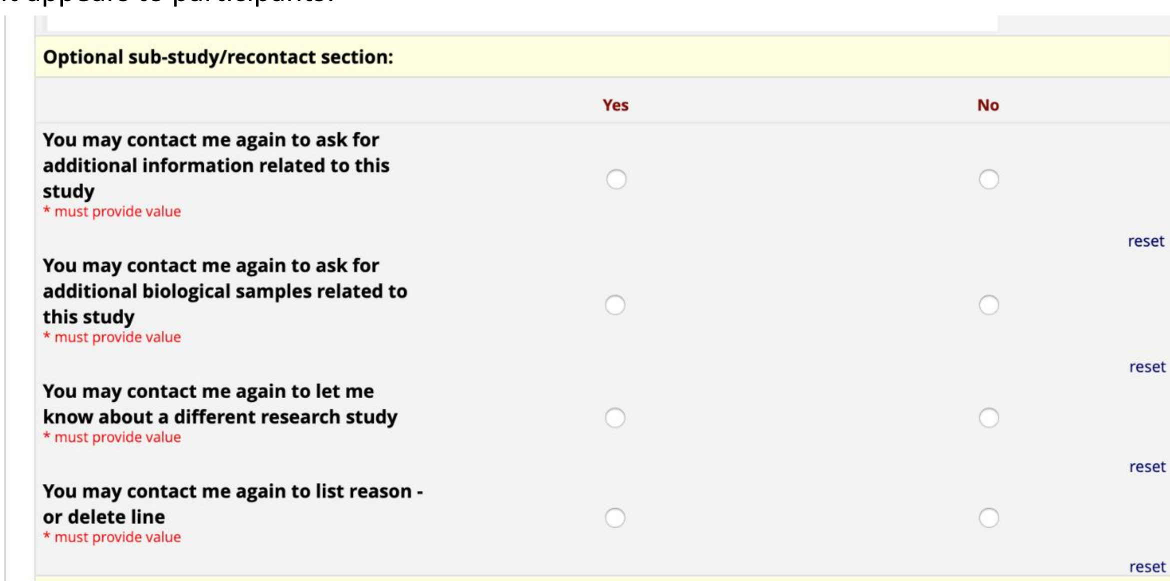
15.2 Under "Field Label," type the choices and give each of them an appropriate variable name. Make sure to click the checkbox for "Required?"

15.3 Under "Matrix Column Choice," enter as shown in the image below (1, Yes; 0, No). The answer format should be "Single Answer (Radio Buttons)".

15.4 Under "Matrix group name," enter an appropriate variable name for this whole section, such as "recontact" or "optional_sec."




How it appears to participants:




## II. Enabling Twilio in REDCap

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

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

1.1 Please follow this link to request the Twilio Module in REDCap: https://redcap.bumc.bu.edu/surveys/?s=HJPXWCME7H

1.2 IRB approval is required to ues Twilio

### III. Additional External Modules

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

Below are modules that may be useful in your study:

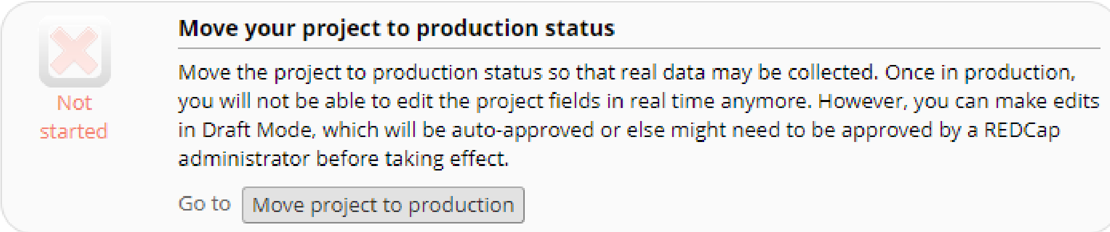
- Multi Signature Consent Module allows you to define one or more instruments to combine into one PDF. Please see section D.VIII for more details. To learn more visit: https://redcap.bumc.bu.edu/redcap_v11.4.0/ExternalModules/?prefix=multi_signature_consent&page=README.md
- Auto Record Generation Module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

## Checking project and moving to production status

1. Please be sure to review the remaining steps prior to finalizing your e-Consent project.
   - Survey design and distribution: https://redcap.bumc.bu.edu/index.php?action=help&newwin=1#ss57
   - Test your project thoroughly: https://redcap.bumc.bu.edu/index.php?action=help&newwin=1#ss37

1.1 Move your project to production status.

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




## Links to additional resources

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

Resources for REDCap:

- REDCap FAQ
- REDCap Training Videos
- BU Medical Campus/BMC REDCap email support: rchelp@bu.edu