Setting up e-Consent in REDCap: The Basics for a Consent Requiring a Signature

Background

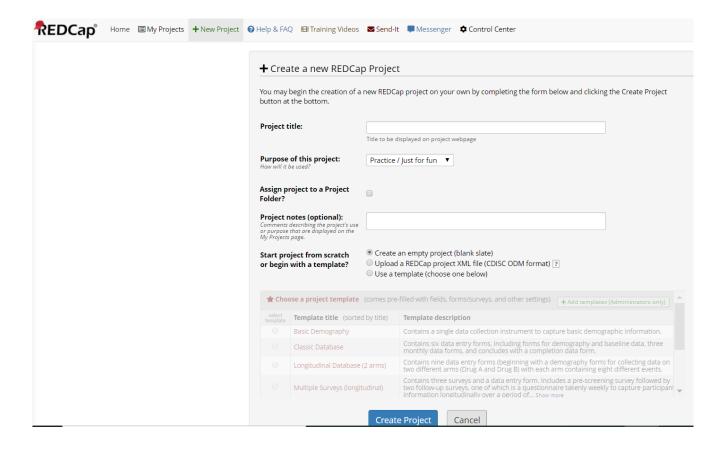
For those who are navigating REDCap to create an e-consent document, the process can be a bit tricky. Thus, the Clinical Research Resources Office (CRRO) has developed a "Building a REDCap e-consent Guidance" for utilizing the REDCap e-consent capability. This guidance will take you step-by-step to build your e-consent from the IRB-approved stamped consent form. **This guidance is specifically intended for research that WILL require a signature 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 the mouse. (Note that 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 be Part 11 compliant.)

If you have comments about the "Building a REDCap e-consent Guidance," suggestions on how to make the guidance easier to use, or other questions about e-consent please contact Mary-Tara Roth at the CRRO (mtroth@bu.edu).

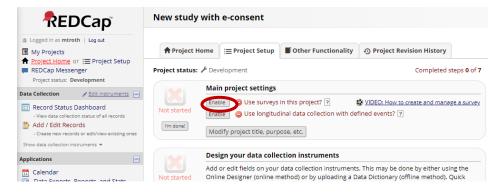
Special thanks to Tasha Coughlin, the BUMC REDCap Administrator, for her help and expertise in developing this guidance!

Setting up your e-consent requiring a signature

- 1. If you plan to obtain e-signatures on your e-consent form, you should submit a consent form version to the IRB that does not contain the signature lines. Keep the consent form template wording: "By signing this consent form, you are indicating that...." (You would not keep this wording if you have IRB approval for Waiver of Documentation of consent.)
- 2. Save your IRB-approved and stamped PDF consent form as a jpeg or png file.
- 3. Sign on to REDCap and go to "My Projects."
- 4. 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 5.0.
 - 4.1 Complete Project title, Purpose (research), PI info, Project notes, etc.)
 - 4.2 At the end of the page, choose "Create empty project (blank slate)" and press the blue "Create Project" button.



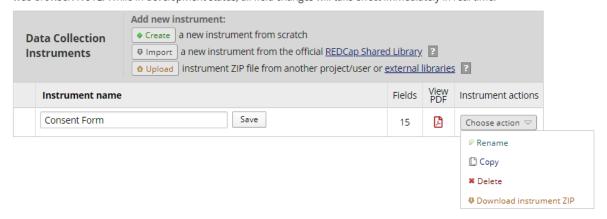
- 5. At "My Projects" page, select the appropriate project that you are creating an e-consent for. This will bring you to the "Project Setup" tab.
 - 5.1 Under "Main Project Settings" within Project Setup tab select the "Enable" button for the question "Use surveys in this project?"



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



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

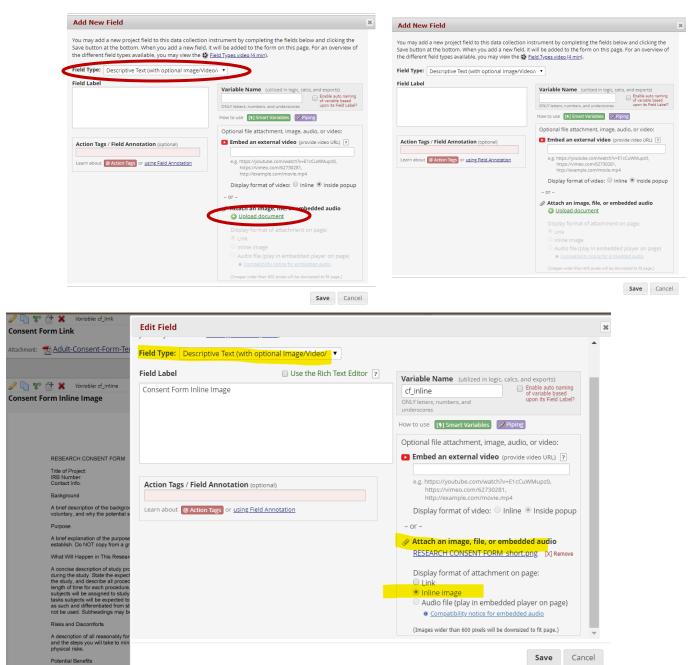


- 6. Now build your consent form.
 - 6.1 Click on your newly named instrument (see 5.3 above).
 - 6.2 Click "Add field" button.



- 6.3 Under the Field Type drop down, choose "Descriptive Text..."
- 6.4 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). Save.
- 6.5 At bottom of first consent form page (the jpeg image), click the "Add field" button.

6.6 Follow the instructions in 6.3 and 6.4 above for all the consent form pages.

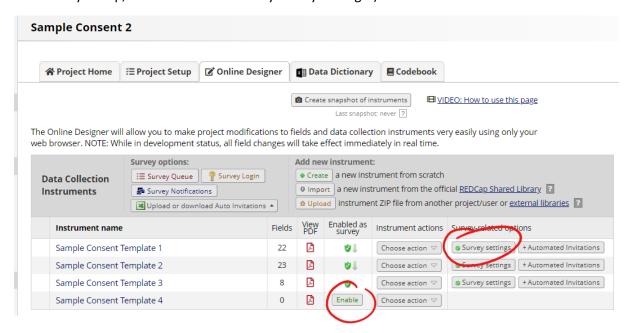


7. When finished uploading all jpeg format pages of the consent form, scroll to the top and click on the blue "Return to list of instruments" button. Then click on "Project Setup" tab.



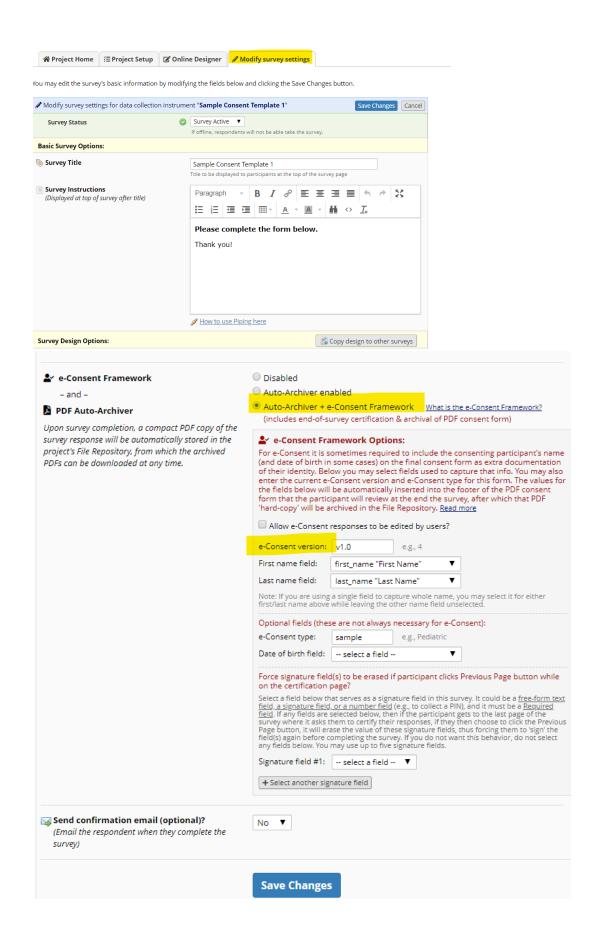
7.1 Under the section "Design your data collection instruments & enable your surveys" click on the "Online Designer" button.

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").

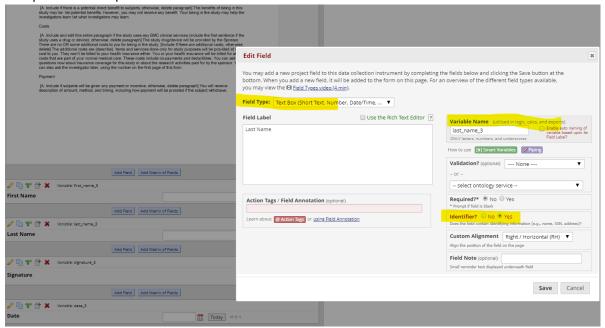


- 7.3 Under "Basic Survey Options" fill in "Survey Title" and "Survey Instructions." This information will appear at the top of your electronic consent survey page.. The instructions can be some simple instruction that makes sense within your consent process, such as: "Please review this electronic consent form with the study coordinator."
- 7.4 Scroll down to "Survey Termination Options" at the bottom of the survey settings page.

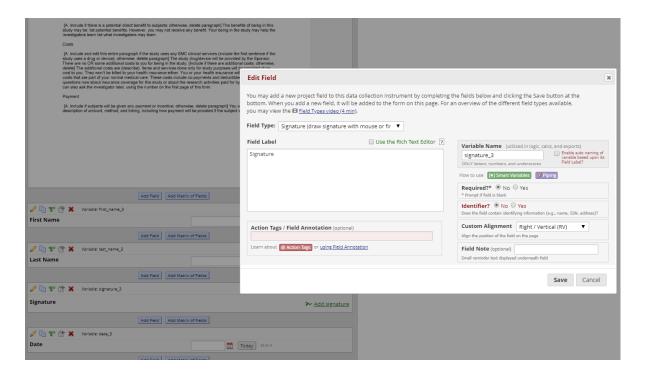
 Next to "Survey Completion Text" provide the text you want to show to the participant after he/she provides an electronic signature. For example: "Thank you for your participation in this research study!" Click the "Save Changes" blue button on the bottom of this webpage.
- 7.5 To the right of the "PDF Auto-archiver" choose the third option: "Auto-Archiver + e-Consent Framework."
- 7.6 Next to "e-Consent version" provide a version number.



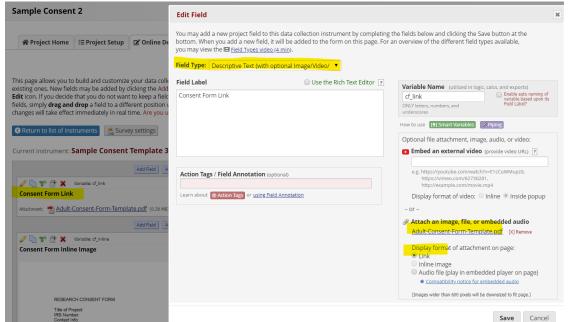
- 8. Add electronic signatures. You can add text box fields for the participant to type in his/her first and last name, and/or you can add a signature field, allowing the participant to provide an e-signature using a stylus, finger, or mouse.
 - 8.1 On the Online Designer tab, click on your consent form under the heading "Instrument name."
 - 8.2 Scroll down to the last page of your electronic consent form.
 - 8.3 Click the "Add Field" blue button at the bottom of the page.
 - 8.4 Select "Text Box..." from the dropdown menu.
 - 8.5 Under the field Label type "First name." Under "Variable Name" type "first_name".
 - 8.6 Complete the "Required?" And "Identifier?" fields as 'Yes'. Click "Save."



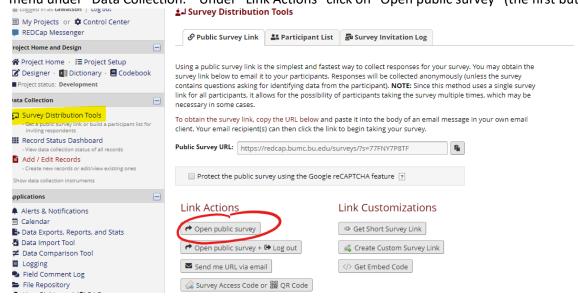
- 8.7 Continue and add Last name field following steps 8.2-8.6.
- 8.8 If you want to, you can add a Stylus Signature field in addition to the typed signature. In Field type, choose "Signature..." from the dropdown menu. Proceed as before with steps 8.5-8.6.



- 8.9 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 (such as "Date (M-D-Y)). Complete additional fields as necessary.
- 8.10 You may also elect to setup a file download field, to allow the participant to download a hardcopy of the consent form.



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



- 10. 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. Move your project to production status.