Guidance on Building a Non-exempt eConsent from a Pre-Built REDCap Template

Boston University Medical Campus
Boston University Charles River Campus
Boston Medical Center

This guidance will explain the technical steps to build an eConsent project in REDCap using pre-built templates for research projects at Boston Medical Center, Boston University Medical Campus (BUMC), and Boston University Charles River Campus (CRC). Specifically, this guidance is intended for research that requires signatures on the consent form. Under Massachusetts law, a person typing their name on an electronic document constitutes a legally valid signature. REDCap has additional functionality for completing a legally valid signature using a stylus, mouse, or finger. For studies occurring outside of Massachusetts, researchers should abide by applicable state laws.

If the study is non-exempt and the IRB has approved a waiver of documentation of consent (no signature required), researchers should use the Guidance on Building REDCap eConsent for Minimal risk or Exempt Research Not Requiring Signatures or Exempt Research that Includes HIPAA authorization.

The Using eConsent: Overview and General Instructions guidance provides information about eConsent, REDCap, DocuSign, and FDA Part 11 compliance requirements. **Reviewing this eConsent Overview should be the first step prior to completing the technical steps for building the project in REDCap.**

Although this guidance has been created with best study practices in mind, certain features or functionalities may need to be altered to match unique study needs and workflow. This guidance assumes intermediate REDCap user knowledge. For beginners, please contact rchelp@bu.edu for a consultation prior to starting the project.

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Create a REDCap Account

A REDCap account must be set up prior to completing any further steps. To request a REDCap account, the End User Agreement must be completed. A REDCap sponsor may need to be listed depending on the requestor's role or affiliation. This sponsor must be an existing BU or BMC REDCap end user with an active account.

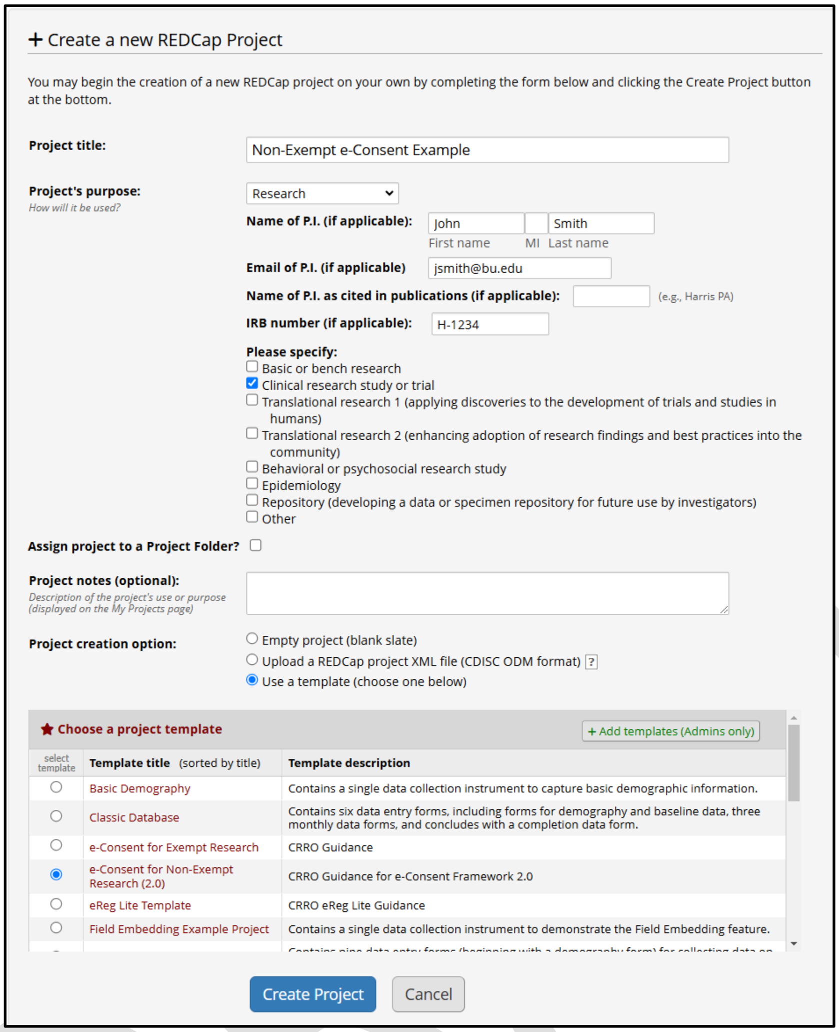
Start a New eConsent Project

It is best practice for REDCap eConsent Instruments/Surveys to be maintained in their own project, separate from the main study database (i.e., you should maintain consent forms in one REDCap project and coded participant study data in another REDCap project). This helps to ensure participant confidentiality by keeping personal (direct) identifiers such as name and date on the consent form separate from the participant study ID and data.

However, this best practice is not an absolute requirement, and your project may differ depending on the study design. Your set-up of the project in REDCap should follow the IRB-approved protocol. If you plan to maintain study data in the same project as the signed consent then this should be described in the Confidentiality of the Data section within the IRB application.

1. Log into REDCap and click 'New Project' at the top menu.
2. Complete Project title, Purpose, and Principal Investigator info.
3. Select 'Use a template (choose one below)' under 'Project Creation Option'.
4. Choose 'eConsent for Non-Exempt Research' under 'Choose a project template' and press the blue 'Create Project' button. See Appendix B for overview of the template instruments.
5. Click 'I agree' on the pop-up notice.

Note: For existing instruments in your projects, please review your project template instruments and settings and update as applicable.



+ Create a new REDCap Project

You may begin the creation of a new REDCap project on your own by completing the form below and clicking the Create Project button at the bottom.

Project title: Non-Exempt e-Consent Example

Project's purpose: Research
How will it be used?

Name of P.I. (if applicable): John | | Smith
First name MI Last name

Email of P.I. (if applicable) jsmith@bu.edu

Name of P.I. as cited in publications (if applicable): (e.g., Harris PA)

IRB number (if applicable): H-1234

Please specify:
- [ ] Basic or bench research
- [x] Clinical research study or trial
- [ ] Translational research 1 (applying discoveries to the development of trials and studies in humans)
- [ ] Translational research 2 (enhancing adoption of research findings and best practices into the community)
- [ ] Behavioral or psychosocial research study
- [ ] Epidemiology
- [ ] Repository (developing a data or specimen repository for future use by investigators)
- [ ] Other

Assign project to a Project Folder?

Project notes (optional):
Description of the project's use or purpose (displayed on the My Projects page)

Project creation option:
- ○ Empty project (blank slate)
- ○ Upload a REDCap project XML file (CDISC ODM format) ?
- ◉ Use a template (choose one below)

Choose a project template + Add templates (Admins only)

select template	Template title (sorted by title)	Template description
○	Basic Demography	Contains a single data collection instrument to capture basic demographic information.
○	Classic Database	Contains six data entry forms, including forms for demography and baseline data, three monthly data forms, and concludes with a completion data form.
○	e-Consent for Exempt Research	CRRO Guidance
◉	e-Consent for Non-Exempt Research (2.0)	CRRO Guidance for e-Consent Framework 2.0
○	eReg Lite Template	CRRO eReg Lite Guidance
○	Field Embedding Example Project	Contains a single data collection instrument to demonstrate the Field Embedding feature.

Create Project Cancel

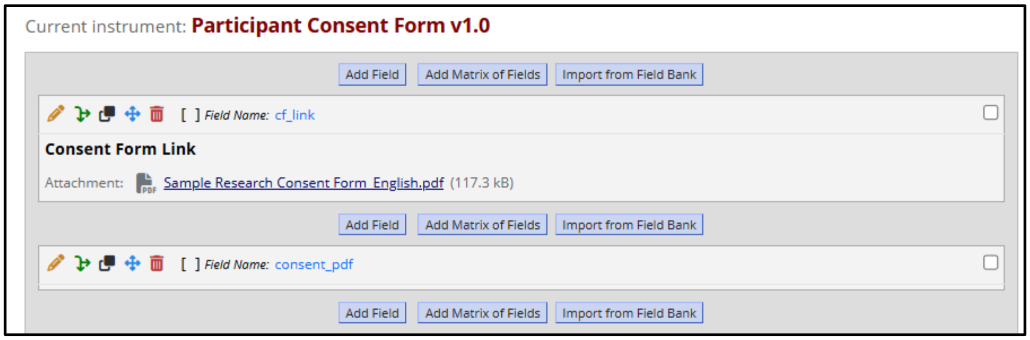
Upload the IRB Approved stamped Informed Consent Form (ICF)

The consent form stamped with the IRB approval must be displayed on the REDCap eConsent. This can be done by creating a placeholder descriptive text field on the 'Participant Consent Form' instrument, then uploading the approved PDF in the eConsent Framework Settings.

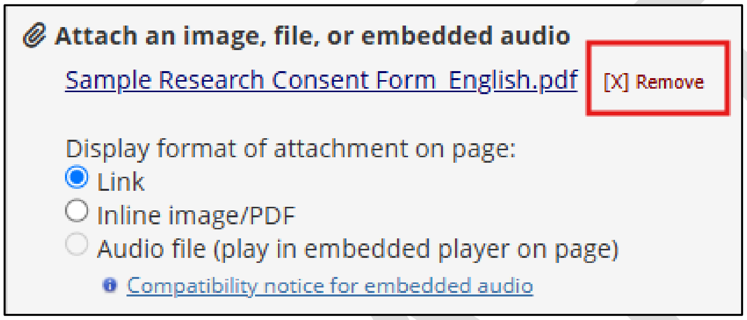
Note, the IRB requires this method of using the REDCap PDF inline display instead of adding the consent text into a text field. This ensures that the IRB-approved stamped consent is what is used as it minimizes risk for the consent form language to be inadvertently changed. Therefore, this guidance will not include step-by-step instructions here for adding consent language as text into REDCap direct data entry/capture of consent language text into REDCap. If there is a good reason why text display is needed instead of PDF display for your study, please reach out to medirb@bu.edu.

To Upload the Approved Consent as Downloadable Link and Set Placement for Inline PDF

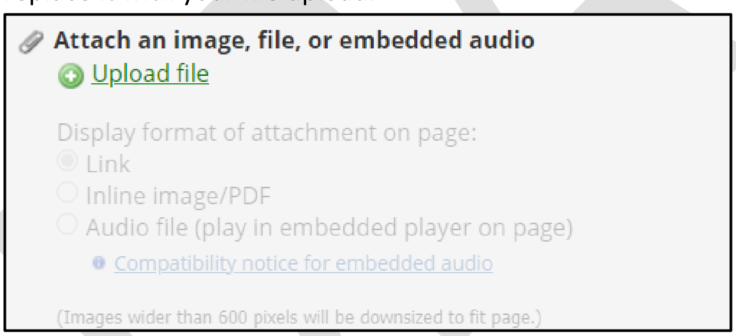
1. From the left menu, click 'Designer' and then the instrument 'Participant Consent Form v1.0'.
2. Click edit on the 'cf_link' field.



3. Click '[X] Remove' under 'Attach an image, file, or embedded audio'



4. This will prompt the deletion of the current PDF of the Sample ICF present in the template and replace it with your file upload.



5. Click '+ Upload file' and follow the prompts to upload a PDF of the study's IRB approved ICF.
6. Select 'Link' under 'Display format of attachment on page' and click 'Save' to display a downloadable PDF link.
7. Just below the downloadable link field is the eConsent display field. This 'consent_pdf' Descriptive text field will be the **location of the displayed eConsent PDF**. DO NOT attach your IRB approved PDF consent form here.

Update the Optional Questions

1. The instrument 'Participant Consent Form v1.0' includes a matrix of fields that reflects an optional sub-study/recontact section that may be present in the IRB approved ICF.

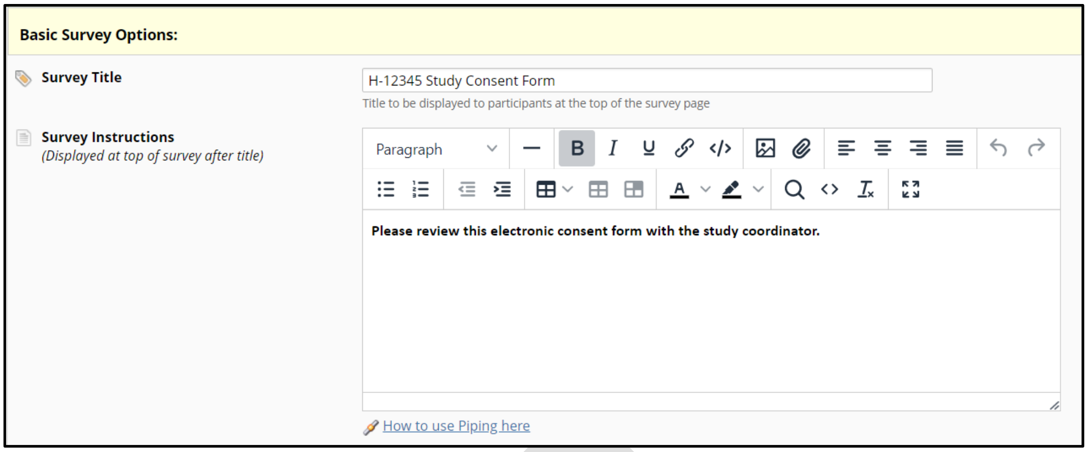
a. If the study's IRB approved ICF does not include a recontact section, delete the matrix using the delete icon
b. If the study's IRB approved ICF includes a recontact section, update all fields accordingly

2. To edit, click the edit icon for each matrix field.
3. From the edit menu, alter the header text, questions (matrix rows), and answers (matrix column choices) to exactly match what is in the IRB-approved consent.
4. Review the re-contact fields below the matrix and delete or edit them as applicable.
5. Any changes should be repeated in the 'Consent Form (participant and study personnel) v1.0' instrument.

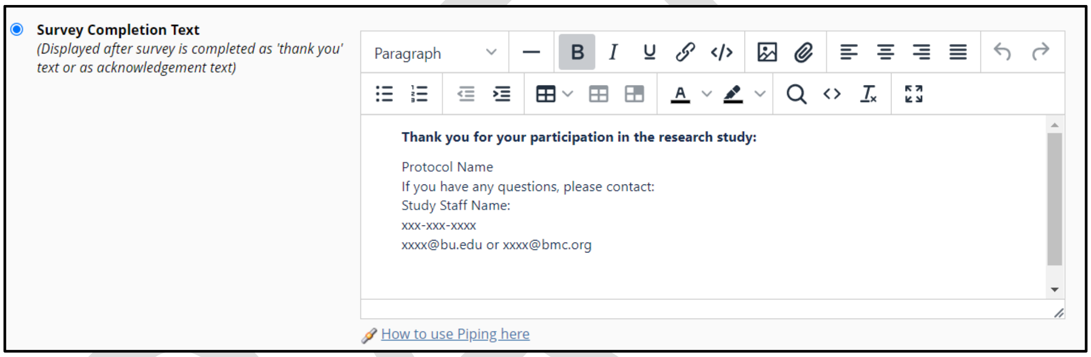
Update the Survey Language for the Participant Consent Form

All information for study participants including survey instructions and survey completion text must be reviewed and approved by the IRB prior to implementation.

1. In 'Survey Settings' under 'Basic Survey Options' fill in 'Survey Title' with the study's H# and 'Survey Instructions' to reflect any study specific consent processes (e.g., Please review this research consent form with the study coordinator). This information will appear at the top of the participant's eConsent survey page.

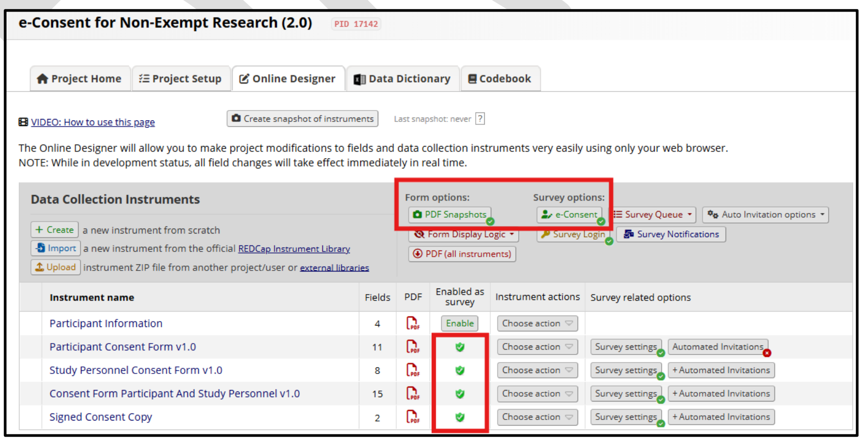


2. Scroll down to 'Survey Termination Options'. Edit the template text as applicable.

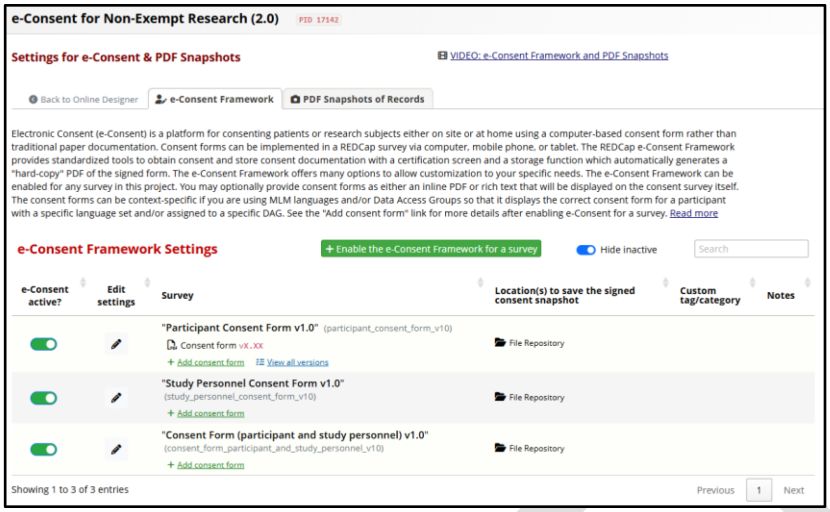


Configuring eConsent and PDF Snapshots Settings

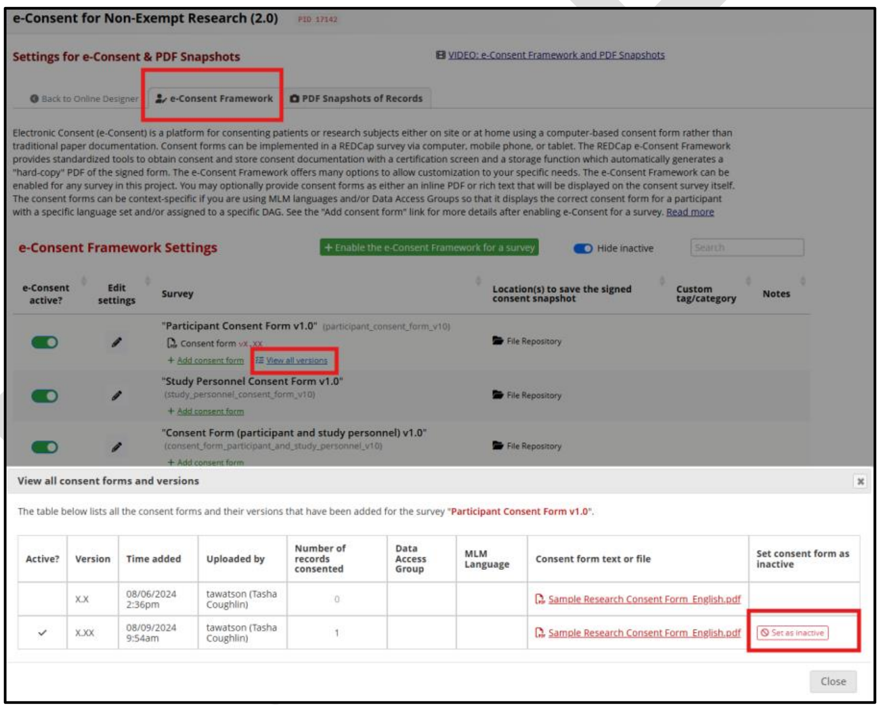
1. After updating required instruments and enabling them as surveys, you will need to configure the settings in the 'eConsent and PDF Snapshots' via Online Designer.



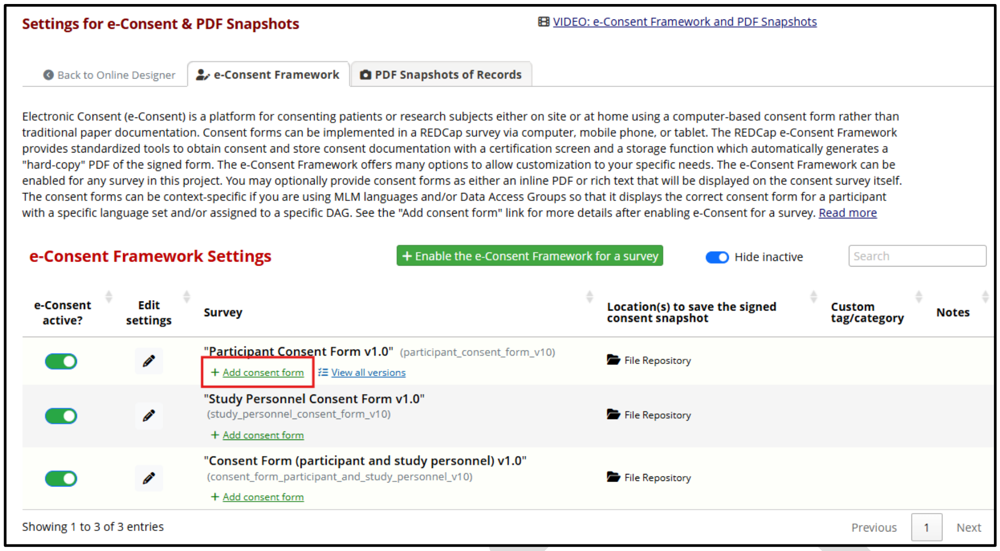
2. Navigate to the 'eConsent and PDF Snapshots' module from the Online Designer.



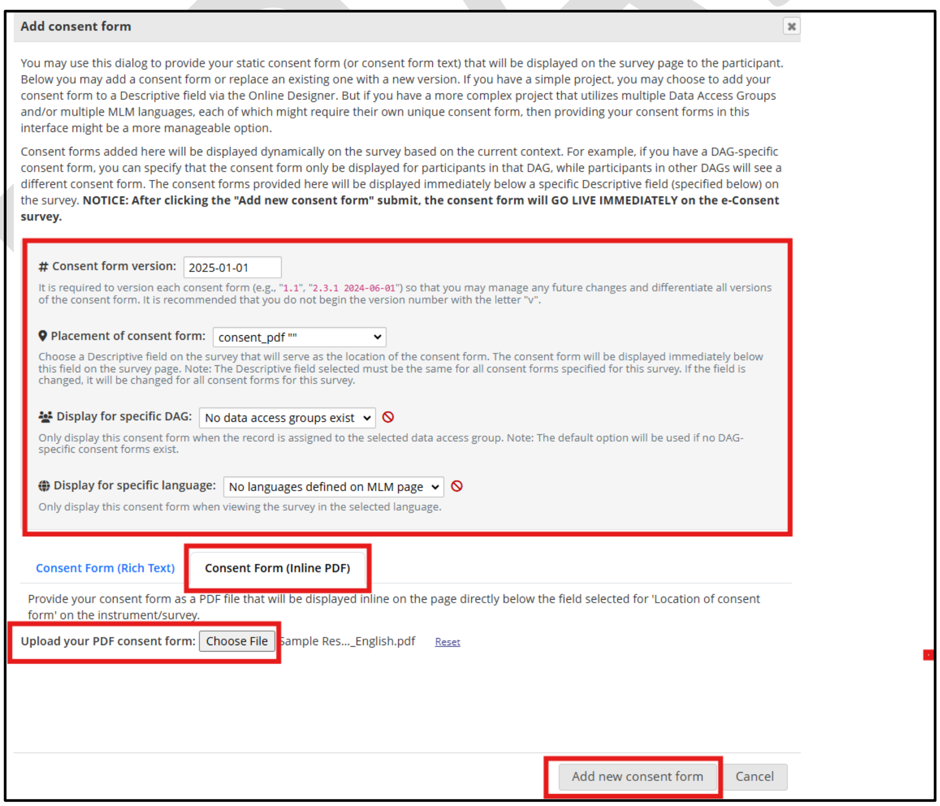
3. On the 'eConsent Framework' tab, confirm that current eConsent surveys are activated and click 'View all versions' to set any pre-existing sample templates as inactive.



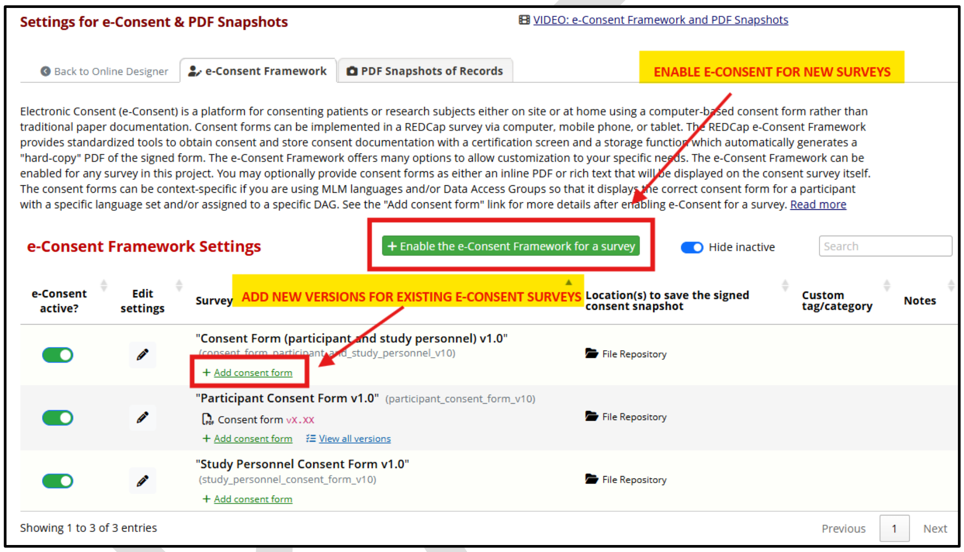
4. Click '+Add consent form' link



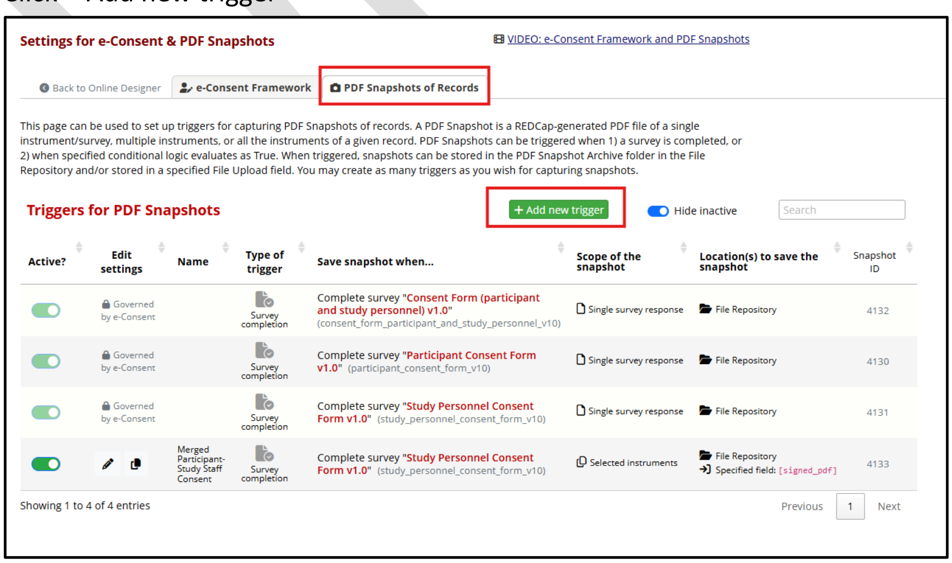
5. Enter the 'Consent form version'. Version nomenclatures are unique and cannot be repeated or deleted.
6. Select the 'Placement of consent form' Descriptive field from step 7 of the [To Upload the Approved Consent as Inline PDF]() section.
7. Select 'Consent Form (Inline PDF)' to upload your IRB approved PDF consent form.
8. Click 'Add new consent form' button to save.



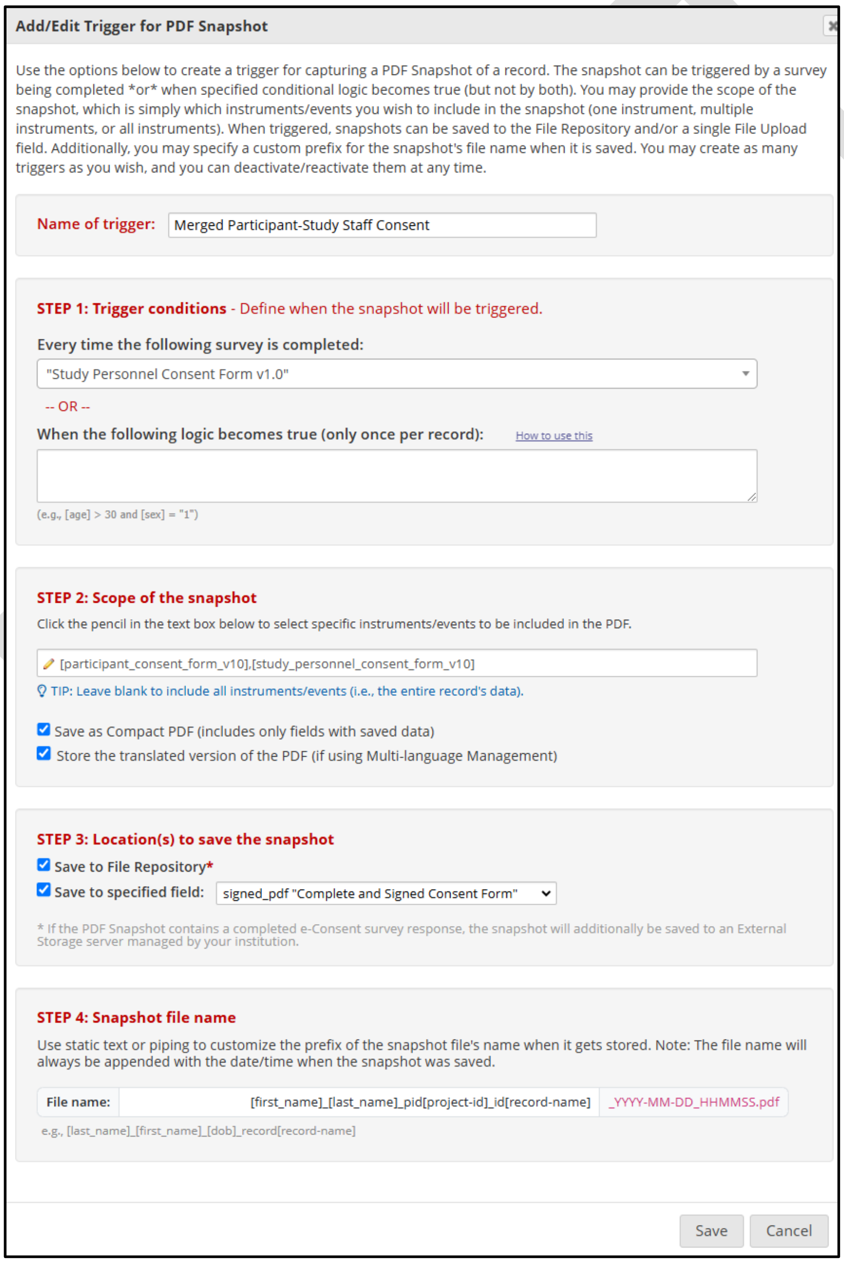
9. All updated or translated consent forms should be IRB-approved PRIOR to use in the eConsent project.
    - New or alternate eConsent versions (e.g., amended consent forms, unique versions, DAGs, or MLM languages) may be added by clicking '+Add consent form' link under an existing 'Participant Consent Form' eConsent Survey.
    - New eConsent Surveys may be added after creating the new instrument, enabling as a survey, and then creating new eConsent Framework settings via clicking the '+ Enable the eConsent Framework for a survey'.
    - You should always specify the new instrument's designated Descriptive field to display the specific consent and any applicable display conditions.



10. To conditionally create completed eConsent PDF snapshots (i.e., triggers), configure the settings on the 'PDF Snapshots of Records' tab.
11. Click '+Add new trigger'

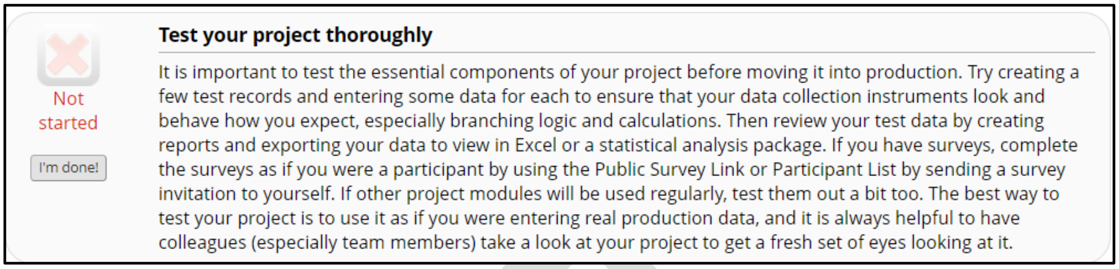


12. Name the trigger.
13. Step 1: Define the conditional logic (e.g., trigger a PDF snapshot every time the 'Study Personnel Consent Form' survey is completed).
14. Step 2: Select the instrument(s) to include in the completed PDF snapshot (e.g., 'Participant Consent Form' and 'Study Personnel Consent Form').
15. Step 3: Select the location and/or field where the completed PDF snapshot should be saved.
    - All eConsent PDFs should be saved to the File Repository.
    - Saving to a specified File Upload field is optional, unless the completed eConsent PDF will be attached to outgoing Alerts & Notifications.
16. Step 4: Enter variable names to include in the file name, if applicable.
17. Click 'Save'.

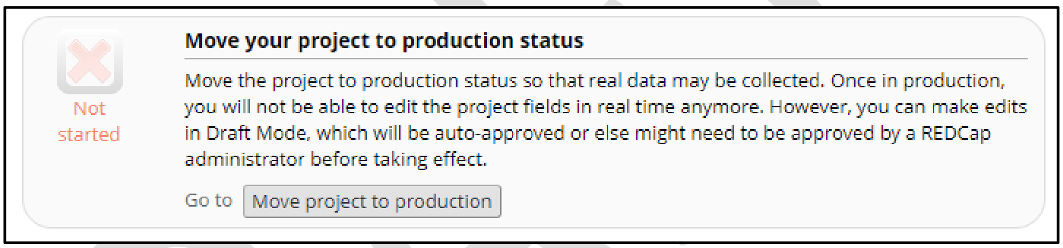


Finalize the Project

1. Review the remaining steps on the Project Setup page prior to finalizing the project.
2. As a best practice for any REDCap project design, please follow the 'Test your project thoroughly' instructions on the Project Setup tab.



3. Move the project to production status.
   a. Go to the 'Project Status' page and scroll to the bottom. Click 'Move project to production.'



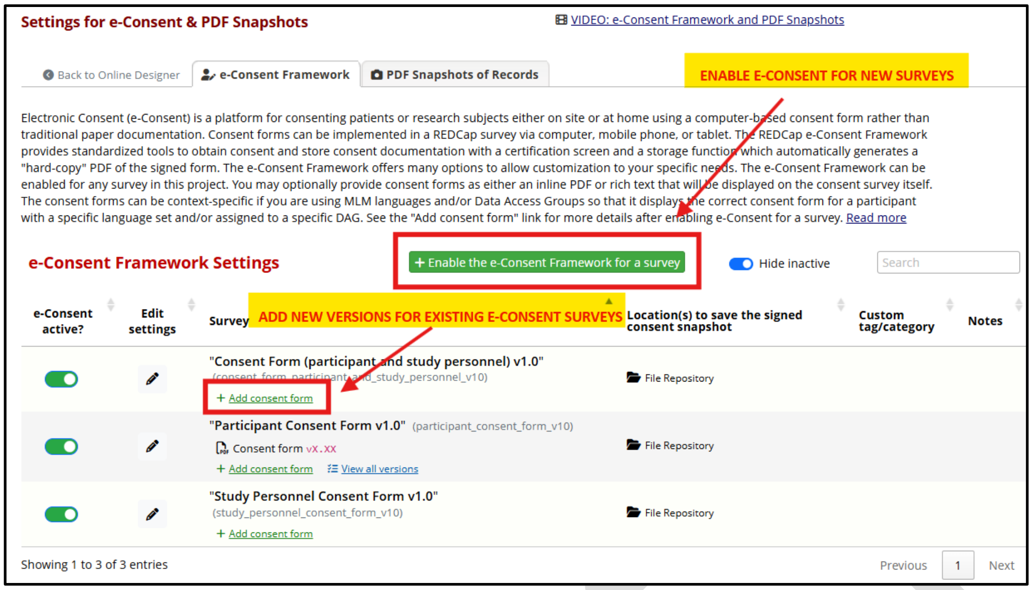
   b. Follow the prompts as applicable.

Add Consent Process Documentation

It is best practice to provide relevant details on the consent process as study documentation. This would typically be done by building a separate form within the project. Please refer to the Informed Consent Documentation Tool on the CRRO website here.

Updating the Project for Updated, Newly Approved, or Alternate Translated ICFs

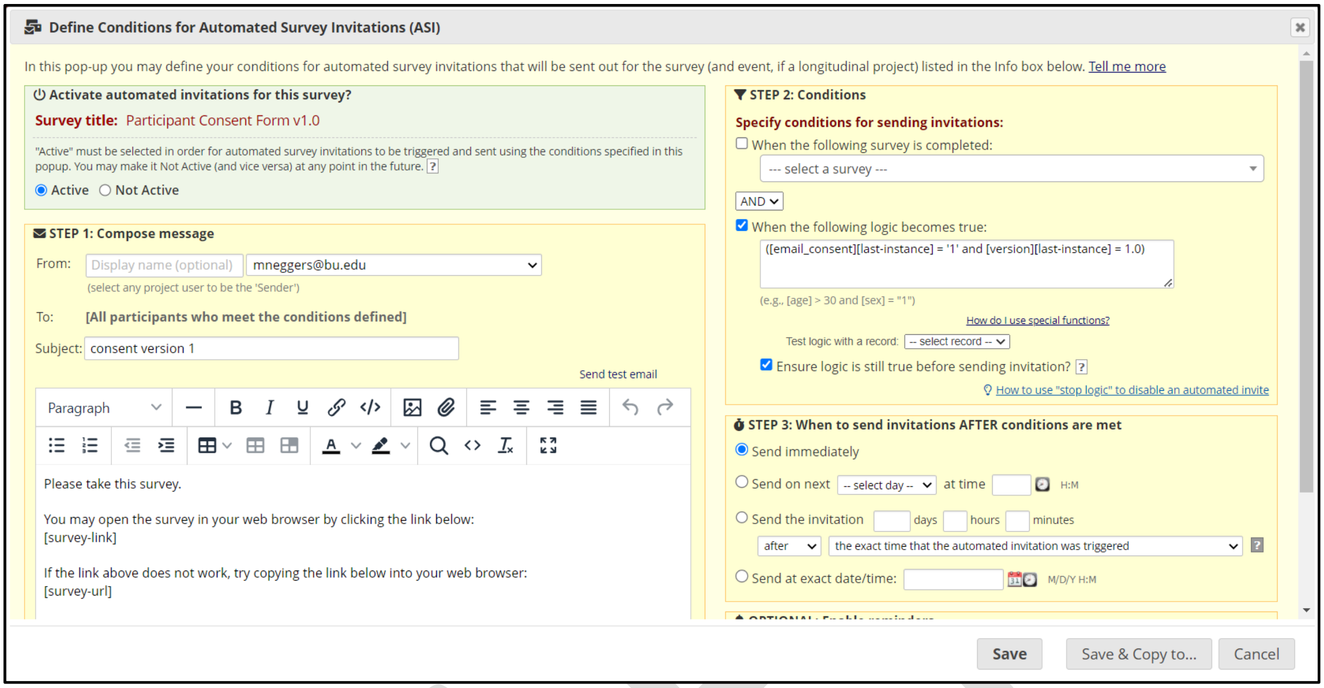
Updated or alternate IRB-approved informed consent forms may be added by clicking '+Add consent form' link under an existing 'Participant Consent Form' eConsent Survey. You should specify the instrument's designated Descriptive field to display the updated consent and any applicable display conditions. **The original consents should never be deleted.**



Turning on Automated Survey Invitations (ASI)

Automated survey invitations allow REDCap to automatically email the participant a link to their individual eConsent form. The six steps below cover how to turn on ASI and the following section called 'Sending the eConsent Invitation Email' covers adding a new participant record to trigger the ASI.

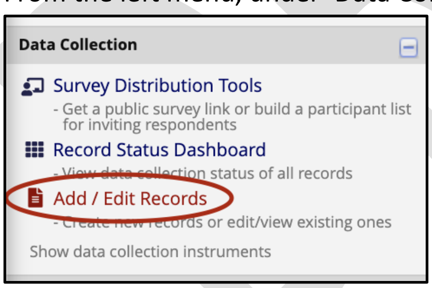
1. In Online Designer under 'Survey-related options' for the participant consent form, click 'Automated invitations'.
2. Customize the body of the email and subject line accordingly.
   a. **Do not delete the [survey-link] and [survey-url] smart variables.**
   b. Click on 'Send test email' to see how the email will appear for the participant.
3. **Check that the following conditions are entered in Step 2.**
   a. **[email_consent][last-instance] = '1' and [version][last-instance]= '#.#'**
      i. **For #.# enter the corresponding consent version number for that eConsent survey (Ex. 1.0).**
4. Set up when the invitation gets sent. By default, it is set up as immediate, meaning that as soon as the 'Version Tracking' form is complete, REDCap will send out the eConsent invitation. It may take a few minutes for the participant to receive the email.
5. Select 'Active' to turn on automated invitations. You may also inactivate ASIs for previous consent versions by selecting 'Not Active' (see green survey title box in screenshot below).
6. Click save to complete the changes.



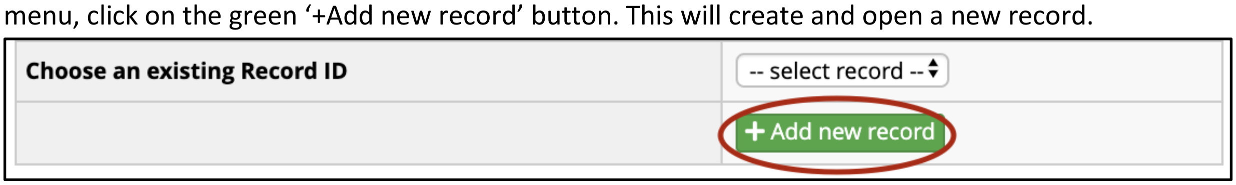
Sending the eConsent invitation Email

REDCap has various survey distribution methods. Please view resources such as REDCap Surveys and consult with rchelp@bu.edu to discuss options.

1. Create a new record to enter the participant's email and eConsent code.
2. From the left menu, under 'Data Collection' click on 'Add/Edit Record' to create a new record.



3. 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. This will create and open a new record.

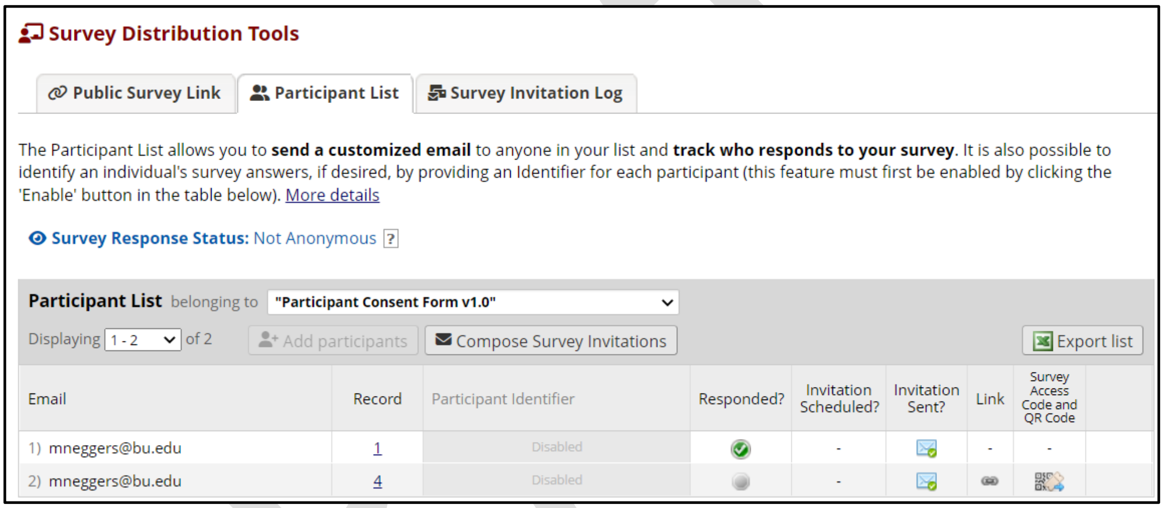


4. Click on the 'Participant Information' instrument.
    a. Enter the participant email and eConsent code.

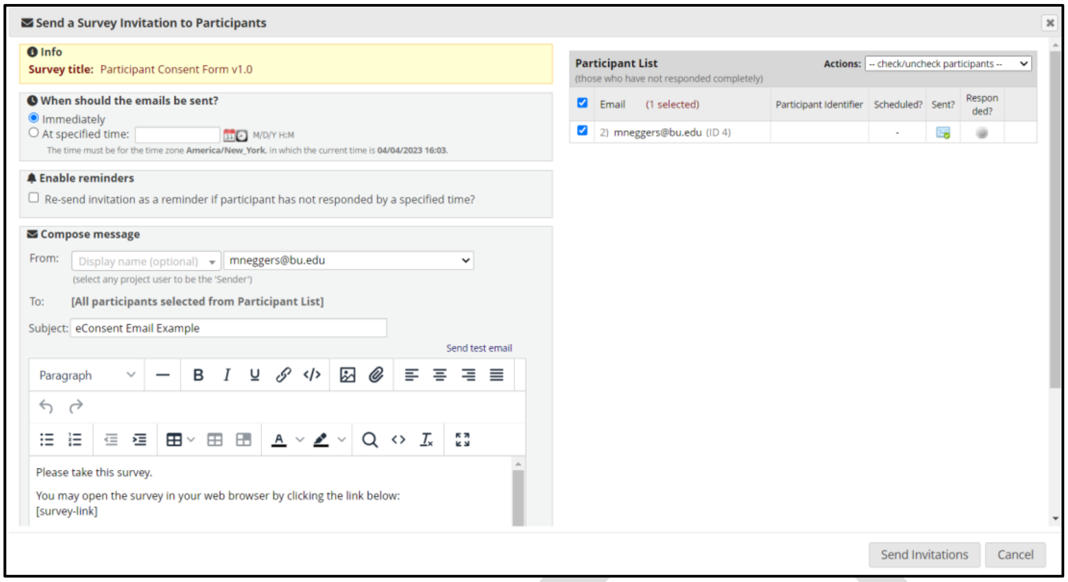
   b. Select 'Complete' for form status and save the form.
5. Click on the 'Version Tracking' instrument.
   a. Enter '1.0' for version number.
   b. Select 'Yes' for email consent form.
   c. Select 'Complete' for form status and save the form.
6. The Automated Survey Invitation (ASI) will now be sent to the participant.

Re-sending and Troubleshooting Survey Invitations

1. If the eConsent link needs to be sent again:
   a. Click on 'Survey Distribution Tools' under 'Data Collection'.
   b. Select 'Compose Survey Invitations'.



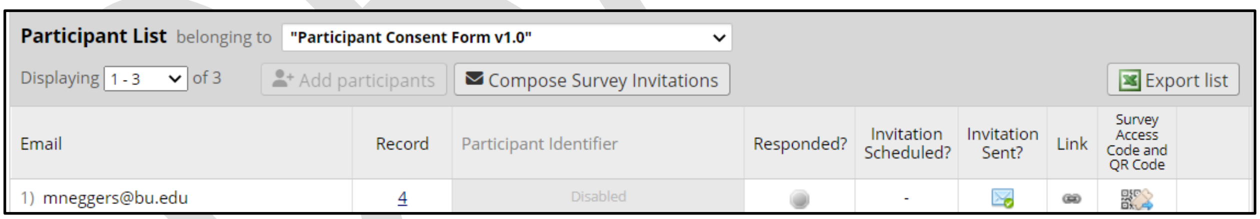
2. Under 'Compose message', edit the subject line and body of the email as applicable. **Do not delete the [survey-link] and [survey-url] smart variables.**
3. Under 'Participant List', select the record/email that needs the new invite and click 'Send Invitations.'



Accessing a Participant's eConsent Link

Sometimes potential research participants do not receive the survey invitation email even when ASI is set-up to send the email immediately. To send the participant a direct link to the consent form linked to their REDCap record, access their individual survey link from the Participant List table under Survey Distribution Tools. Be sure to check that you are using the correct link.

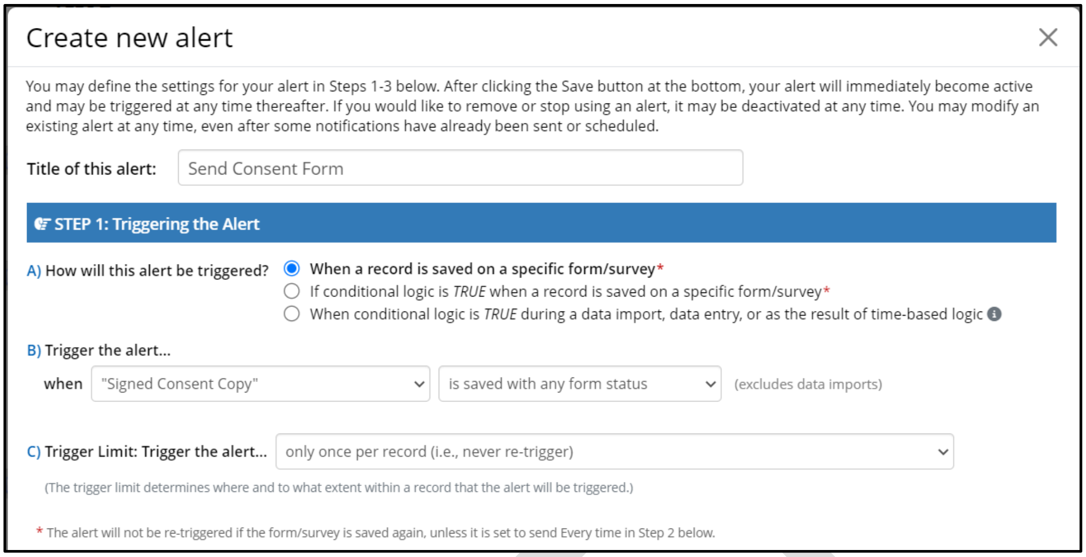
1. On the left menu, click on 'Survey Distribution Tools.'
2. Find the participant's record and right click under 'Link' to copy the link address. This link is specific to the participant's record and will prompt them to enter their eConsent code when accessed.



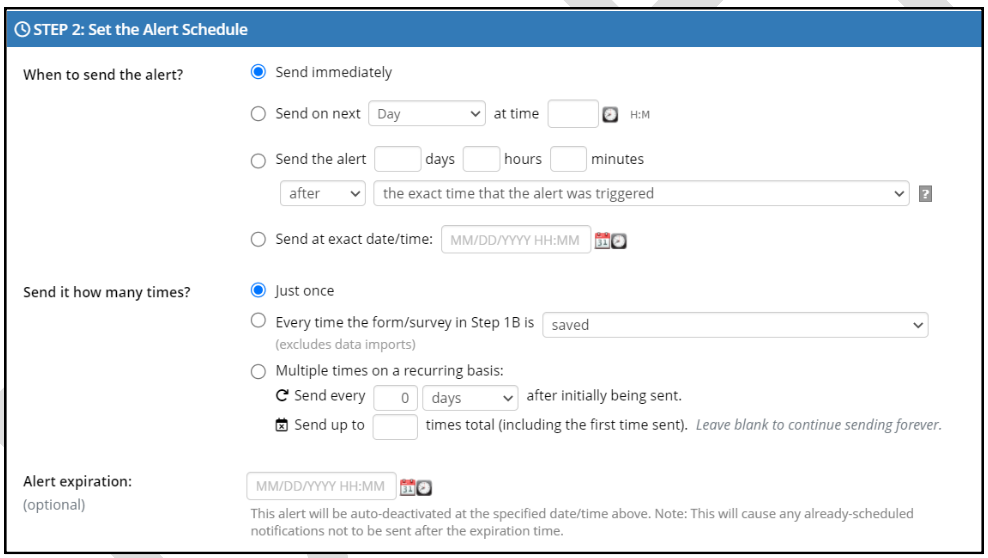
Sending the Participant a Copy of their Signed ICF

REDCap has various survey distribution methods, please view resources such as [REDCap Surveys](), and consult with [rchelp@bu.edu]() to discuss options. The alerts and notifications function can be used to automatically send the participant a copy of the combined PDF of the consent form.

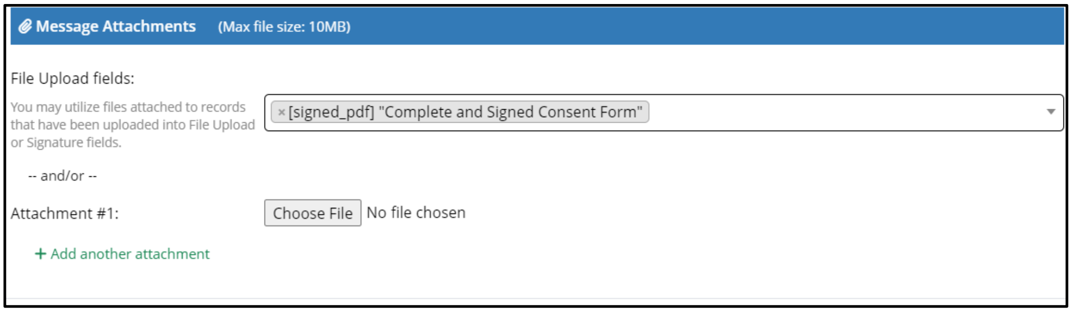
1. Select 'Alerts and Notifications' from the left menu.
    a. If this option is not available, select 'User Rights' to edit user privileges to allow access to alerts and notifications.
2. Click '+ Add New Alert'.
3. Edit the alert to include the information shown in the screenshot below.



4. By default, the alert is set up to be sent immediately once the trigger logic is satisfied and will only be sent to the participant once. Edit these settings as applicable to the study's needs.



5. Edit the message settings as applicable.
6. Click the green 'Add Attachments' button.
7. Select '[signed_pdf] 'Complete and Signed Consent Form''. This will attach the combined PDF to the email notification sent to the participant.



8. Click 'Save'. REDCap will now automatically email the combined PDF to the participant when complete.

Additional Modules

You may use optional modules and applications to customize your REDCap project for defined workflows. External Modules are add-on packages of software that can extend REDCap's current functionality to provide additional customizations and enhancements.

- Auto Record Generation Module allows for a new record to be generated in another project or within the same project. Data fields can be transferred to the new record as well. This may be useful to transfer a participant's record ID from the eConsent project into the study database. To learn more click here.
- The Multi-Language Management (MLM) allows the creation and configuration of multiple display languages for the project which should be used when enrolling non-English speakers. This module will appear on the project's left-hand dashboard under Applications. To learn more about the MLM view the REDCap Application video and contact rchelp@bu.edu.
- The deprecated Multi-Signature Module allowed users to combine data from one or more forms into a single PDF. It was designed for use in projects where you have multiple consent forms completed by multiple participants or coordinators and wish to merge them into a single, 'final', consent. This functionality has been replaced by the updated eConsent Framework and PDF Snapshot settings.

Additional Resources and Information

OHRP and FDA Resources

- OHRP and FDA Joint Guidance: Use of Electronic Informed Consent in Clinical Investigations – Questions and Answers, December 2016
- FDA Regulations: 21 CFR Part 11 Electronic Documents and Signatures
- FDA Guidance: Part 11, Electronic Records; electronic Signatures – Scope and Application, September 2003

Relevant HRPP Policies

- 8.4.1 Written Consent
- 8.4.2 Waiver of Documentation of Consent
- 8.4.3 Waiver or Alteration of Consent
- 8.5.1 Authorization to Use and Disclose PHI
- 8.5.2.2 Waiver or Alteration of Authorization for Use and Disclosure of PHI

Educational Resources

- Clinical Research Seminar - December 2020: Remote and eConsent (including REDCap)
- RPN Workshop - March 2023: eConsent: Benefits, Challenges, and Considerations
- RPN Workshop - December 2020: Remote and eConsent: Lightning Talks and Group Discussion

Boston Medical Center Guidance *(only accessible with BMC account)*

- HIPAA Information
- Record Retention

REDCap and Part 11 Compliance for FDA-Regulated Research

- BU REDCap Part 11 Request Form
- REDCap Part 11 Process & Training

General Contact Information

- Clinical Research Resources Offices
- Boston University Charles River Campus IRB
- REDCap Help
    - REDCap FAQ (only accessible once logged in)
    - REDCap Training Videos (only accessible once logged in)

Appendix A: Relevant Features - List of Functionality

Instrument – A data collection tool that can be left as a data entry form or enabled as a participant-facing survey.

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

Survey – An instrument in which a research participant can enter data or answer questions without a REDCap account. This instrument is accessed through a secure URL.

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

Record ID – The record ID is the primary key in REDCap that uniquely identifies a record and its attributable data within a project

Survey Login – A way to increase security on private surveys. This is enabled in the eConsent template project and utilizes the 'eConsent Code' from the 'Participant Information' instrument.

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 as an alternative to the Online Designer for building or editing projects.

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.

eConsent Framework – A survey setting option that allows for a standardized method of obtaining consent and storing consent documentation through generating a PDF of the signed consent form.

Project Template – A 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 enabled by a BUMC REDCap administrator.

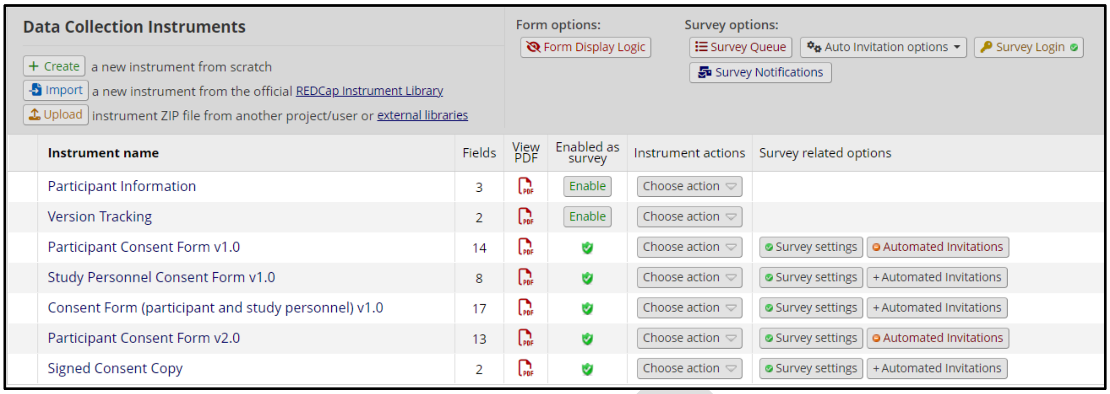
Alerts & Notifications - Located in the left-hand tool bar under Applications. This is where creation and management of the Alerts & Notifications are done.

User Rights - This function gives the project owner the ability to limit access to various data features for other users, such as editing, exporting, or locking records. This can be done by assigning individual user rights, or by creating 'User Roles' that have defined rights, then adding users to a role.

> **NOTE:** BU/BMC PIs or Project Administrators are responsible for assigning AND revoking project level User Rights. Keep your project access (user rights) up-to-date. **Enter and manage data responsibly!**

Logging - Allows users to view logged events. This includes data exports, design changes, record history (creation, updating, and deletion), adding/removing project users, record locking, and page views.

Appendix B: eConsent for Non-Exempt Research Template



Data Collection Instruments

Form options: Form Display Logic

Survey options: Survey Queue | Auto Invitation options | Survey Login | Survey Notifications

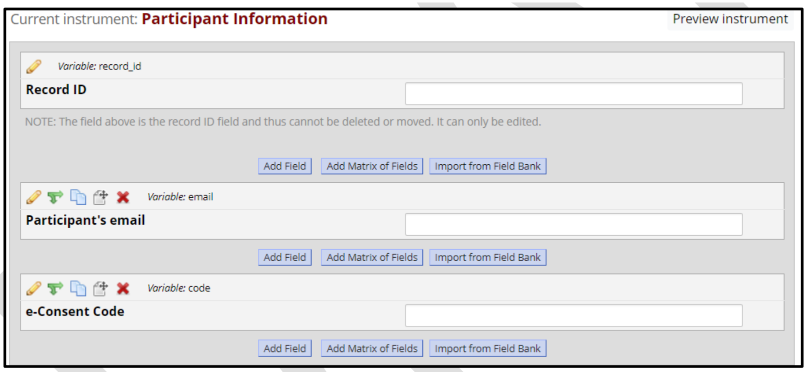
+ Create a new instrument from scratch
Import a new instrument from the official REDCap Instrument Library
Upload instrument ZIP file from another project/user or external libraries

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) v1.0	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

Participant Information

Data Collection Instrument (DCI) to collect participant information for login credentials (e.g., email address and password).

- This DCI is completed by study personnel.
- This DCI is **required** if the REDCap Survey Login feature will be used for identity verification and additional security purposes.
    a. The eConsent code should be a unique string of characters, created by the study team. This code serves as password and a secondary login credential for secure survey access.



Participant Consent Form v1.0

Participant consent form enabled as a survey and the REDCap eConsent Framework survey setting enabled.

- A separate consent form for participant signature is required for remote eConsenting.
    a. A PDF Snapshot Trigger may be used to merge the signed PDFs of both participant and study personnel eConsent surveys upon completion.
- Versioning each consent form (e.g., v1.0) is necessary for administered consent forms and reconsenting. This allows all any updated consent form to be appropriately tracked throughout the project life cycle.
- The consent form stamped with the IRB approval must be displayed on the REDCap eConsent.
    a. Create a placeholder descriptive text field on the 'Participant Consent Form' instrument, then upload the approved PDF in the eConsent Framework Settings.

- This eConsent form must be administered as a survey in order for the eConsent Framework to be applied.
- You should create a new instrument for an updated consent form and apply the appropriate eConsent settings.
    a. You will need to update the eConsent & PDF Snapshots settings as well.
    b. Update the Alerts & Notifications (if applicable) with the new instrument name (i.e., select the updated instrument in the 'Trigger the alert...' drop down).
    c. Update ASIs if applicable.

Study Personnel Consent Form v1.0

Study personnel section of an eConsent form.

- When a study personnel signature is required on a remote eConsent form, the study personnel section must be separated as its own survey, to collect the required study personnel signature.
- Versioning each consent form (e.g., v1.0) is necessary for administered consent forms and reconsenting. This allows all any updated consent form to be appropriately tracked throughout the project life cycle.
- This eConsent form must be administered as a survey in order for the eConsent Framework to be applied.
- You should create a new instrument for an updated study personnel section of the consent form and apply the appropriate eConsent settings.
    a. You will need to update the PDF Snapshot Trigger settings as well.
    b. Update the Alerts & Notifications (if applicable) with the new instrument name (i.e., select the updated instrument in the 'Trigger the alert...' drop down).
    c. Update ASIs if applicable.

Consent Form (participant and study personnel) v1.0

Consent form for both participant and study personnel when administering and signing the eConsent in the same location.

- If the consenting process will happen in person, a version of the consent form with both the participant and study personnel signature may be administered.
- Versioning each consent form (e.g., v1.0) is necessary for administered consent forms and reconsenting. This allows all any updated consent form to be appropriately tracked throughout the project life cycle.
- This eConsent form must be administered as a survey in order for the eConsent Framework to be applied.
- You should update consent versions in the eConsent & PDF Snapshots settings.
- Update the Alerts & Notifications (if applicable) with the new instrument name (i.e., select the updated instrument in the 'Trigger the alert...' drop down).

Signed Consent Copy

Generated PDF of combined remote eConsent surveys.

- The PDF Snapshots Trigger is utilized to combine remote eConsent surveys administered for both participant and study personnel signatures, separately. The feature merges the two separate (remote) PDFs, producing a final eConsent PDF.

- If distributing the merged PDF via email, the File Upload field is required as a placeholder to store the final remote eConsent PDF file upon merge completion.
- A copy of this completed, merged eConsent PDF or a link to the 'Signed Consent Copy' survey may be distributed to the participant via the Alerts & Notifications, Survey settings, or manually.