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

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

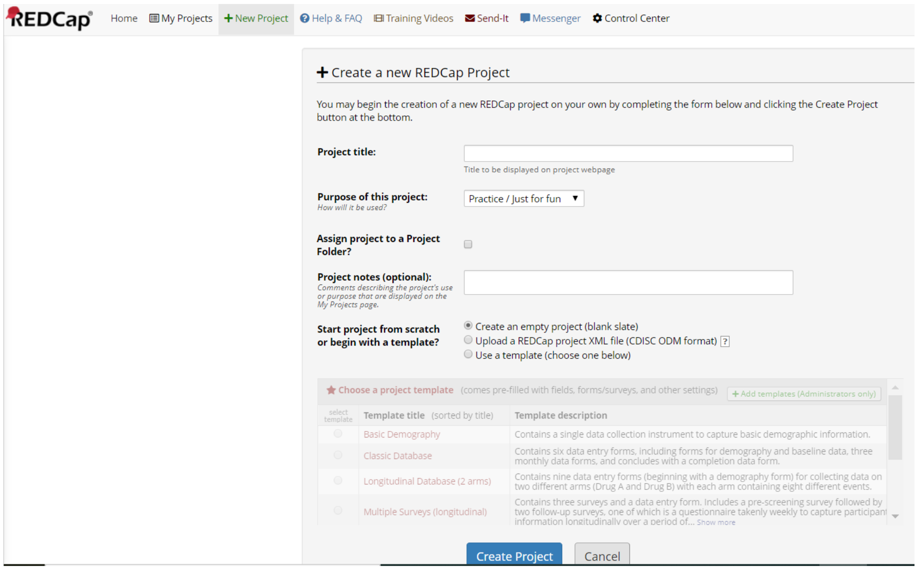
Please note that though this guidance that has been created with best study practices in mind, you may need or want to change certain features or functionalities to match your own unique study needs and workflow. If you have any questions regarding how to make certain changes, please contact rchelp@bu.edu.

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

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

Creating your REDCap project

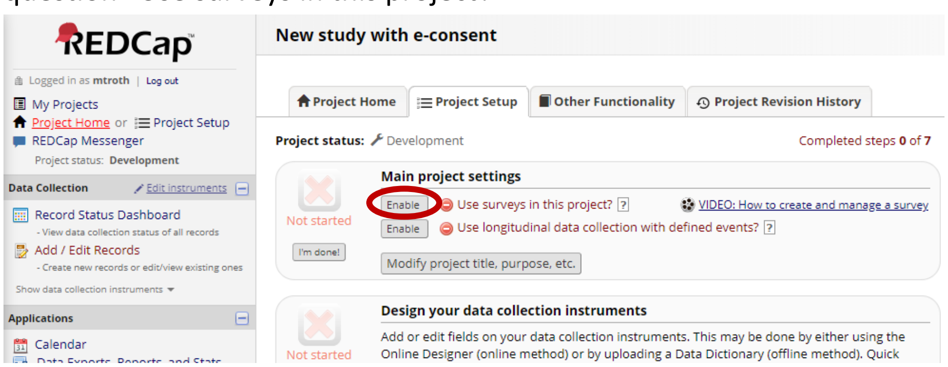
1. Save your IRB-approved and stamped PDF consent form as a .jpeg or .png file.
   1.1 Note: this approved consent form *will* contain signature lines applicable to this study.
2. Sign on to REDCap and go to "My Projects." https://redcap.bumc.bu.edu/
3. If you are starting a new project, you should click "New Project" at the top menu. If you already have a project set up in REDCap, proceed to 4.0.
   3.1 Complete Project title, Purpose (research), PI info, Project notes, etc.
   3.2 At the end of the page, choose e-Consent for Non-Exempt Research" under "Choose a project template" and press the blue "Create Project" button.
      3.2.1 This template provides you with a default layout to help you get started. Please note that the default template provides you with examples for both in-person e-consent and contactless e-consent. Also, the automatic survey features have been enabled template. If you are not going to utilize this feature, disable it.
      3.2.2 Edit the fields and survey settings accordingly accordingly for your study.



Enabling Survey mode for REDCap Project

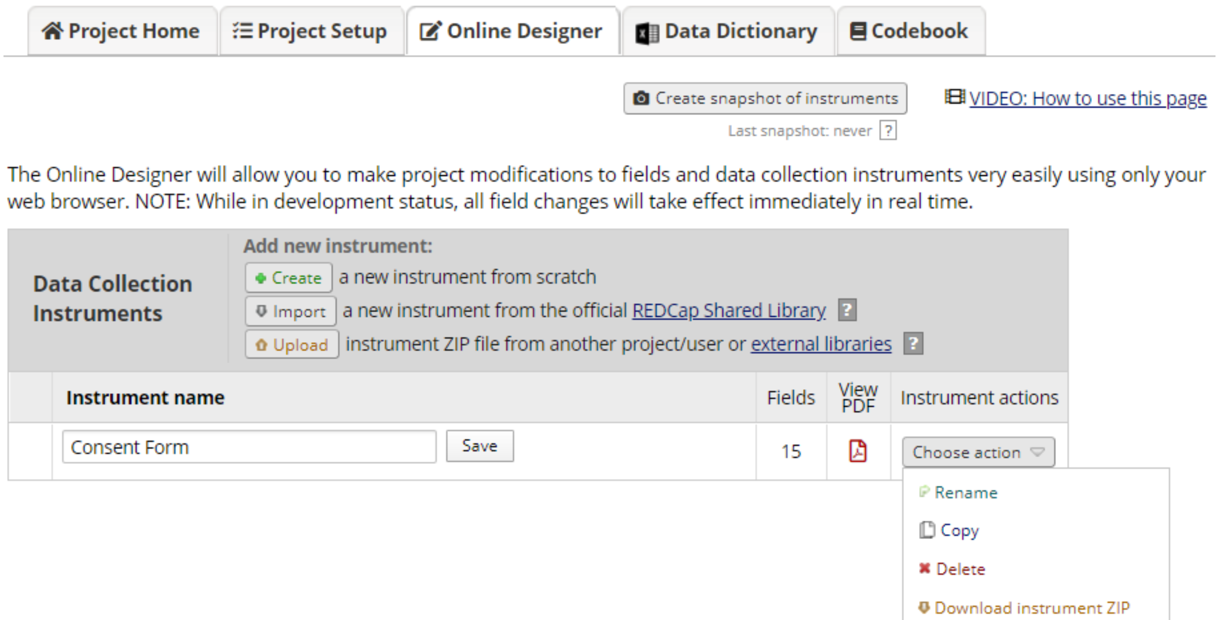
4. At the "My Projects" page, select the appropriate project that you are creating an e-consent for. This will bring you to the "Project Setup" tab.

4.1 Under "Main Project Settings" within Project Setup tab, select the "Enable" button for the question "Use surveys in this project?"



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

4.3 Rename "My First Instrument" by selecting "Choose action" drop down button to "Rename." Name the instrument (your consent document) and then click the "Save" button.

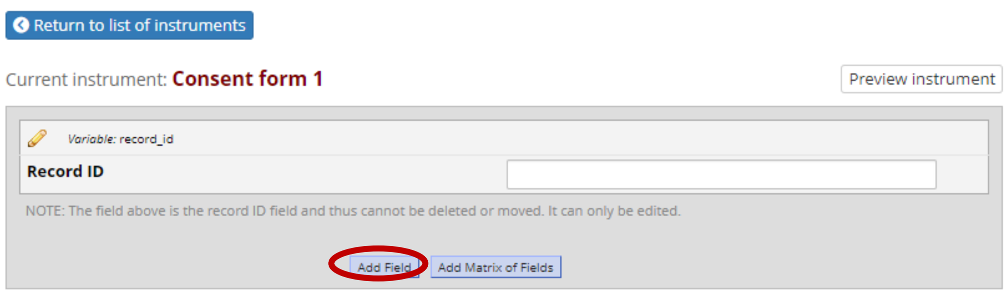


Creating the consent form instrument

5. Now, build your consent form.

   5.1 Click on your newly named instrument (see 4.3 above).

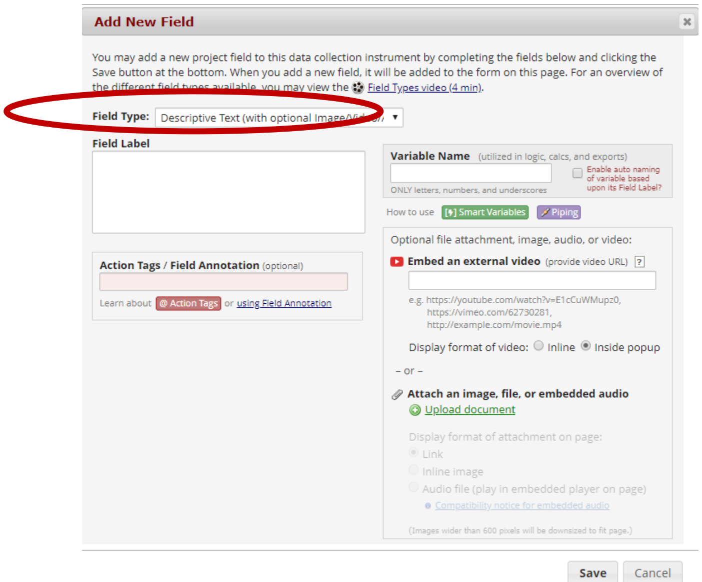
   5.2 Click “Add field” button.

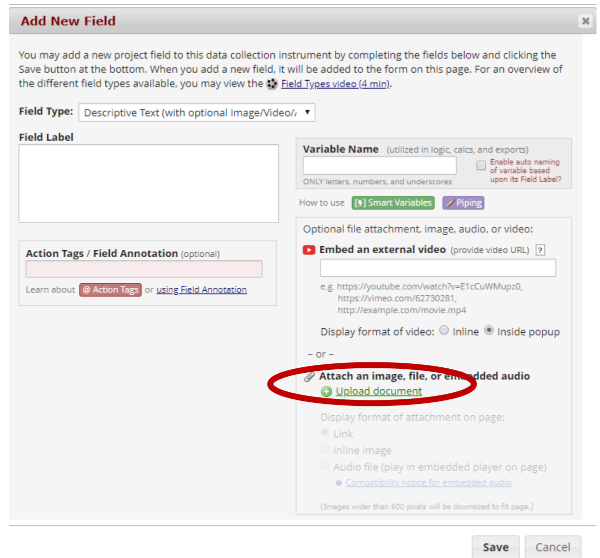


   5.3 Under the Field Type drop down, choose “Descriptive Text.” You can keep the “Field Label” blank. It is not necessary to complete this field to upload the file.

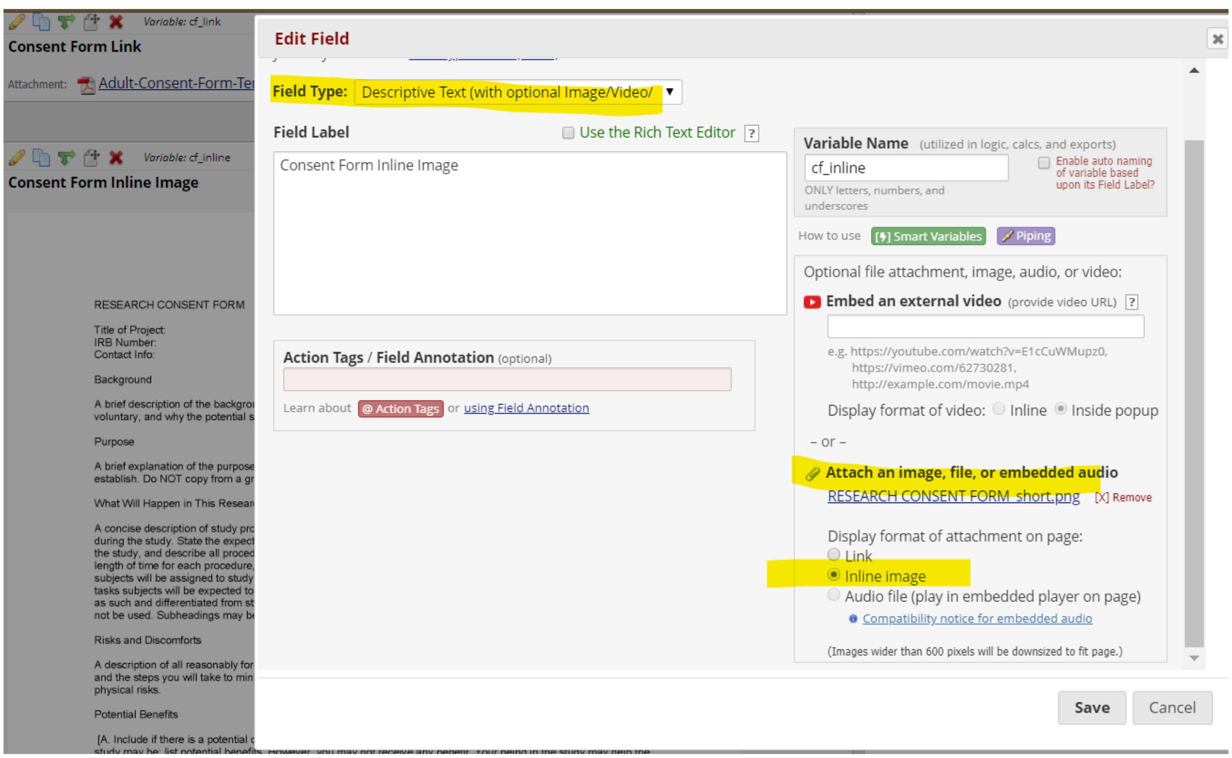
   5.4 Click on “Upload document.” Choose first page of your jpeg format consent form and upload the file. Then click on “In-line image.” Give the page a variable name (such as page_1). Click save.

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





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



Adding fields in e-Consent instrument

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

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

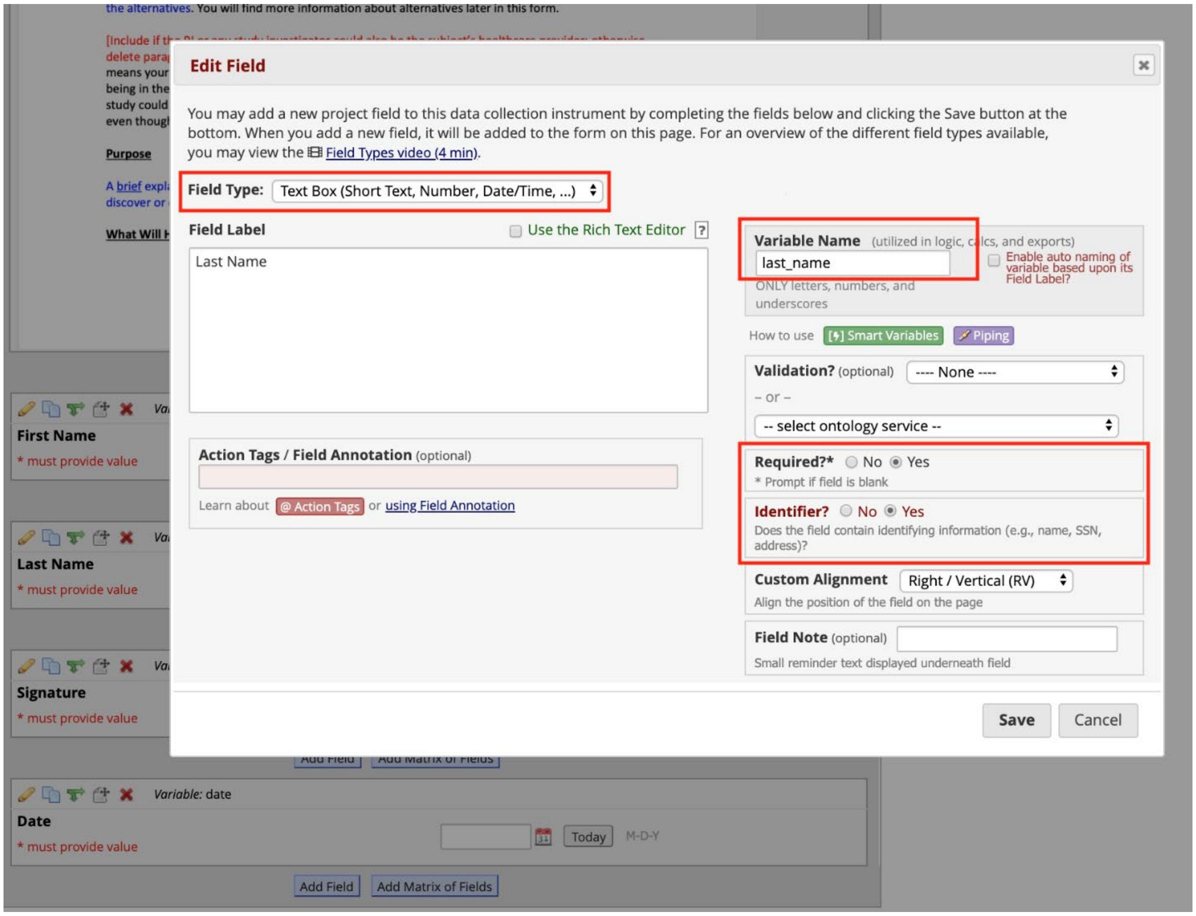
6.2 Scroll down to the last page of your electronic consent form.

6.3 Click the “Add Field” blue button at the bottom of the page.

6.4 Select “Text Box…” from the dropdown menu.

6.5 Under the Field Label type “First name.” Under “Variable Name” type “firstname”.

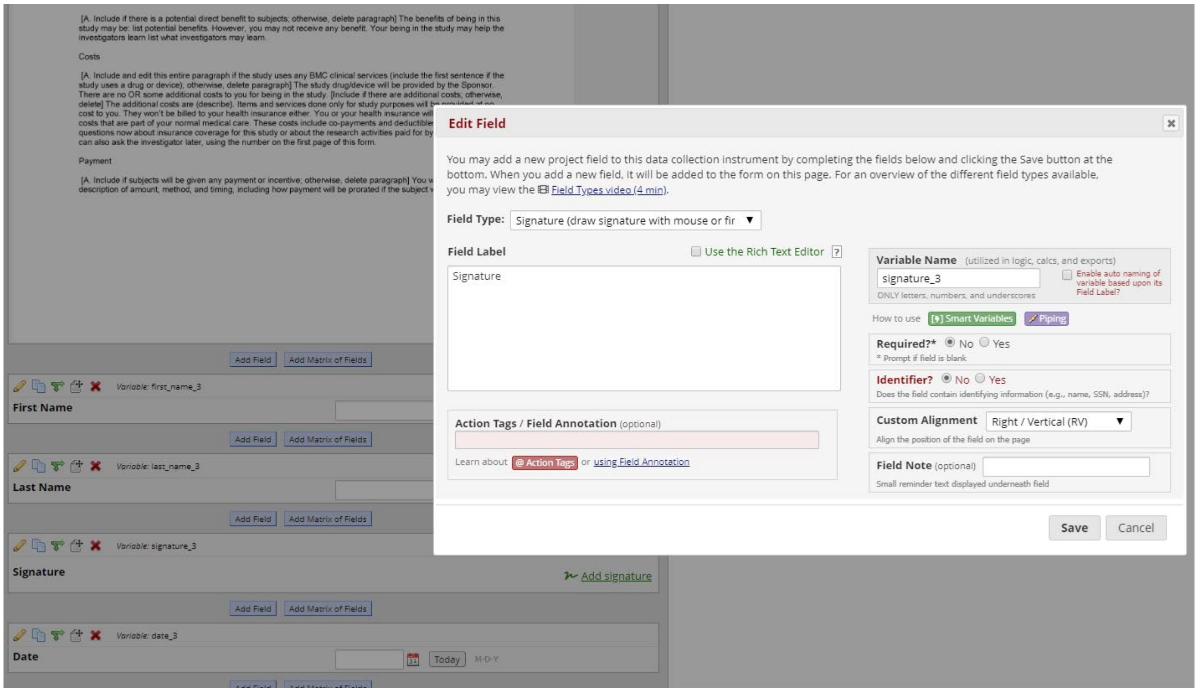
6.6 Complete the “Required?” and “Identifier?” fields as ‘Yes’. Click “Save.”



6.7 Continue and add Last name field following steps 6.3-6.6.

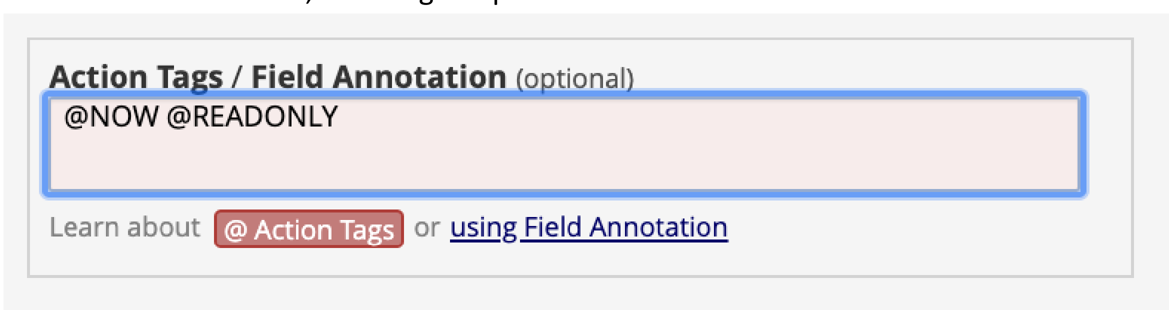
6.8 Adding the Stylus Signature field is optional but is recommended as it offers an experience similar to providing a physical signature. In Field type, choose “Signature…” from the dropdown menu. Proceed as before with steps 6.5-6.6.

6.8.1 If you are adding the signature field, complete the “Field Label” as follows: “Signature (if possible sign with finger, stylus or mouse).” Choose “No” for the “Required” box and choose “Yes” for the “Identifier” box.

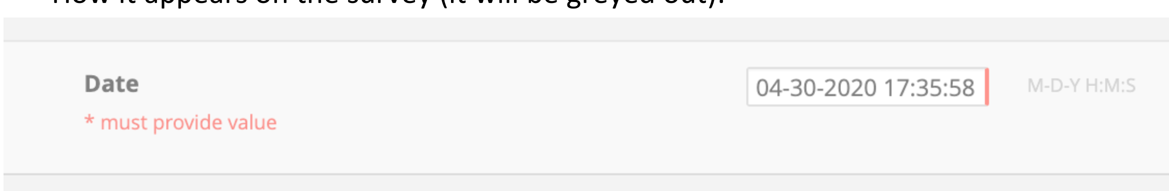


6.9 Add a date field. Choose "Add field" blue button. Under "Field Type", choose "Text Box." Complete "Field Label" and "Variable Name." Under "Validation?" choose a date option from the dropdown menu. We recommend that you use the "Datetime w/ seconds" option (e.g "Datetime w/ seconds (M-D-Y H:M:S)).

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

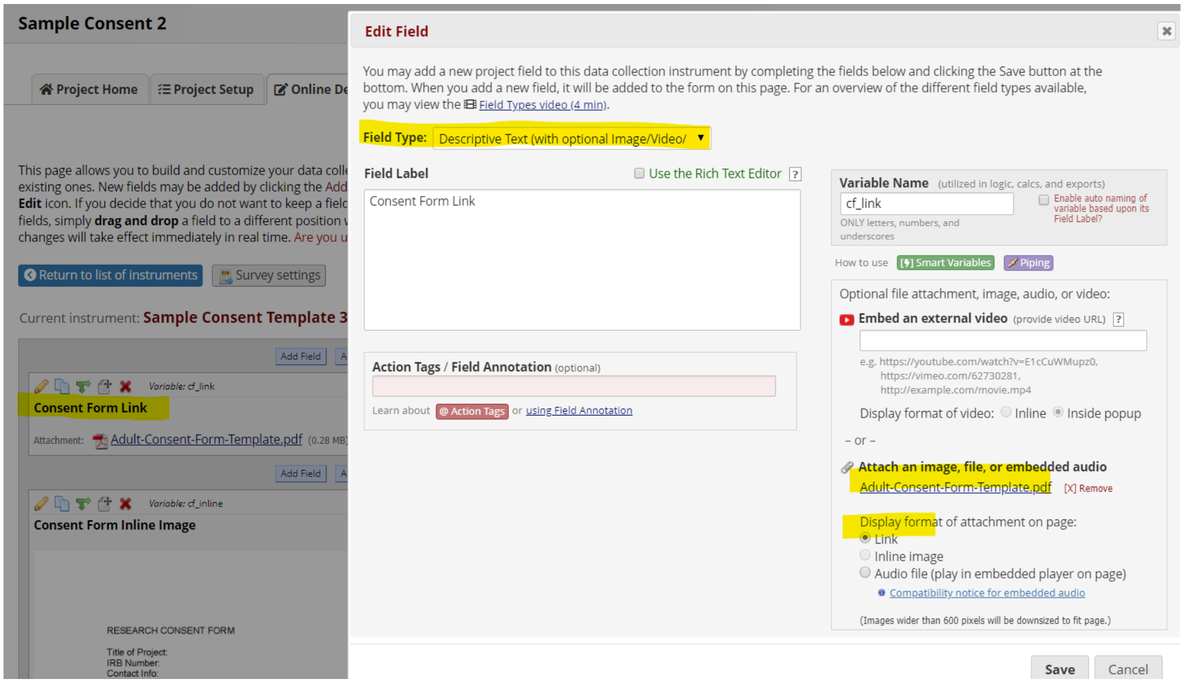


How it appears on the survey (it will be greyed out):

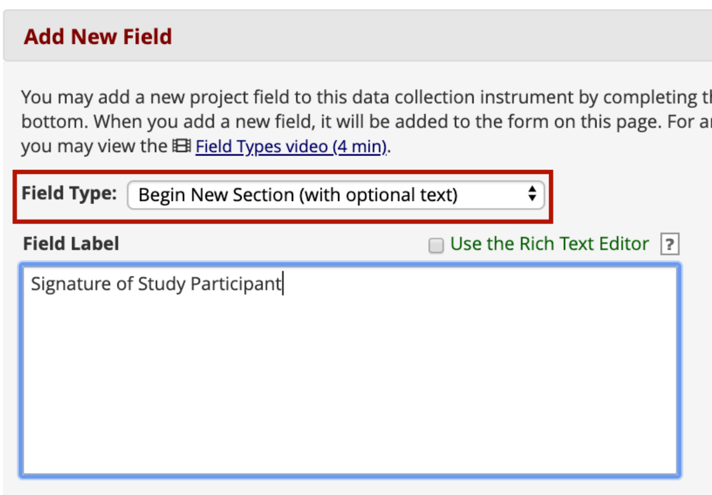


6.9.2 Complete additional fields as necessary.

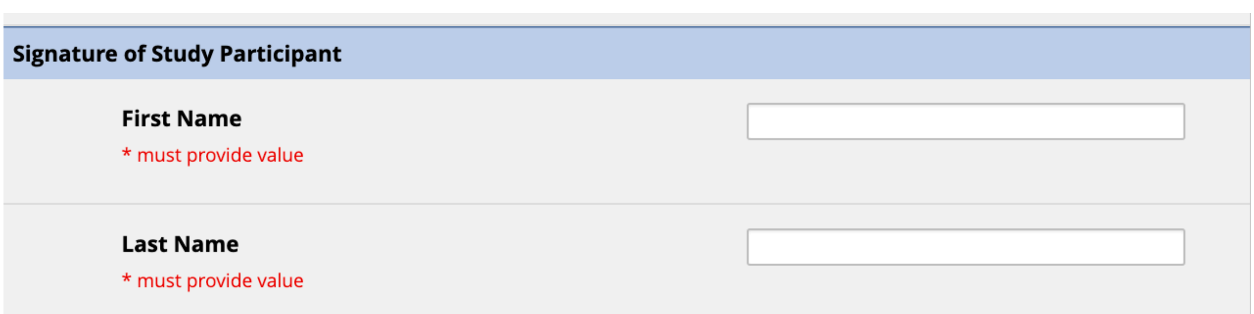
6.10 You may also elect to set up a file download field, to allow the participant to download a hardcopy of the blank consent form.



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



How it will look:



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

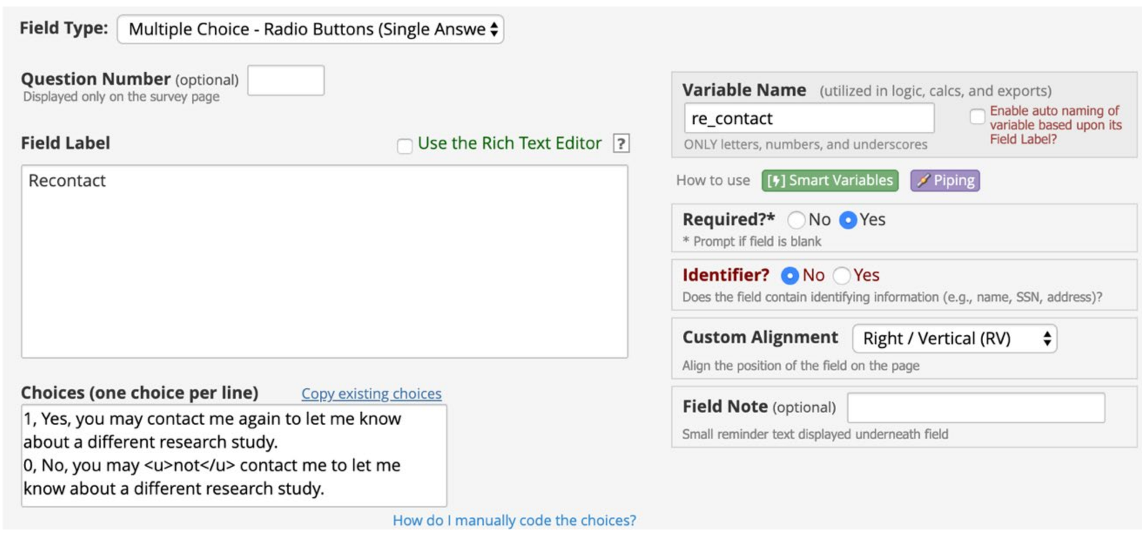
6.12 To break up the checkbox sections, add a heading prior to the participant's signature section. Click the "Add field" button, and under "Field Type" choose "Begin New Section (with optional text)" and label the section appropriately.

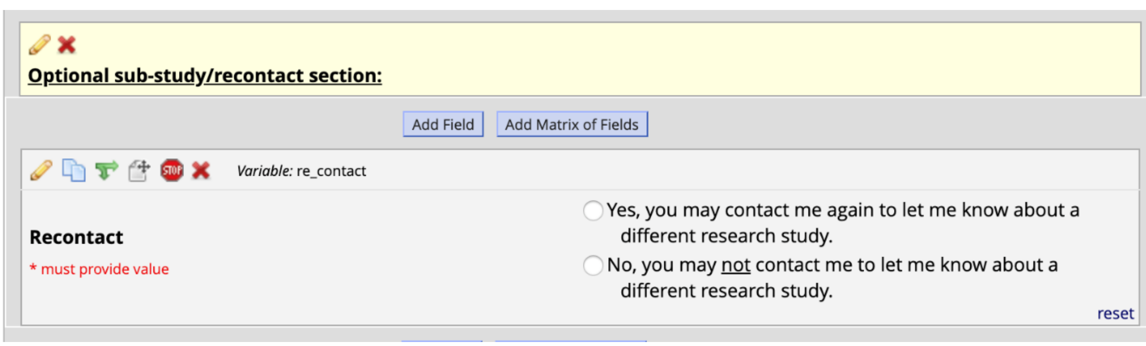
6.13 To add the Yes/No options, click "Add Field" below the new section and choose "Multiple Choice – radio options." Enter an appropriate "variable name."

6.13.1 Under the "Field Label", you have the option to repeat the name of the optional section.

6.13.2 Under "Choices," type out the choices.

6.13.3 Make sure to click "Yes" for "Required?"





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

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

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

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

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

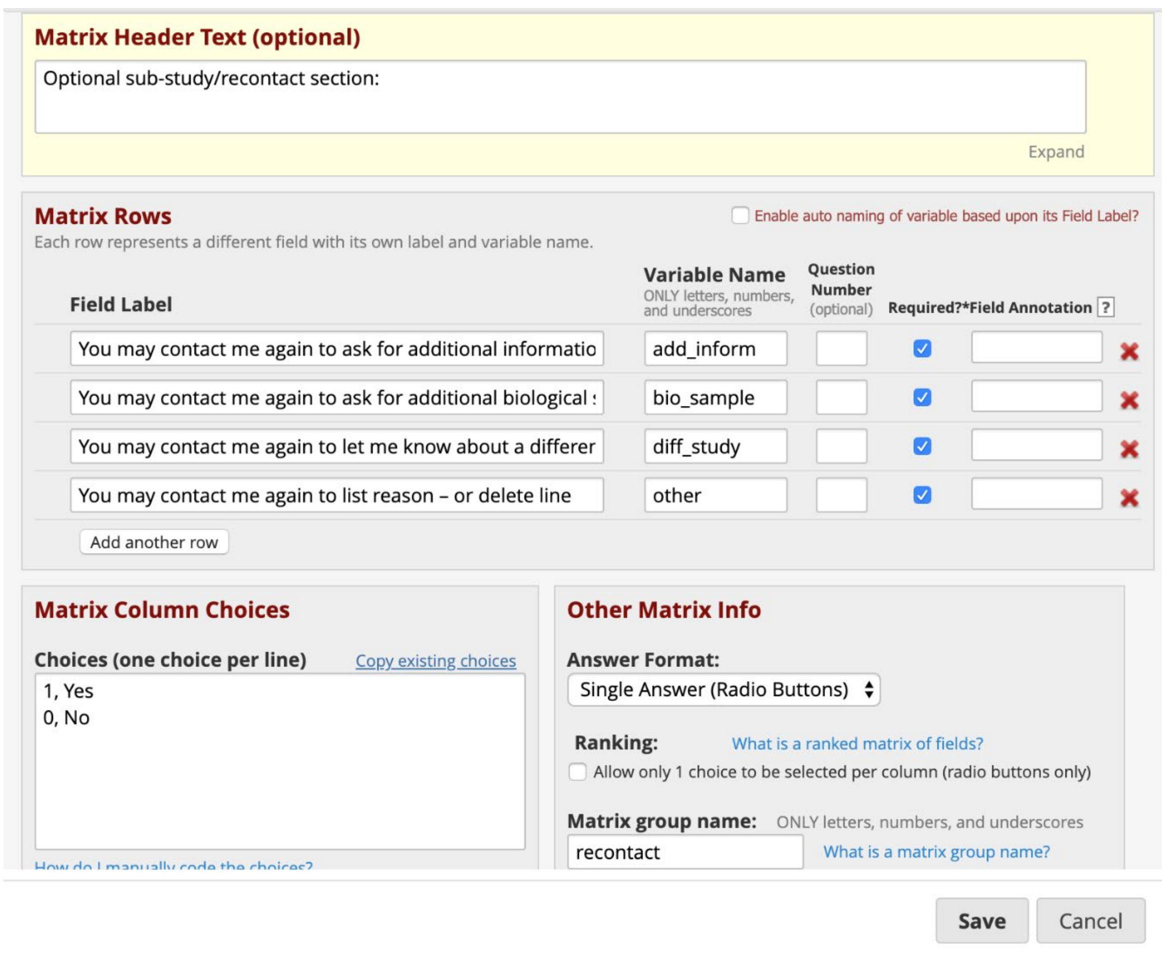
____Yes ____No You may contact me again to list reason – or delete line

6.14.1 Under “Matrix Header Text”, enter the name of the optional section.

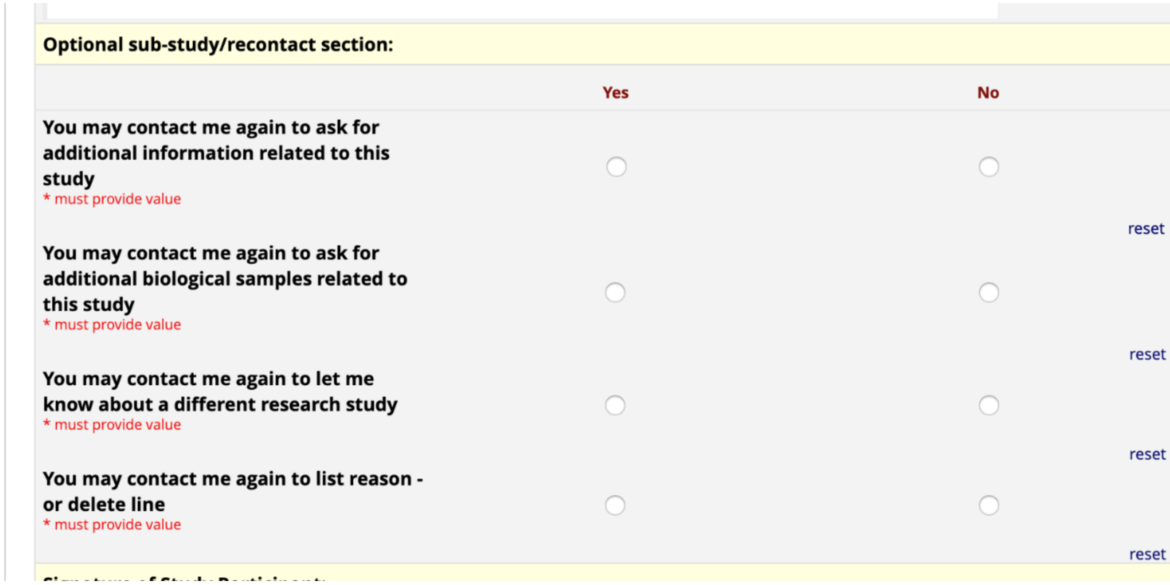
6.14.2 Under “Field Label,” type the choices and give each of them an appropriate variable name. Make sure to click the checkbox for “Required?”

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

6.14.4 Under “Matrix group name,” enter an appropriate variable name for this whole section, such as “recontact” or “optional_sec.”

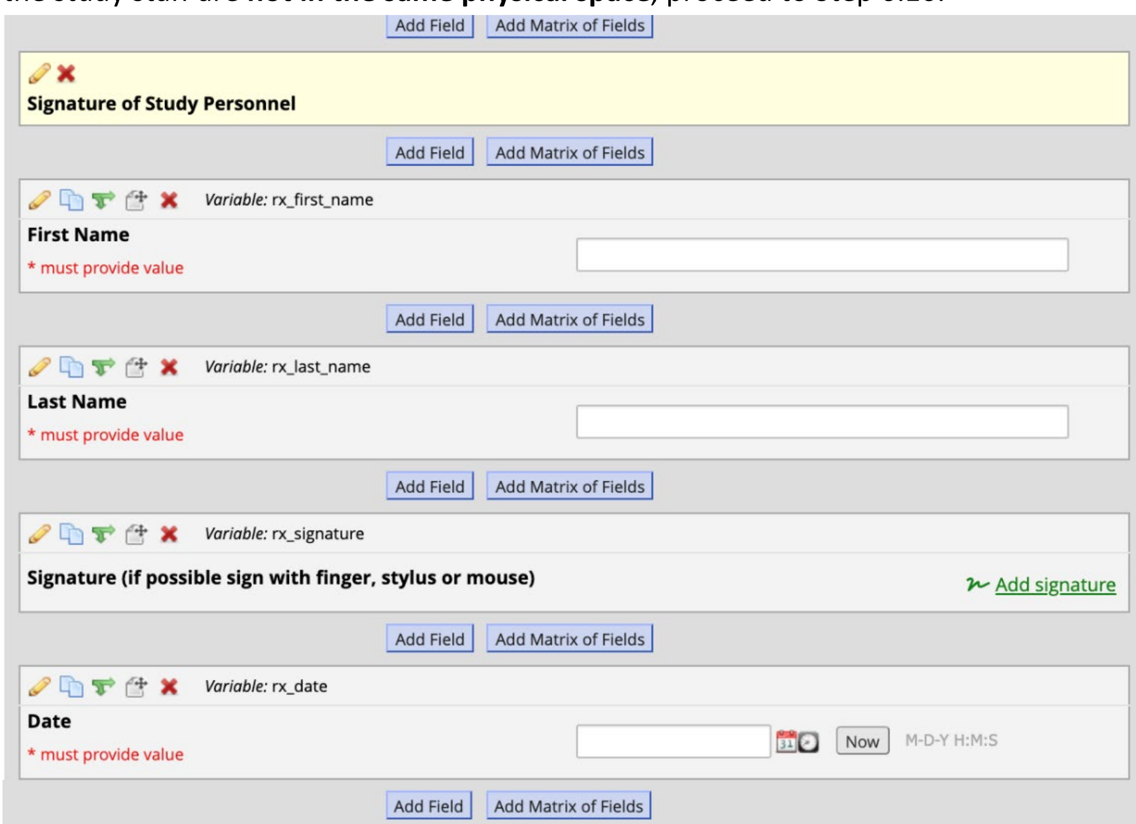


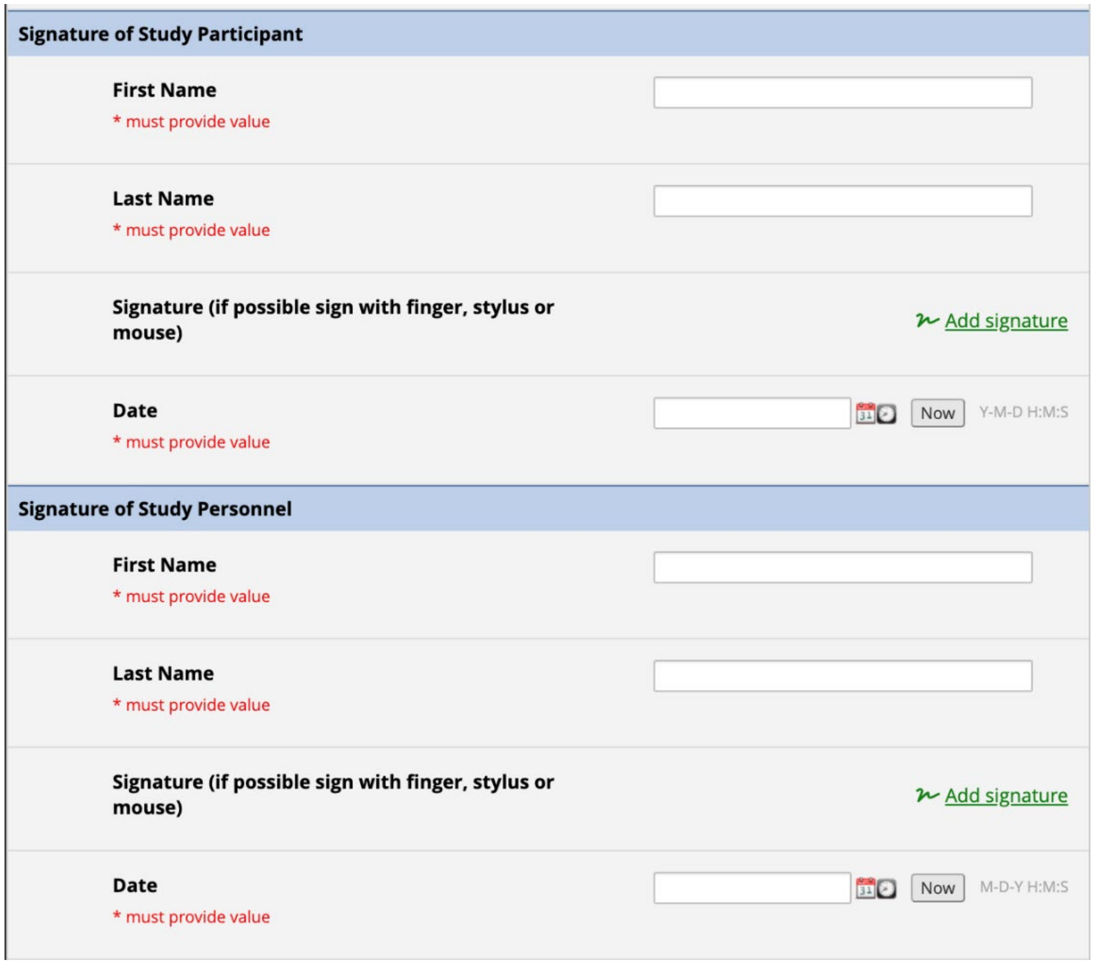
How it appears to participants:



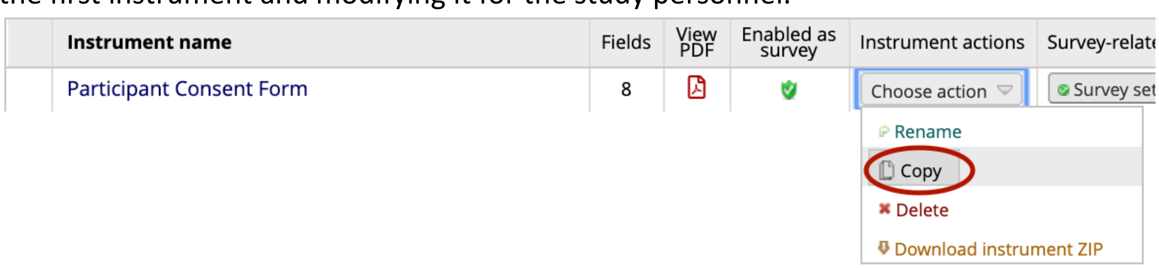
Modifying Consent instrument for in-person consent vs. contactless consent

6.15 If you are conducting the consent discussion with the participant in-person, where you will each be in the **same physical space**, proceed as before starting at step 6.3 to create the section for "Signature of Study Personnel" within the same instrument (example images below). If you are conducting **a contactless consent discussion**, where the participant and the study staff are **not in the same physical space**, proceed to Step 6.16.

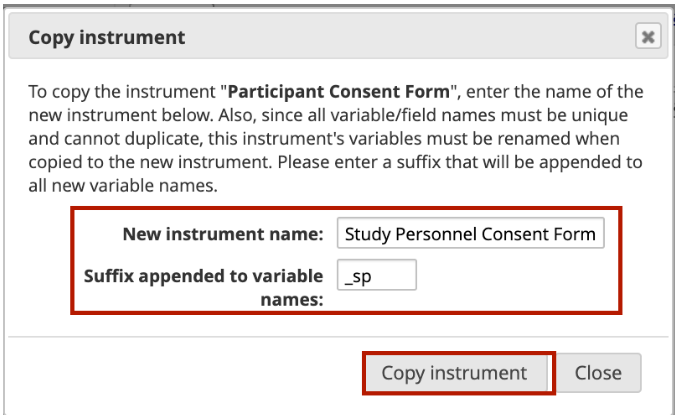




6.16 For contactless consenting, it is necessary to create two separate e-Consent instruments, one for the participant to sign and one for the study personnel to sign (these two consent instruments will both be tied to the same record ID). This can be easily done by just copying the first instrument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

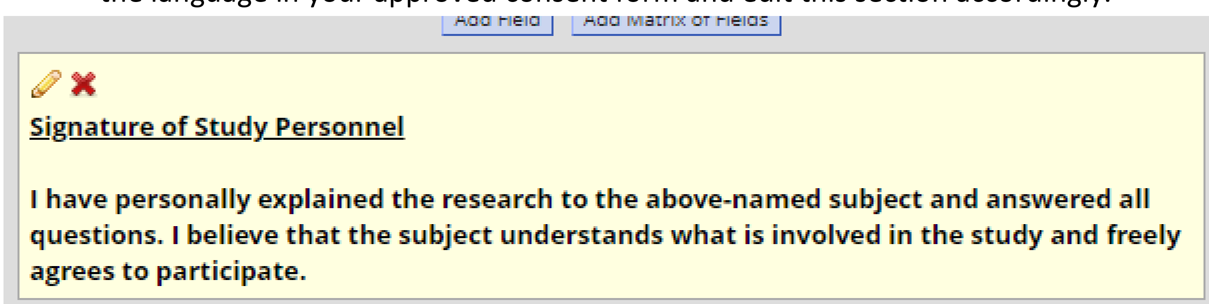


6.17 A window will pop-up. Update the fields accordingly and click the “Copy instrument” button.



6.18 Click on the "Study Personnel Consent Form" instrument to edit the fields accordingly. For example, the section title should be updated from "Signature of Study Participant" to "Signature of Study Personnel."

6.18.1 If the study team chooses, they can remove the consent form pages and the copy of the pdf link of the consent for the Study Personnel Consent Form instrument. However, it is recommended that the following sentence, <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.

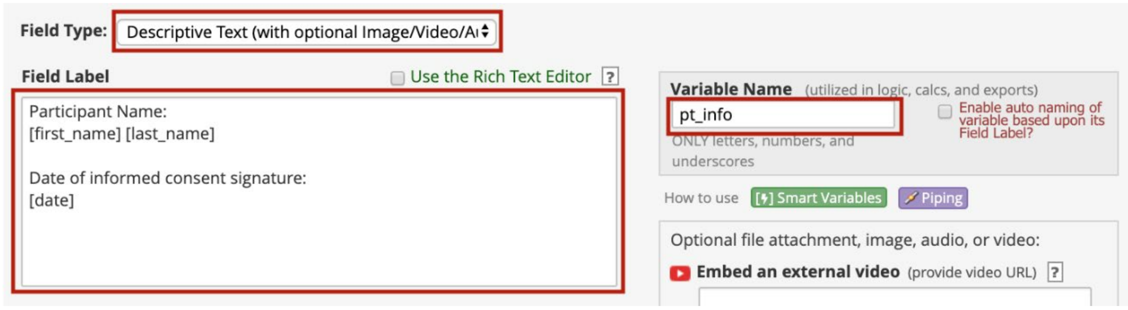


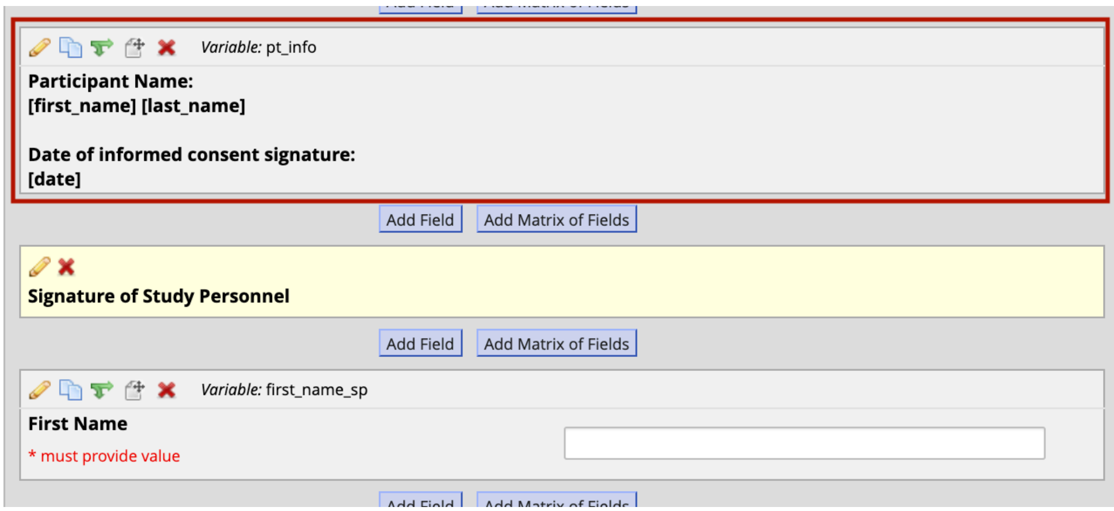
6.19 To ensure that the study personnel are signing the consent form for the correct participant, you can use the REDCap "piping" feature so that the participant's information from the "Study Personnel Consent Form" instrument is auto-added. Piping pulls data from one instrument to another by referencing the variable name of the data. Please note that the participant consent form must be completed prior to the study personnel opening the consent form for the piping to work.

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

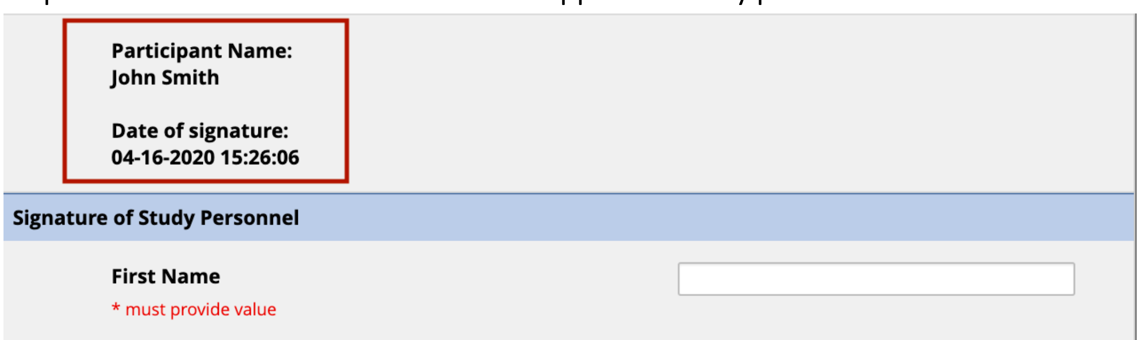
6.19.2 For the “Field Label” refer to the variable name from the “Participant Consent Form” instrument to pipe in the participant’s First Name, Last Name, and Date of signature.

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





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

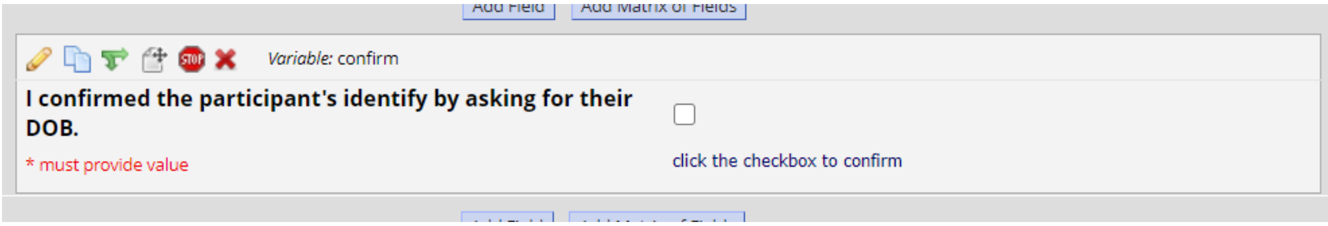


6.20 It is recommended that you add a field for “comments” or “notes,” where you can explain any situations that may come up during the consent process.

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

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

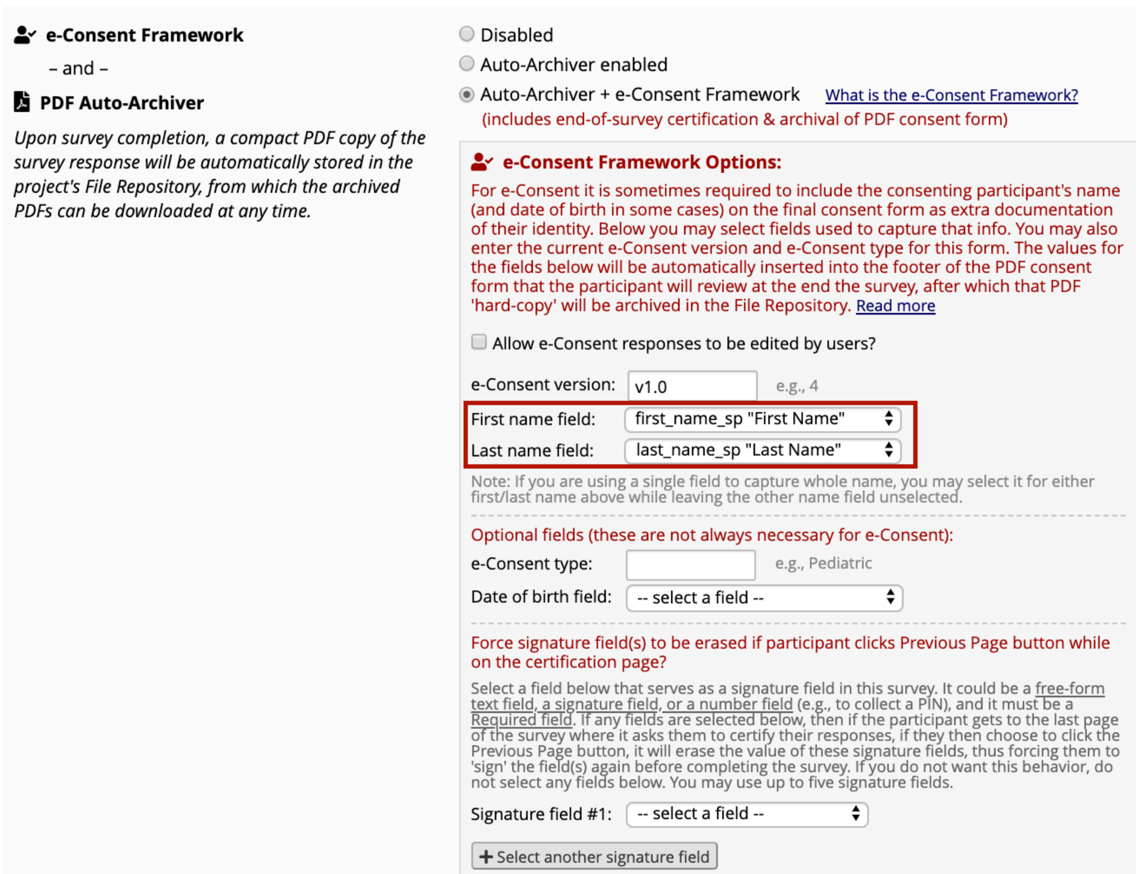
6.21.1 The below image is just an example. Edit the wording as you see fit.



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

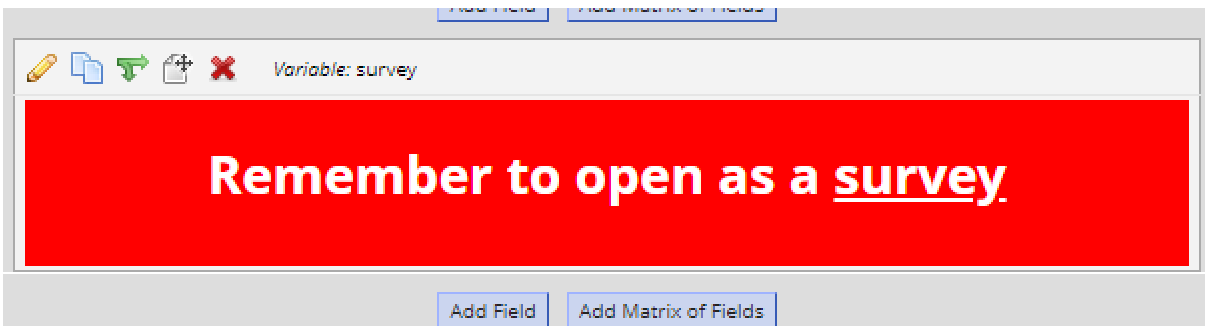
6.22.1 MOST IMPORTANTLY, you need to make sure to update the “First Name Field” and “Last Name Field” on the e-consent framework setting so that they refer to the variable names from the “Study Personnel Consent Form” instrument.

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



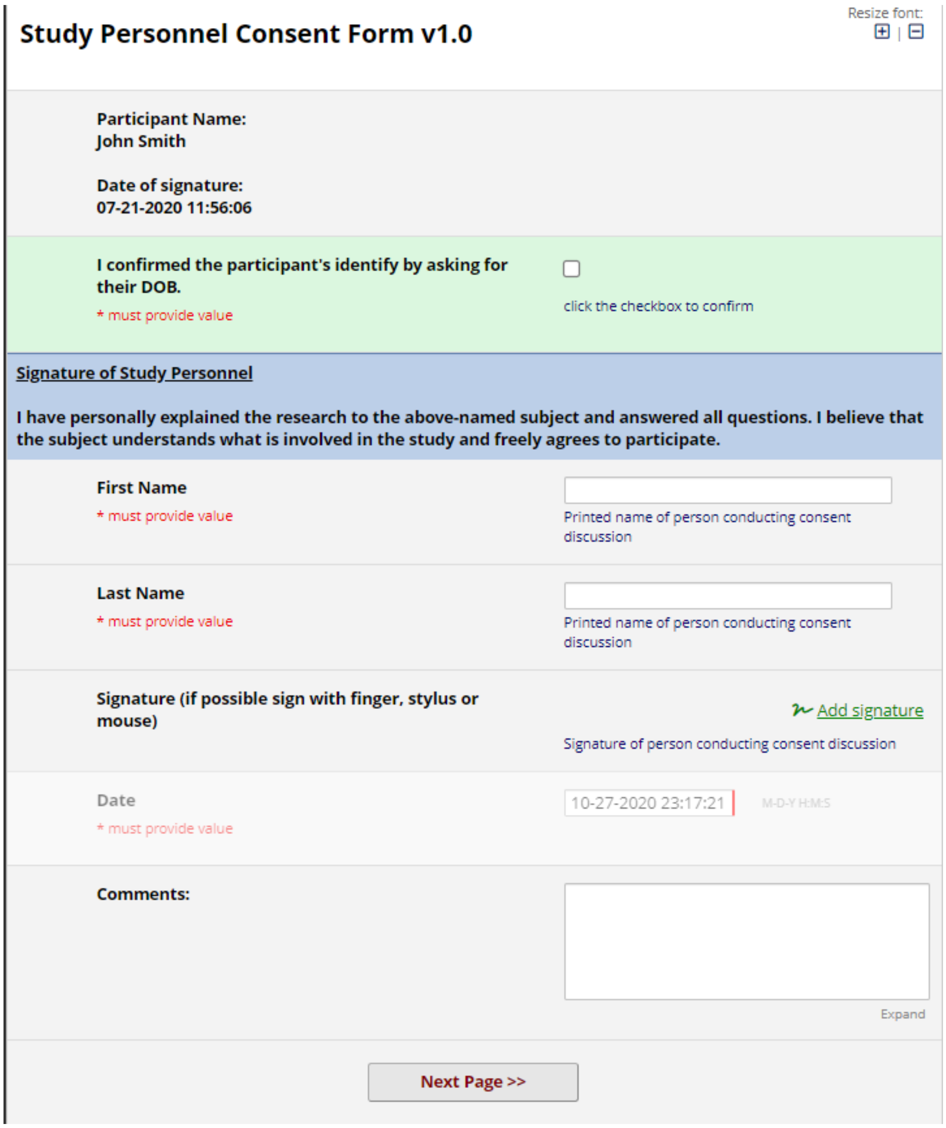
6.23 Since the e-consent framework is turned on for the study personnel consent form, the form must be completed as a survey for the file to be appropriately archived once completed.

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



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

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

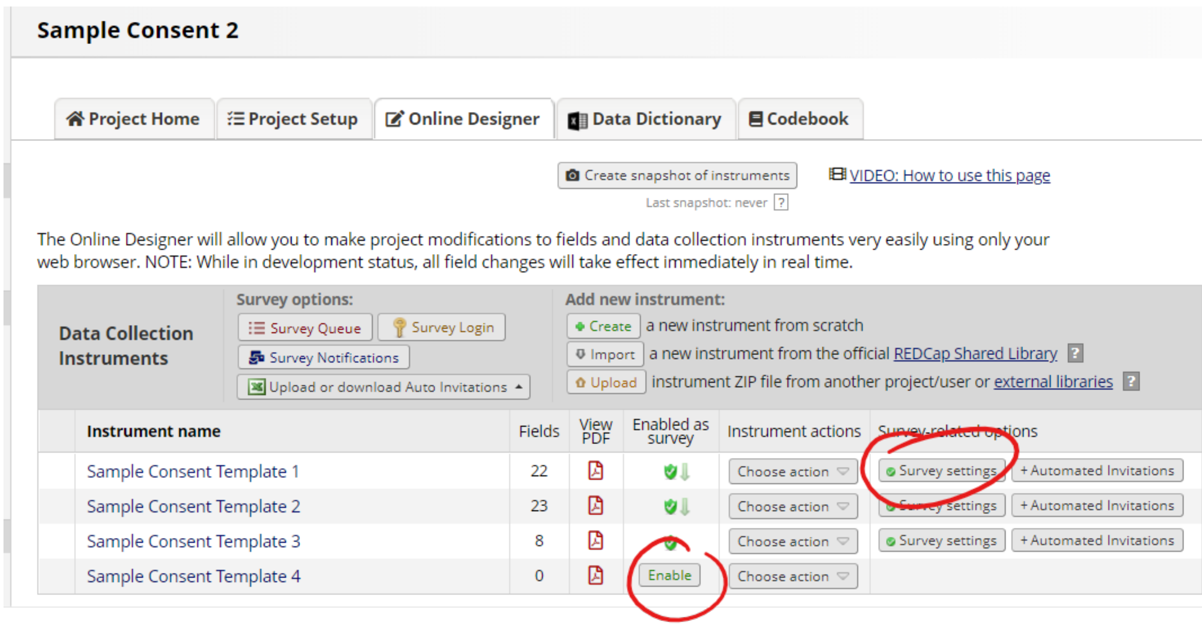


Enabling survey feature and updating survey settings

7. When you have finished uploading all jpeg format pages of the consent form, scroll to the top and click on the blue “Return to list of instruments” button. Then click on “Project Setup” tab.

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 consent 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. Adapt the instructions to suit your consent process, for instance: “Please review this electronic consent form with the study coordinator.”

7.4 Scroll down to “Survey Termination Options” at the bottom of the survey settings page. Next to “Survey Completion Text”, provide the text you want to show to the participant after he/she provides an electronic signature. Then click the “Save Changes” blue button on the bottom of this webpage.

7.4.1 For example:

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

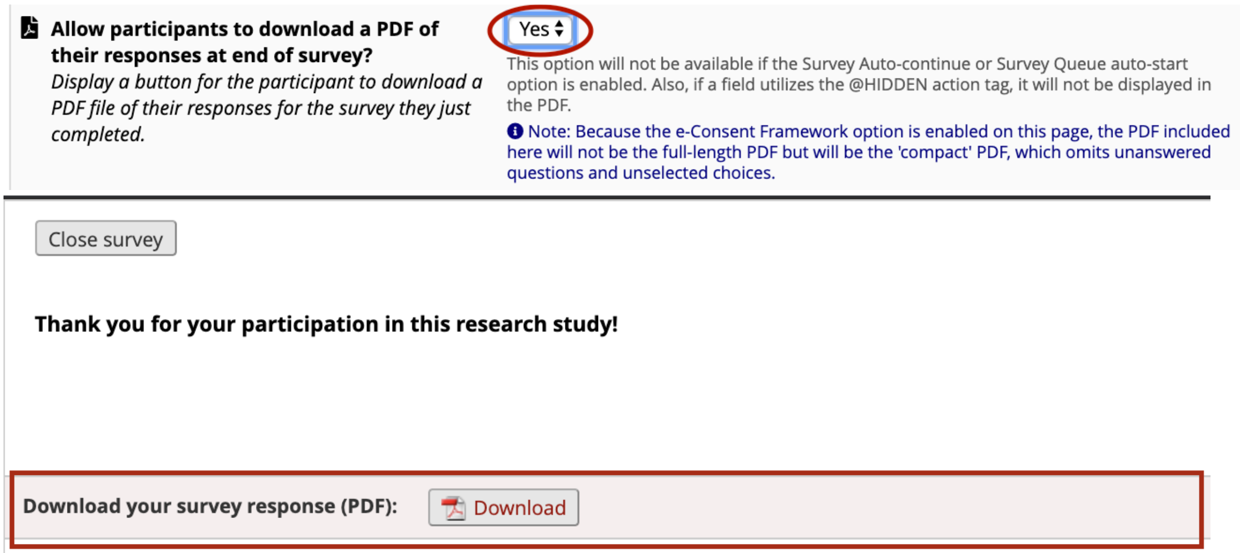
Please download the copy of your signed consent form below. *(It might be helpful to prompt the participant to download a copy of the informed consent here since the option to allow participants to download a pdf of their completed survey is turned on in the survey settings (see 6.5.2 below) and so the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

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

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

Vs.

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

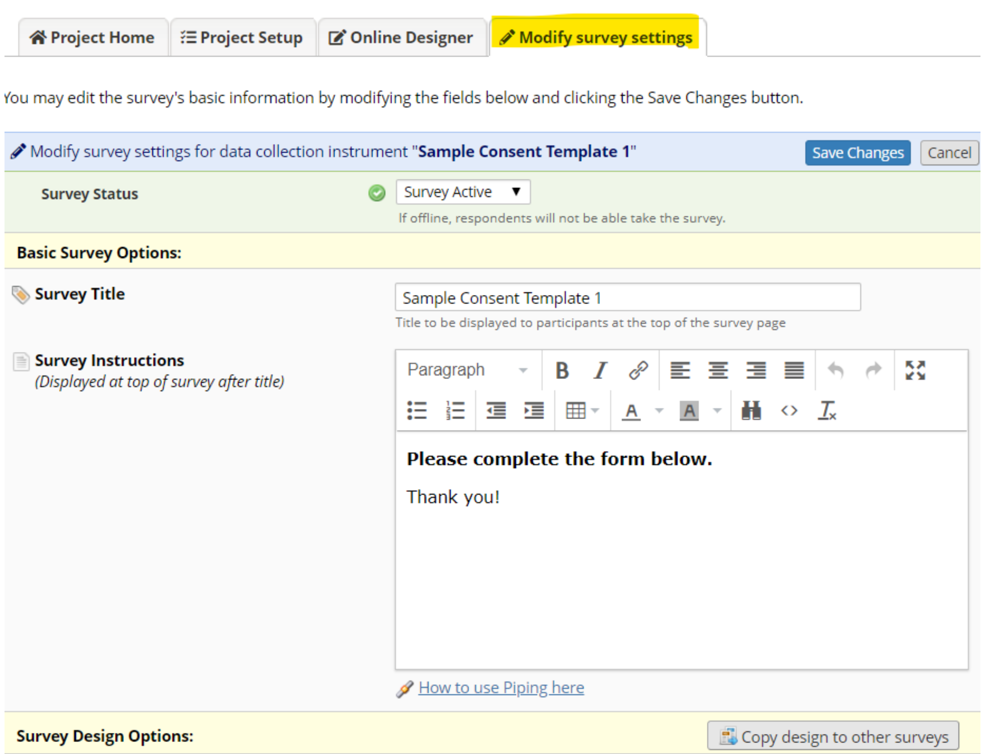


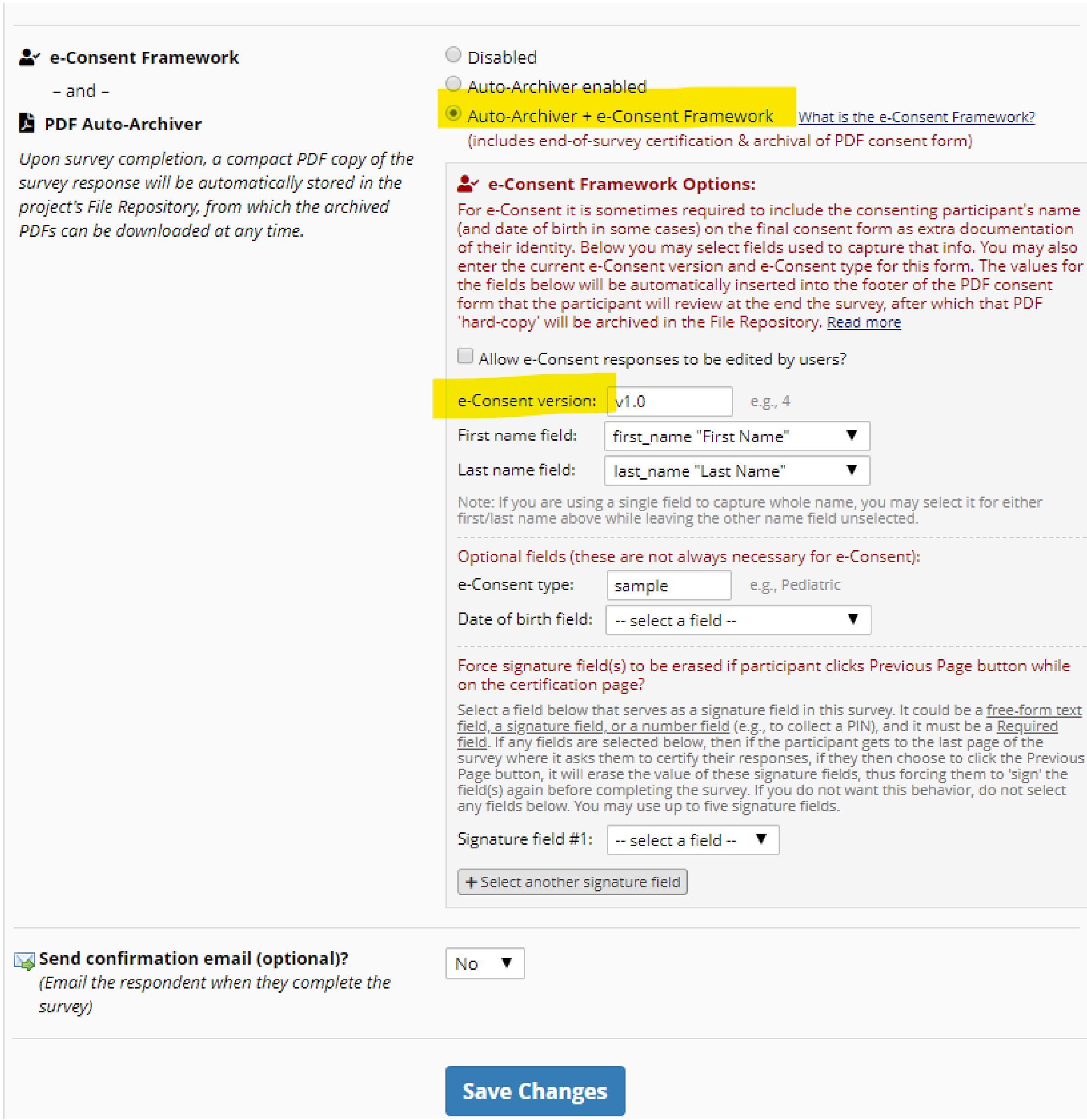
7.6 To the right of the "PDF Auto-archiver" choose the third option: "Auto-Archiver + e-Consent Framework."

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

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

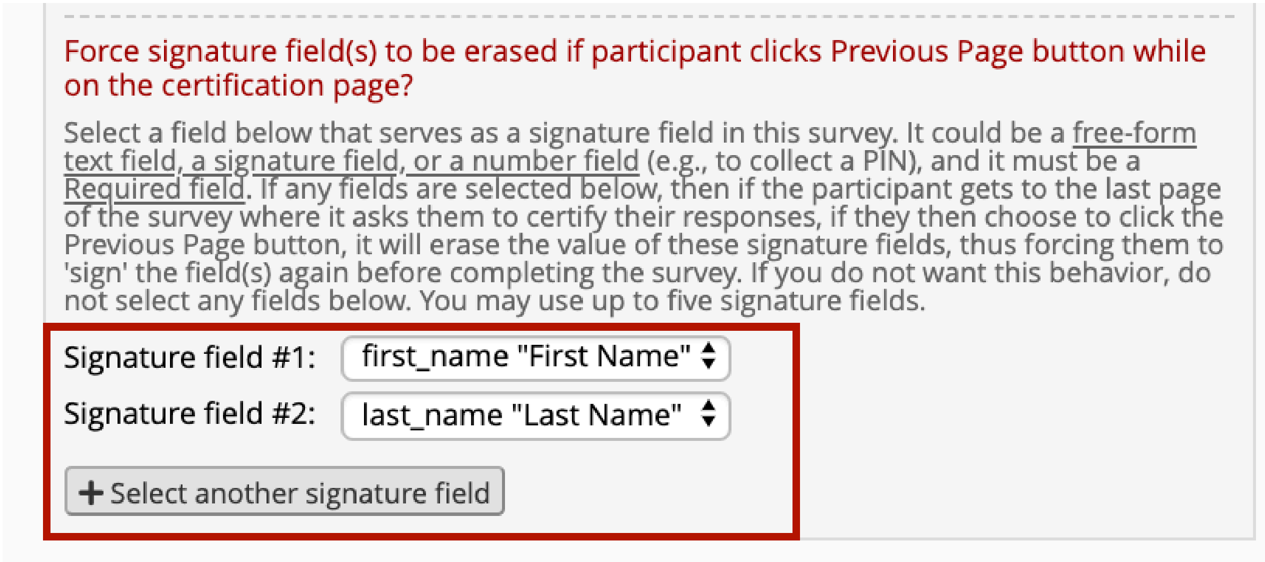
7.8 Next to "e-Consent version" provide a version number. This is to help you keep track of the consent version utilized to consent the participants.





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

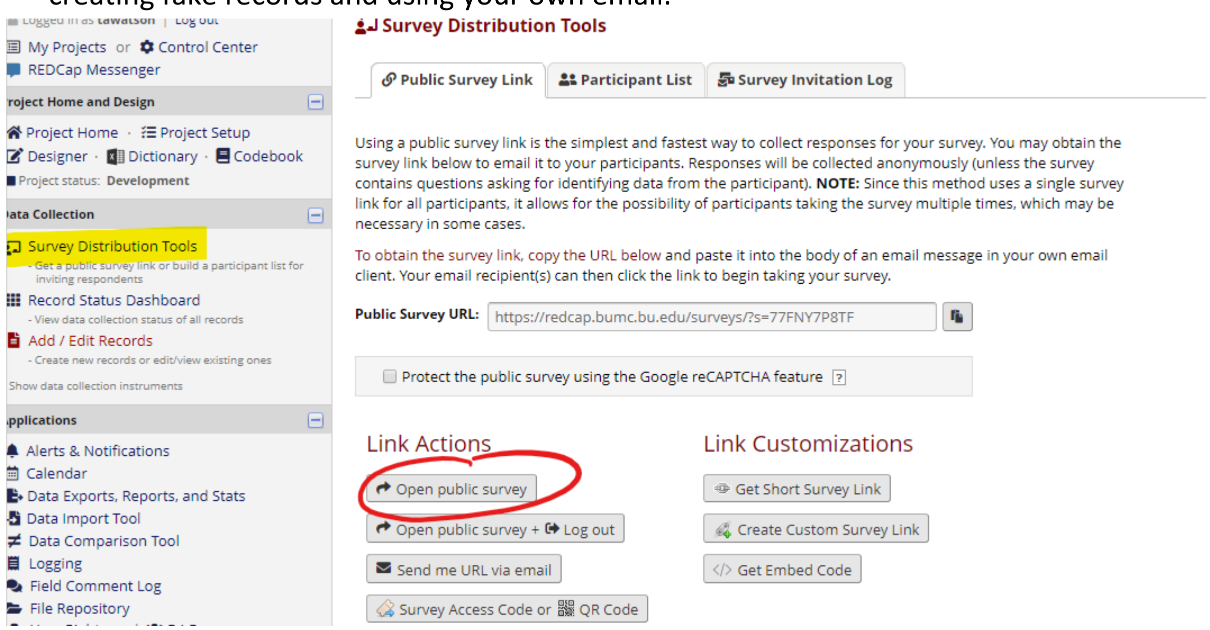
7.9.1 NOTE: Only required fields will appear as options in the drop-down menu. Therefore, since the "Signature" field (signature with finger/mouse/stylus) is an optional field, it will not be listed in the drop-down menu.



How to test out the Consent link during Development Mode

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

8. Please note that if you proceed to step 9 and enable the Survey Login feature and create the “Participant Information” instrument, you will not be able to utilize the public survey link since the first instrument will no longer be a survey.
   8.1 Once the Survey Login feature is turned on, you can still test out the consent links by creating fake records and using your own email.

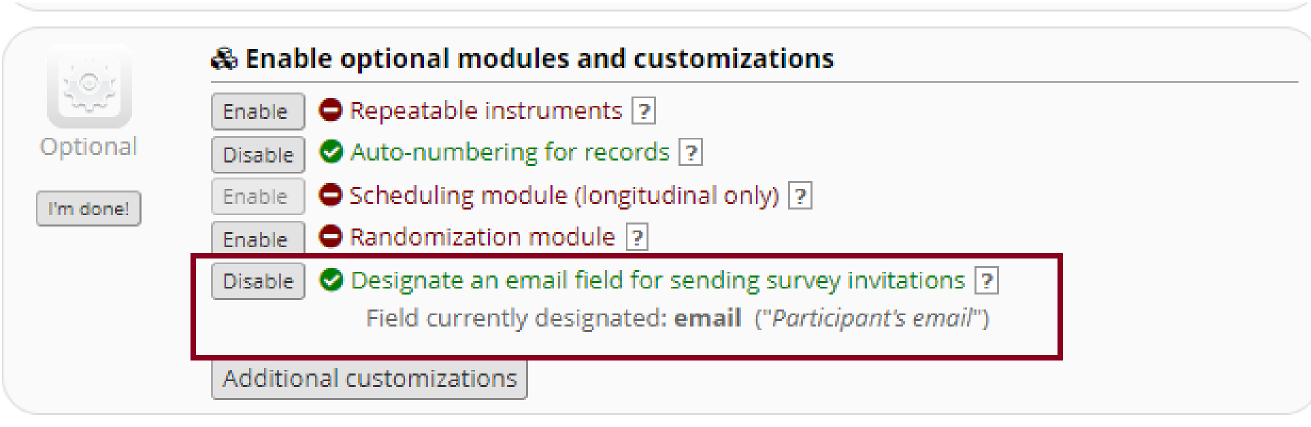


Creating passwords for consent link

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

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

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

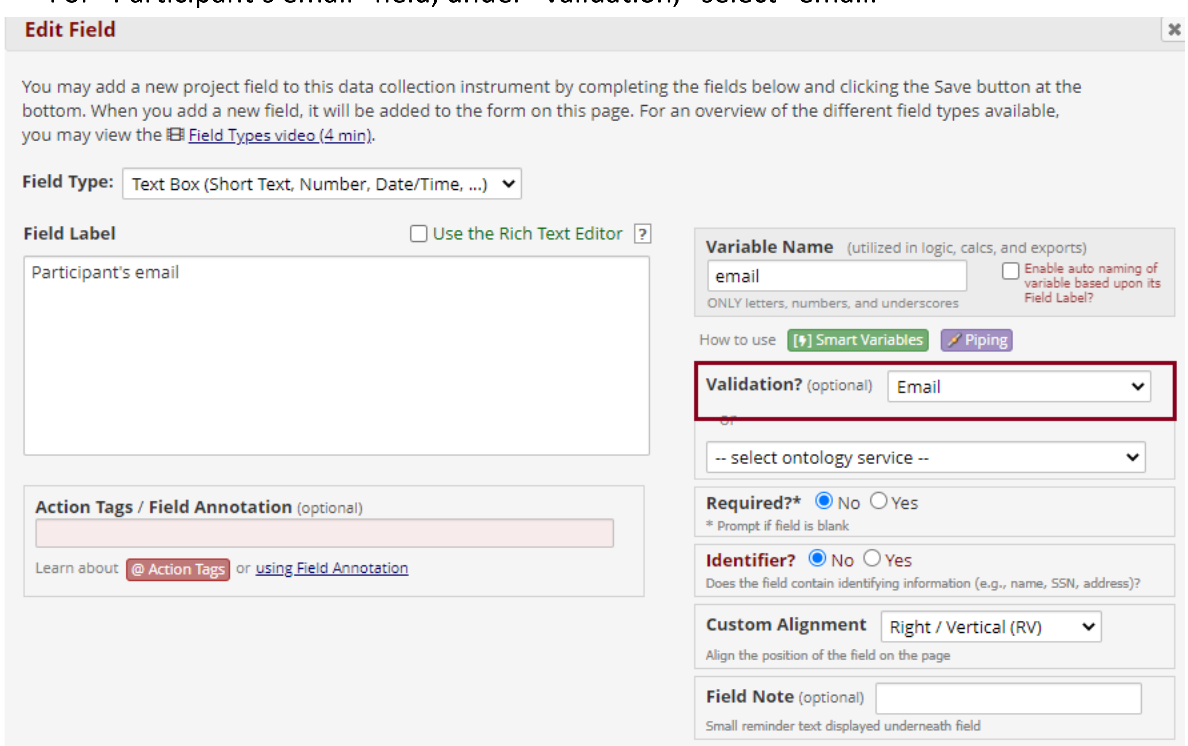


9.1 Go to “Online Designer” and click “create a new record.” Name this instrument something like “Participant Information.” This is where you will enter the participant’s email and code.

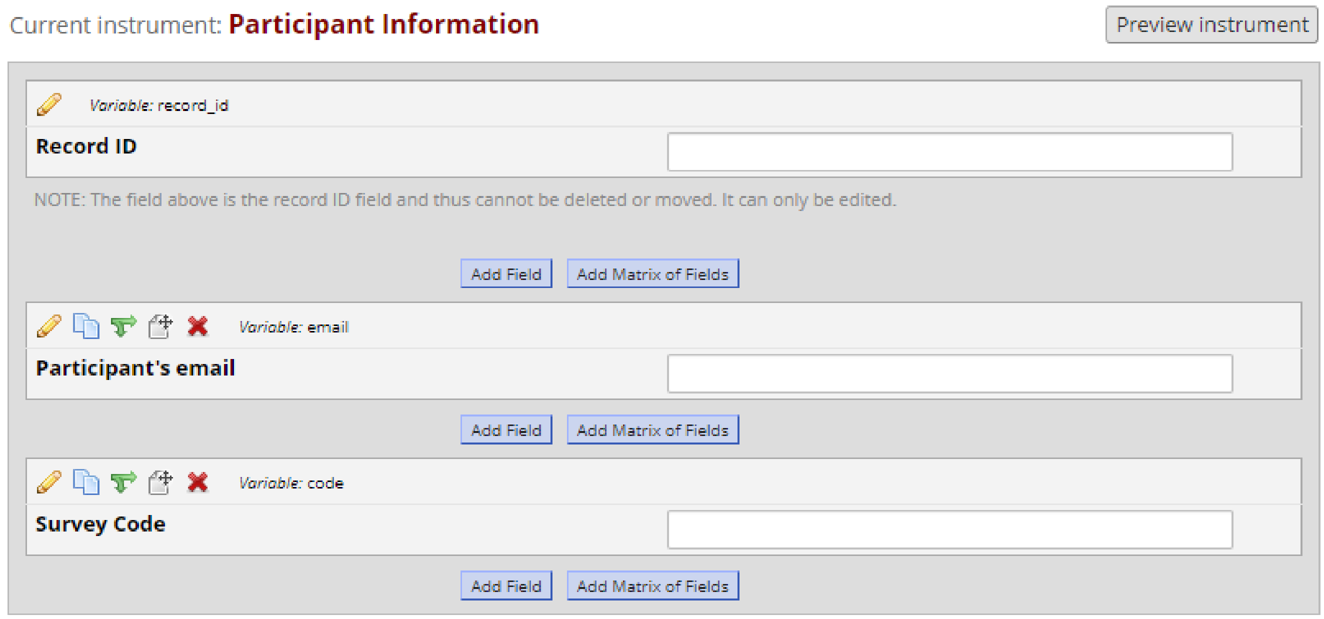
9.2 Open the newly created instrument.

9.3 Click add field and add the two fields, “Participant’s email” and “e-Consent Code.”

9.3.1 For “Participant’s email” field, under “validation,” select “email.”



9.4 The completed instrument should look like this:



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

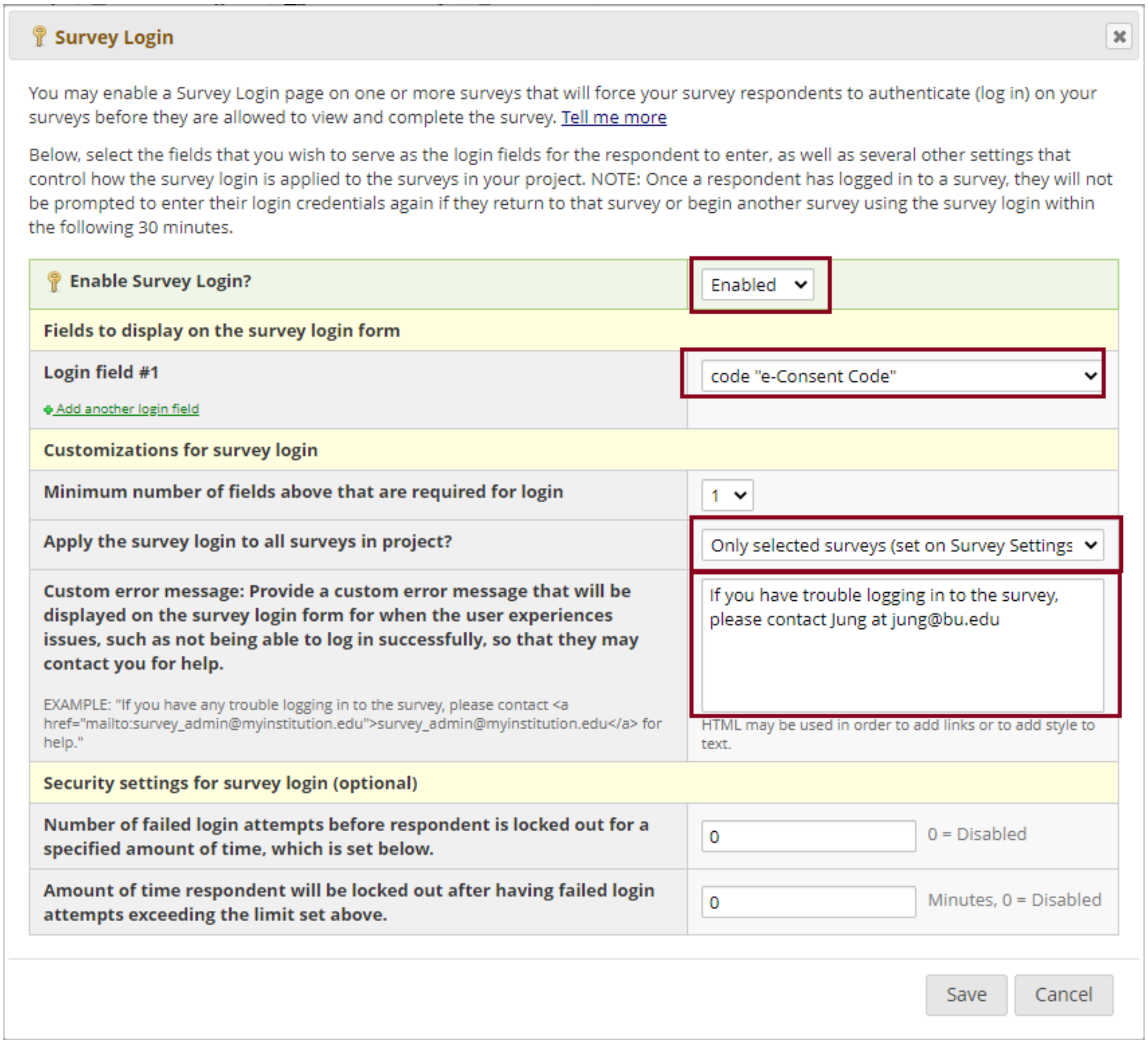
9.5.1 The changes that must be made are marked in red.

9.5.1.1 Enable the Survey Login.

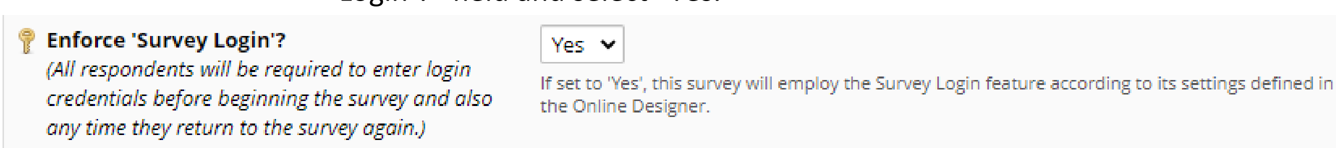
9.5.1.2 For “Login field #1,” select “e-Consent Code” field.

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

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



9.5.1.4.1 To enable this, go to Survey settings and go to “Enforce ‘Survey Login’?” field and select “Yes.”

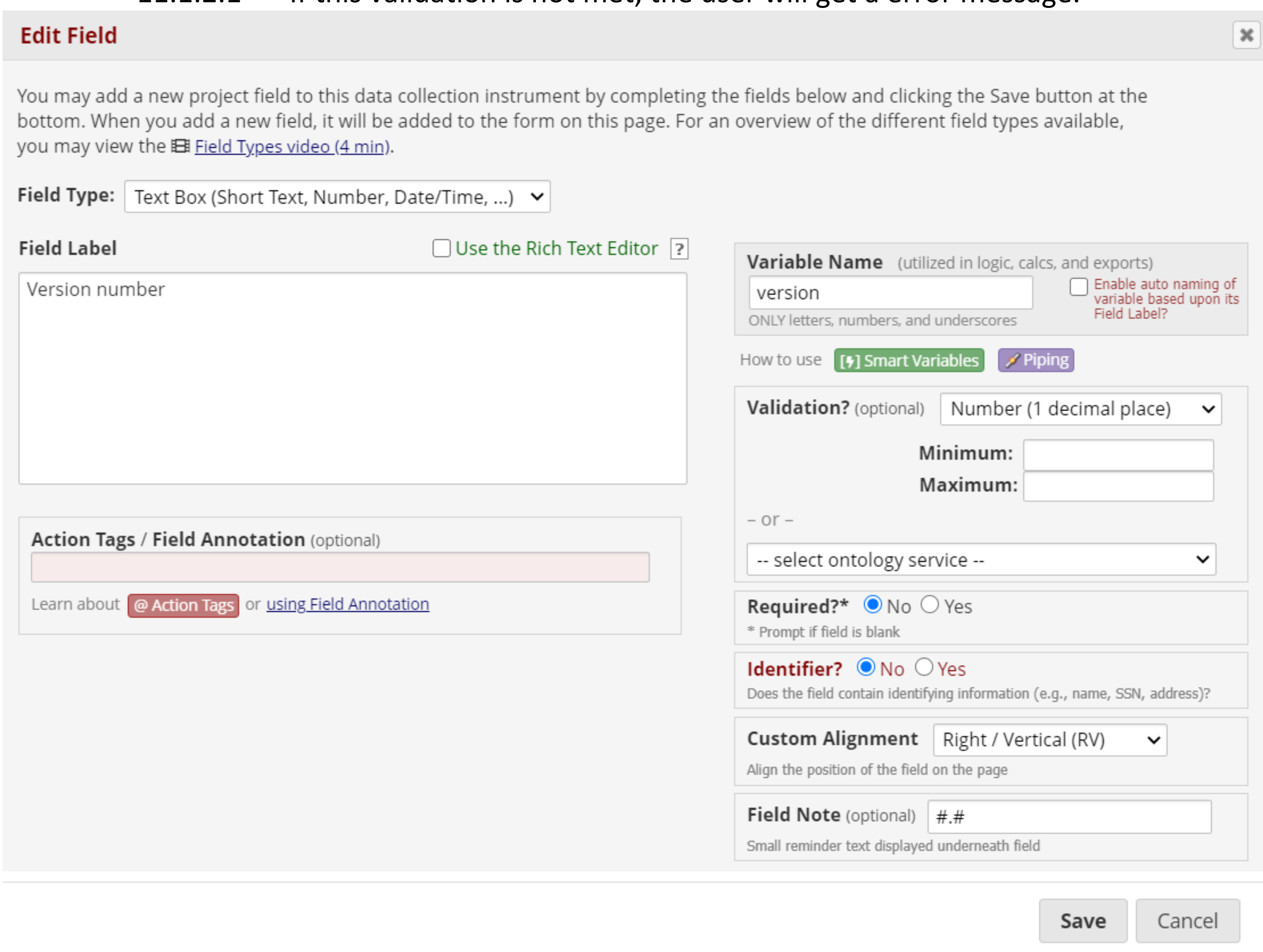


What to do for updated approved informed consent forms

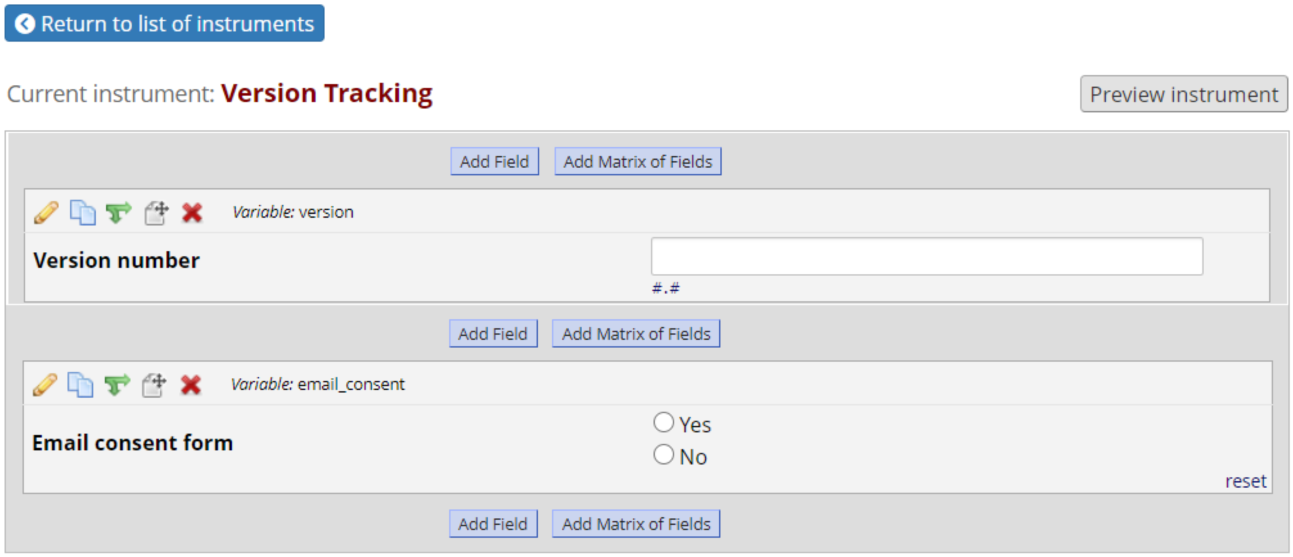
10. When you have an updated approved informed consent, create a NEW e-consent survey. This can easily be done by copying the original or previous e-consent instrument.
    - 10.1 Replace the informed consent pdf link and the images of the informed consent form pages.
    - 10.2 Go to the survey settings and update the settings accordingly. Please refer to step 7!

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

11. To keep track of informed consent versions, create a Version Tracking instrument. The fields in this instrument will be utilized to set up the Automated Survey Invitation (step 12).
    - 11.1 Add a Text Box field to enter the informed consent version number.
        - 11.1.1 It is recommended that you add a validation option for this field because if theres a blank space next to the value entered, this space will be treated as a character. So the field value “1.0” is different from “1.0_” (the underscore represents the blank space).
        - 11.1.2 For the validation option, you can select “Number (1 decimal place).” So this field will have to be in the format “#.#”
            - 11.1.2.1 If this validation is not met, the user will get a error message.



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

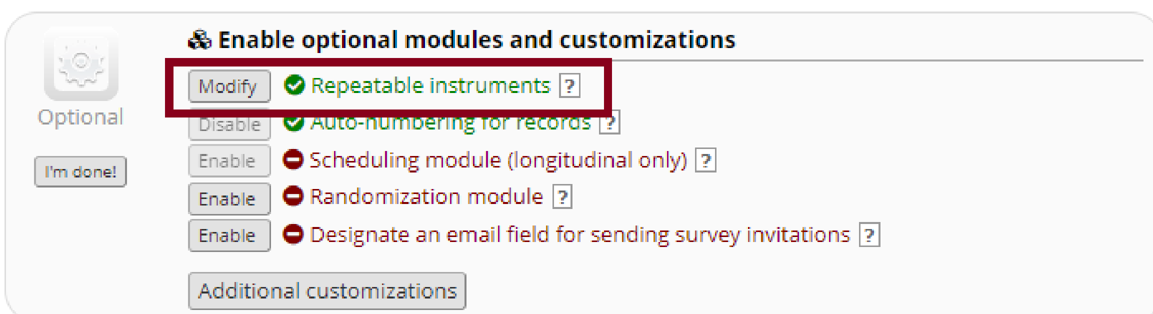


11.4 Go to Step 12 to enable this instrument as a repeatable instrument.

Enabling repeatable instruments for Version Tracking instrument

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

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



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

Repeatable instruments

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

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

Repeat this instrument?	Instrument name	Custom label for repeating instruments (optional) Example: [visit_date], [weight] kg
☐	Participant Information	
☑	Version Tracking	[version]
☐	Participant Consent Form v1.0	
☐	Study Personnel Consent Form v1.0	
☐	Consent Form (participant and study personnel)	
☐	Participant Consent Form v2.0	

Save Cancel

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

Record ID **12**

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

Repeating Instruments

Version Tracking (2)

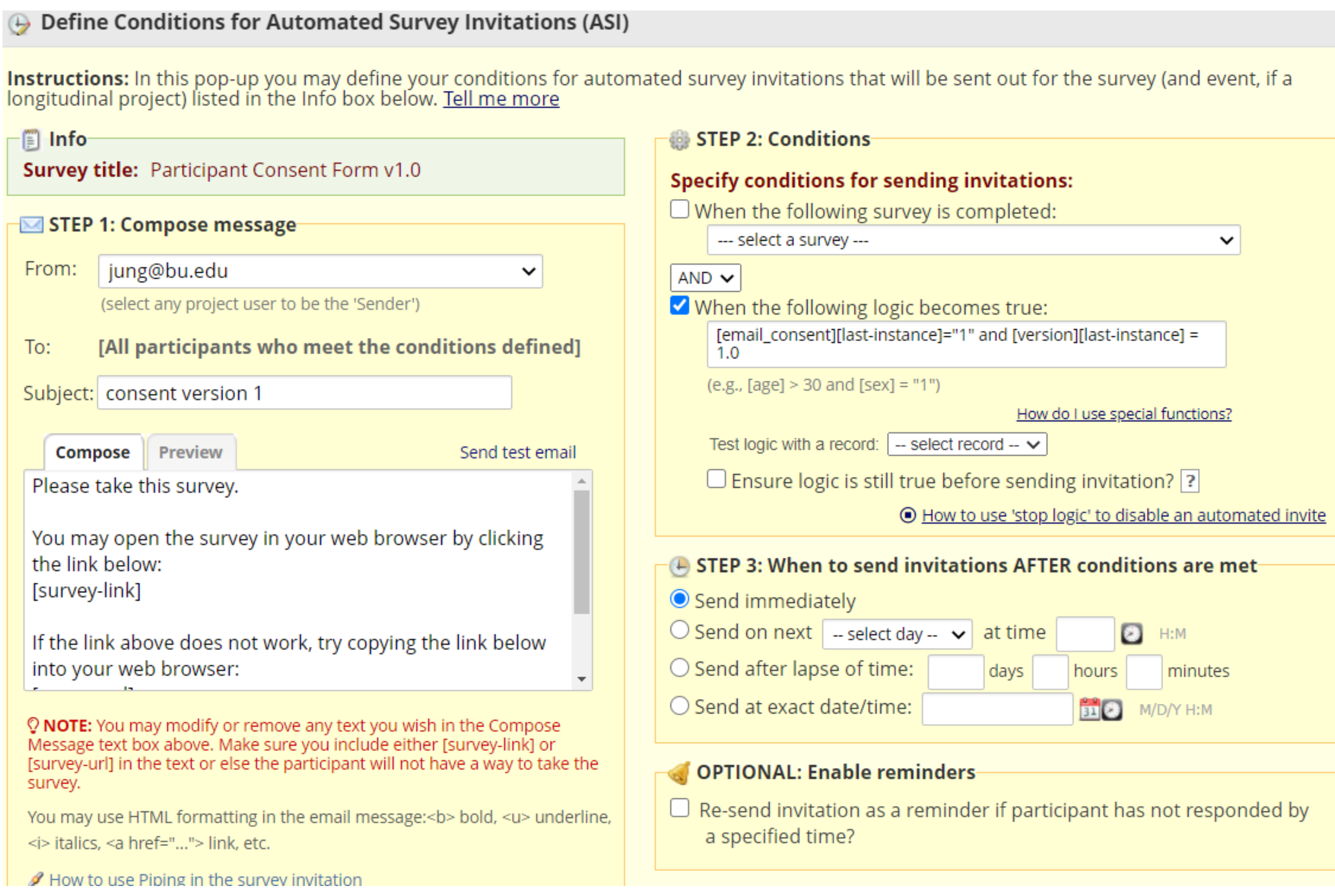
1		1.0
2		2.0

+ Add new

Turning on Automated Survey Invitations (ASI)

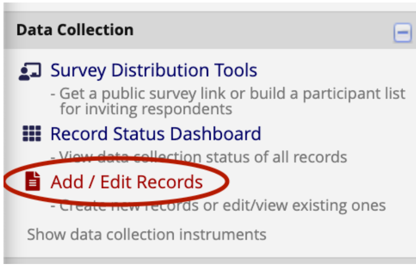
This is to set up the ASI feature, which will automatically send the link to the e-consent form depending on specific conditions. **Please follow the specific conditions outlined in step 12.2 carefully!** The conditions that will trigger the ASI have been set so that the variables refer to the latest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

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



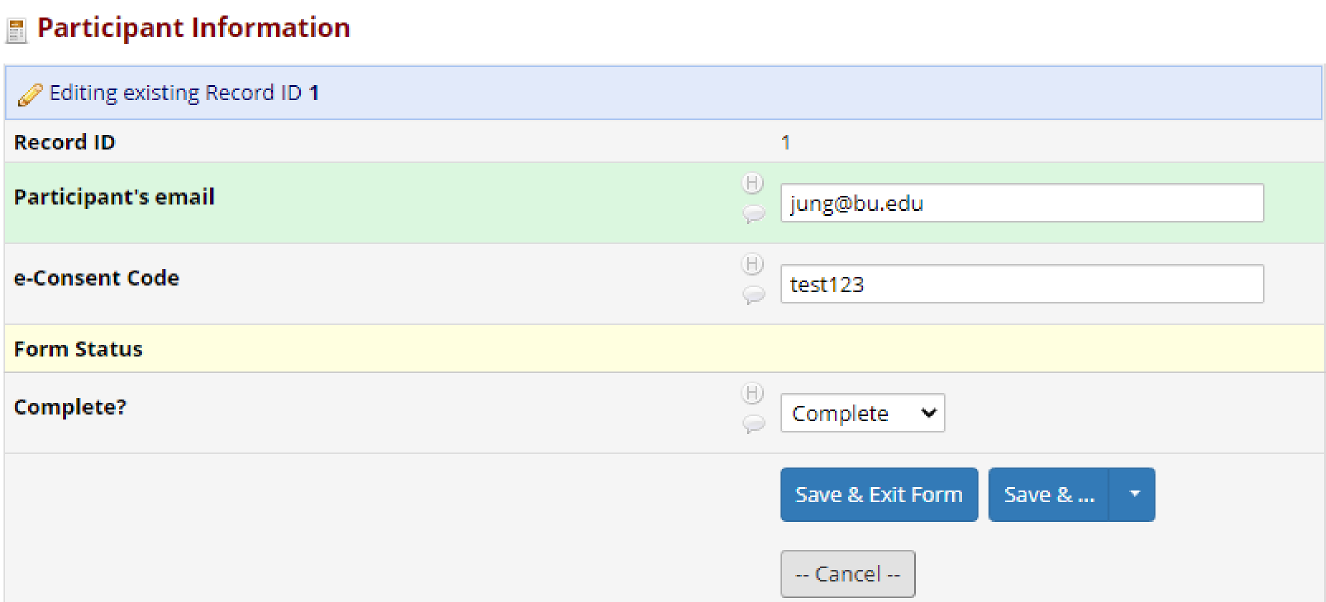
Sending out the e-consent invitation email

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



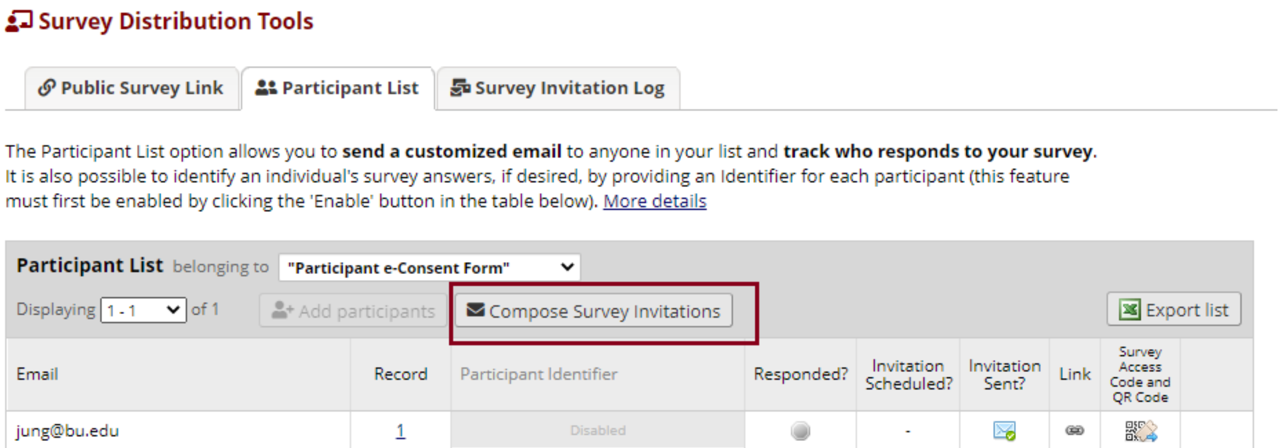
    13.2 Next, navigateto the "Choose an existing Record ID" heading and under the "select record" drop down menu, click on the green "+Add new record" button and this will create a new and open up the new record.

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



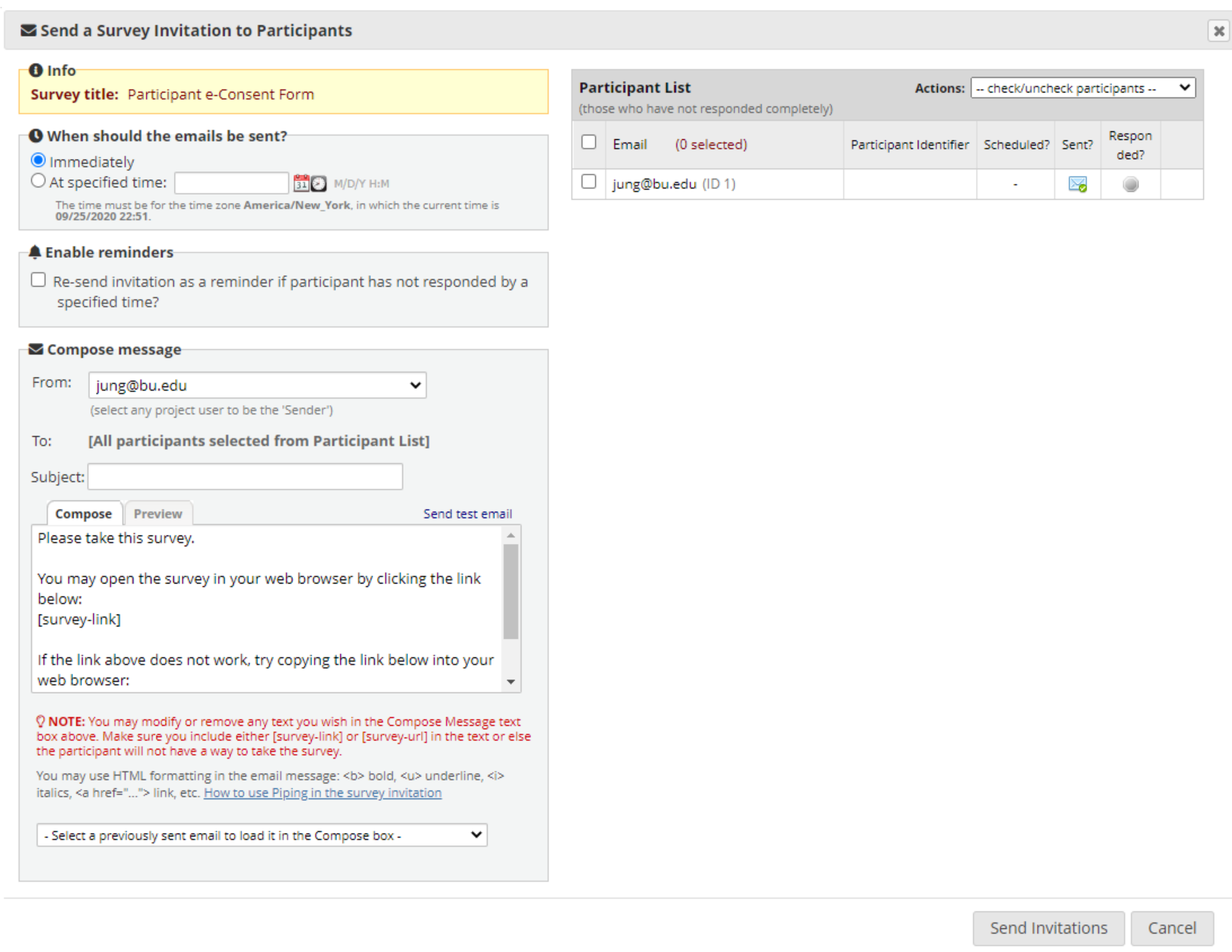
Re-sending the e-Consent invitation email

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



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

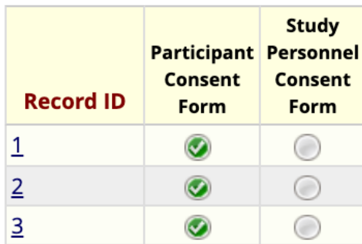
14.2 Under "Participant List" select the record/email that needs the new invite and click "Send Invitations."

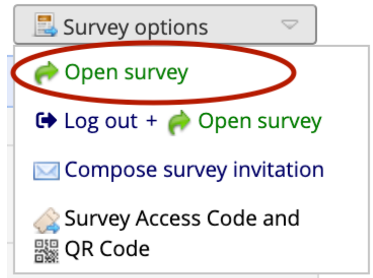


Completing the Study Personnel Consent Form – Reminder for Contactless Consent

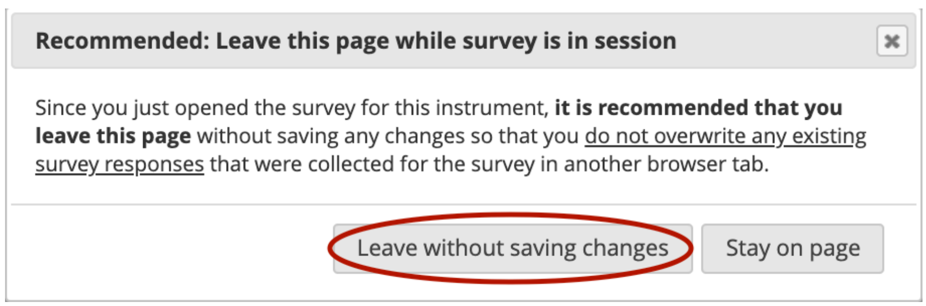
15. Since the e-consent framework is turned on for the Study Personnel Consent Form, it must be completed as a survey. To access the consent link for study personnel, go to the participant's record and click on the "Study Personnel Consent Form" instrument.

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

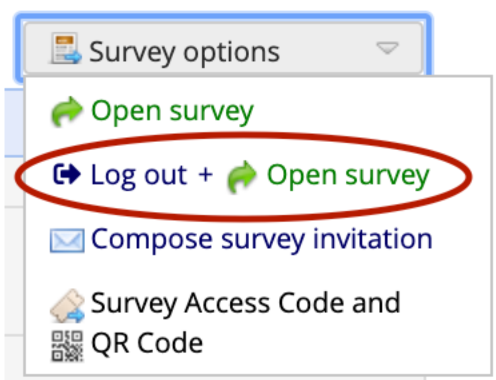




15.2 Once you complete the e-consent survey and click "Close survey", It will lead you back to the original data entry form of the "Study Personnel Consent Form." IMPORTANT: Make sure that you click "Leave without saving changes." Clicking this option will save the changes made in the consent via the survey link. If you click "Stay on page" instead, the responses entered in the consent via the link will not be saved to the record.



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



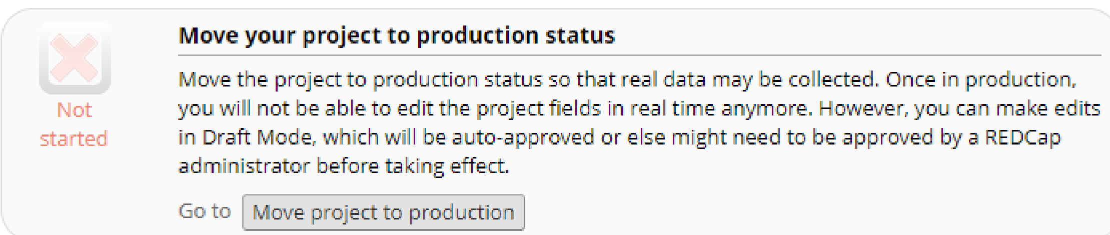
Enabling Twilio in REDCap

16. REDCap has the capability to send SMS text messages to survey respondents by using a third-party web service named Twilio. Costs associated with this service are managed from your Twilio account. For more information about Twilio in REDCap, please visit the request link below. Please note that you need to obtain specific IRB approval to use Twilio.
    - 16.1 Please follow this link to request the Twilio Module in REDCap: https://redcap.bumc.bu.edu/surveys/?s=HJPXWCME7H
    - 16.2 IRB approval is required to ues Twilio

Checking project and moving to production status

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

    - 17.1 Move your project to production status.
        - 17.1.1 Go to the “Project Status” page and scroll to the bottom. Click “Move project to production.”



Enabling the Multilingual External Module in REDCap

External Modules are add-on packages of software that can extend REDCap's current functionality, as well as provide customizations and enhancements for REDCap's existing behavior and appearance. Modules will need to be installed and enabled by a BUMC REDCap administrator. Please contact Tacha Coughlin, Coughlin, tawatson@bu.edu, with the name of your REDCap project to set this up.

The Multilingual EM allows surveys and data entry forms to be translated into multiple languages. The module and your language choices should be setup first, before building your instruments. To learn more visit https://redcap.bumc.bu.edu/redcap_v9.3.0/ExternalModules/?prefix=multilingual&page=README.md

18. Please follow this link to request an External Module in REDCap: https://redcap.bumc.bu.edu/surveys/?s=F8W4LLXJRP

Links to additional resources

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

Resources for REDCap:
REDCap FAQ

REDCap Training Videos

REDCap email support: rchelp@bu.edu