Using REDCap for Participant eConsent – Instructional Setup – Ver 3.0

A new template has been created for REDCap users to leverage eConsent functionality for their REDCap project. eConsent use and operation is strictly standardized and controlled in both how it is implemented in REDCap and how it should be conducted by researchers when using the REDCap eConsent template. A majority of the functionality for eConsenting paticipants in a study is already built into the REDCap eConsent template. However, a portion of any eConsent setup is unique to each study and therefore all users who want to eConsent participants in REDCap need to follow the below guidelines in order to properly setup their project and prepare it for compliant eConsenting of study participants.

This instructional setup brief (along with a paired instructional use brief) provides you with a series of steps for assuring your project will be compliant. REDCap has the technical features necessary to serve as the database component of a 21 CFR Part 11 compliant study. However, a project in REDCap must have policies, procedures, training, validation and documentation meeting the requirements of Part 11 and the predicate rules for the underlying legislation. Keep in mind that an FDA auditor would review all project documentation to determine AT THE PROJECT LEVEL if a study is compliant.

Steps for Users to finish setting up an eConsent Compliant REDCap Project

1) Firstly, you may NOT edit or change any existing eConsent settings as they are originally set in the REDCap project template. Doing so will likely affect your project's compliant status.

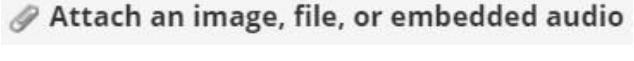
2) Go to Online Designer > Survey Settings of the eConsent instrument:

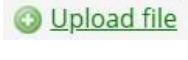
- *Survey Title* – name your eConsent form with whichever name you feel is appropriate for your study
- *Survey Instructions* – add any relevant instructions to be placed at the front/top of your eConsent form
- *Survey Completion Text* – add any relevant closing statement to be placed at the end/bottom of your eConsent form

3) Go to Online Designer > eConsent instrument:

- Find all fields with *(Delete if Not Needed)* or *(setup required)* and either use and edit the Field Labels, or delete the field entirely if not needed for your study.

4) Each study has their own unique consent form. You will need to upload this. Go to Online Designer > eConsent instrument:

- Convert / Save each page of your consent document (.pdf or .doc/x) as an image (.jpeg or .png) - Using Adobe Acrobat Pro is recommended
- Scroll down to the first consent form page field, … - *Page 1 (Setup Required),* click 
- To the right of the Edit window, look for 

- Click 

, Choose File (find your page images, and choose the correct page), and Upload File
- Edit the field Label of this field as needed (at least removing the *(Setup Required)* text)

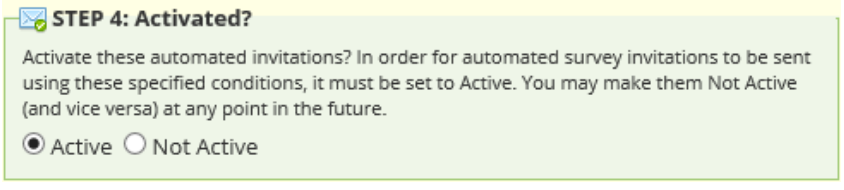
5) Your study may have a separate HIPAA Consent Form. If so, you will need to upload this. Go to Online Designer > eConsent instrument:

- Follow all steps in Step 4 above, only now for your HIPAA Consent Form

6) On the Online Designer page, go to 

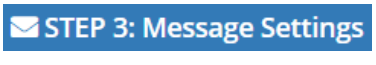
button for the "eConsent" instrument:

- Set the email From, Subject, and Message as per your study's need.
- Finally, activate the ASI settings:



7) On the left side of your REDCap window, go to Alerts & Notifications, under Applications:

- In the Alert #1 section, click 

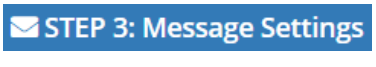
- Scroll down to 

and customize **ONLY** the *Email To*, *Subject*, and *Message* fields as needed to be appropriate and specific for your study.
- Click 

at the bottom of the window.

8) On the left side of your REDCap window, go to Alerts & Notifications, under Applications:

- In the Alert #2 section, click 

- Scroll down to 

and customize **ONLY** the *Email From*, *Subject*, and *Message* fields as needed to be appropriate and specific for your study.
- Click 

at the bottom of the window.

9) Continue with setting up the rest of your project as needed.