

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
☒ 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
<input type="radio"/>	Basic Demography	Contains a single data collection instrument to capture basic demographic information.
<input type="radio"/>	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.
<input type="radio"/>	e-Consent for Exempt Research	CRRO Guidance
<input checked="" type="radio"/>	e-Consent for Non-Exempt Research (2.0)	CRRO Guidance for e-Consent Framework 2.0
<input type="radio"/>	eReg Lite Template	CRRO eReg Lite Guidance
<input type="radio"/>	Field Embedding Example Project	Contains a single data collection instrument to demonstrate the Field Embedding feature. Contains also data entry forms (including with a demography form) for collecting data on

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

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

Current instrument: **Participant Consent Form v1.0**

Add Field Add Matrix of Fields Import from Field Bank

[] Field Name: cf_link

Consent Form Link

Attachment: Sample Research Consent Form_English.pdf (117.3 kB)

Add Field Add Matrix of Fields Import from Field Bank

[] Field Name: consent_pdf

Add Field Add Matrix of Fields Import from Field Bank

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

Attach an image, file, or embedded audio

[Sample Research Consent Form_English.pdf](#) **[X] Remove**

Display format of attachment on page:

☒ Link

☐ Inline image/PDF

☐ Audio file (play in embedded player on page)

[Compatibility notice for embedded audio](#)

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

Attach an image, file, or embedded audio

[Upload file](#)

Display format of attachment on page:

☒ Link

☐ Inline image/PDF

☐ Audio file (play in embedded player on page)



[Compatibility notice for embedded audio](#)

(Images wider than 600 pixels will be downsized to fit page.)

- Click '+ Upload file' and follow the prompts to upload a PDF of the study's IRB approved ICF.
- Select 'Link' under 'Display format of attachment on page' and click 'Save' to display a downloadable PDF link.
- 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

- 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.

Basic Survey Options:

Survey Title H-12345 Study Consent Form
Title to be displayed to participants at the top of the survey page

Survey Instructions
(Displayed at top of survey after title)

Paragraph

Please review this electronic consent form with the study coordinator.

[How to use Piping here](#)

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

Survey Completion Text
(Displayed after survey is completed as 'thank you' text or as acknowledgement text)

Paragraph

Thank you for your participation in the research study:

Protocol Name
If you have any questions, please contact:
Study Staff Name:
xxx-xxx-xxxx
xxxx@bu.edu or xxxx@bmc.org

[How to use Piping here](#)

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.

e-Consent for Non-Exempt Research (2.0) PID: 17142

Project Home Project Setup Online Designer Data Dictionary Codebook

VIDEO: How to use this page Create snapshot of instruments Last snapshot: never [?]

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.

Data Collection Instruments

Form options: PDF Snapshots e-Consent Survey Queue Auto Invitation options

Form Display Logic Survey Login Survey Notifications

Instrument name	Fields	PDF	Enabled as survey	Instrument actions	Survey related options
Participant Information	4	PDF	Enable	Choose action	
Participant Consent Form v1.0	11	PDF	Enable	Choose action	Survey settings Automated Invitations
Study Personnel Consent Form v1.0	8	PDF	Enable	Choose action	Survey settings Automated Invitations
Consent Form Participant And Study Personnel v1.0	15	PDF	Enable	Choose action	Survey settings Automated Invitations
Signed Consent Copy	2	PDF	Enable	Choose action	Survey settings Automated Invitations

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

e-Consent for Non-Exempt Research (2.0) PID: 17142

Settings for e-Consent & PDF Snapshots VIDEO: e-Consent Framework and PDF Snapshots

Back to Online Designer e-Consent Framework PDF Snapshots of Records

Electronic Consent (e-Consent) is a platform for consenting patients or research subjects either on site or at home using a computer-based consent form rather than traditional paper documentation. Consent forms can be implemented in a REDCap survey via computer, mobile phone, or tablet. The REDCap e-Consent Framework provides standardized tools to obtain consent and store consent documentation with a certification screen and a storage function which automatically generates a "hard-copy" PDF of the signed form. The e-Consent Framework offers many options to allow customization to your specific needs. The e-Consent Framework can be enabled for any survey in this project. You may optionally provide consent forms as either an inline PDF or rich text that will be displayed on the consent survey itself. The consent forms can be context-specific if you are using MLM languages and/or Data Access Groups so that it displays the correct consent form for a participant with a specific language set and/or assigned to a specific DAG. See the "Add consent form" link for more details after enabling e-Consent for a survey. [Read more](#)

e-Consent Framework Settings + Enable the e-Consent Framework for a survey Hide inactive Search

e-Consent active?	Edit settings	Survey	Location(s) to save the signed consent snapshot	Custom tag/category	Notes
<input checked="" type="checkbox"/>		"Participant Consent Form v1.0" (participant_consent_form_v1.0) Consent form vs_xx + Add consent form View all versions	File Repository		
<input checked="" type="checkbox"/>		"Study Personnel Consent Form v1.0" (study_personnel_consent_form_v1.0) + Add consent form	File Repository		
<input checked="" type="checkbox"/>		"Consent Form (participant and study personnel) v1.0" (consent_form_participant_and_study_personnel_v1.0) + Add consent form	File Repository		

Showing 1 to 3 of 3 entries Previous 1 Next

- 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.

e-Consent for Non-Exempt Research (2.0) PID: 17142

Settings for e-Consent & PDF Snapshots VIDEO: e-Consent Framework and PDF Snapshots

Back to Online Designer e-Consent Framework PDF Snapshots of Records

Electronic Consent (e-Consent) is a platform for consenting patients or research subjects either on site or at home using a computer-based consent form rather than traditional paper documentation. Consent forms can be implemented in a REDCap survey via computer, mobile phone, or tablet. The REDCap e-Consent Framework provides standardized tools to obtain consent and store consent documentation with a certification screen and a storage function which automatically generates a "hard-copy" PDF of the signed form. The e-Consent Framework offers many options to allow customization to your specific needs. The e-Consent Framework can be enabled for any survey in this project. You may optionally provide consent forms as either an inline PDF or rich text that will be displayed on the consent survey itself. The consent forms can be context-specific if you are using MLM languages and/or Data Access Groups so that it displays the correct consent form for a participant with a specific language set and/or assigned to a specific DAG. See the "Add consent form" link for more details after enabling e-Consent for a survey. [Read more](#)

e-Consent Framework Settings + Enable the e-Consent Framework for a survey Hide inactive Search

e-Consent active?	Edit settings	Survey	Location(s) to save the signed consent snapshot	Custom tag/category	Notes
<input checked="" type="checkbox"/>		"Participant Consent Form v1.0" (participant_consent_form_v1.0) Consent form vs_xx + Add consent form View all versions	File Repository		
<input checked="" type="checkbox"/>		"Study Personnel Consent Form v1.0" (study_personnel_consent_form_v1.0) + Add consent form	File Repository		
<input checked="" type="checkbox"/>		"Consent Form (participant and study personnel) v1.0" (consent_form_participant_and_study_personnel_v1.0) + Add consent form	File Repository		

View all consent forms and versions

The table below lists all the consent forms and their versions that have been added for the survey "Participant Consent Form v1.0".

Active?	Version	Time added	Uploaded by	Number of records consented	Data Access Group	MLM Language	Consent form text or file	Set consent form as inactive
	X.X	08/06/2024 2:36pm	tawatson (Tasha Coughlin)	0			Sample Research Consent Form_English.pdf	
<input checked="" type="checkbox"/>	X.XX	08/09/2024 9:54am	tawatson (Tasha Coughlin)	1			Sample Research Consent Form_English.pdf	Set as inactive

Close

4. Click '+Add consent form' link

Settings for e-Consent & PDF Snapshots VIDEO: e-Consent Framework and PDF Snapshots

Back to Online Designer e-Consent Framework PDF Snapshots of Records

Electronic Consent (e-Consent) is a platform for consenting patients or research subjects either on site or at home using a computer-based consent form rather than traditional paper documentation. Consent forms can be implemented in a REDCap survey via computer, mobile phone, or tablet. The REDCap e-Consent Framework provides standardized tools to obtain consent and store consent documentation with a certification screen and a storage function which automatically generates a "hard-copy" PDF of the signed form. The e-Consent Framework offers many options to allow customization to your specific needs. The e-Consent Framework can be enabled for any survey in this project. You may optionally provide consent forms as either an inline PDF or rich text that will be displayed on the consent survey itself. The consent forms can be context-specific if you are using MLM languages and/or Data Access Groups so that it displays the correct consent form for a participant with a specific language set and/or assigned to a specific DAG. See the "Add consent form" link for more details after enabling e-Consent for a survey. [Read more](#)

e-Consent Framework Settings + Enable the e-Consent Framework for a survey Hide inactive Search

e-Consent active?	Edit settings	Survey	Location(s) to save the signed consent snapshot	Custom tag/category	Notes
<input checked="" type="checkbox"/>		"Participant Consent Form v1.0" (participant_consent_form_v10) + Add consent form View all versions	File Repository		
<input checked="" type="checkbox"/>		"Study Personnel Consent Form v1.0" (study_personnel_consent_form_v10) + Add consent form	File Repository		
<input checked="" type="checkbox"/>		"Consent Form (participant and study personnel) v1.0" (consent_form_participant_and_study_personnel_v10) + Add consent form	File Repository		

Showing 1 to 3 of 3 entries Previous 1 Next

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

Add consent form

You may use this dialog to provide your static consent form (or consent form text) that will be displayed on the survey page to the participant. Below you may add a consent form or replace an existing one with a new version. If you have a simple project, you may choose to add your consent form to a Descriptive field via the Online Designer. But if you have a more complex project that utilizes multiple Data Access Groups and/or multiple MLM languages, each of which might require their own unique consent form, then providing your consent forms in this interface might be a more manageable option.

Consent forms added here will be displayed dynamically on the survey based on the current context. For example, if you have a DAG-specific consent form, you can specify that the consent form only be displayed for participants in that DAG, while participants in other DAGs will see a different consent form. The consent forms provided here will be displayed immediately below a specific Descriptive field (specified below) on the survey. **NOTICE: After clicking the "Add new consent form" submit, the consent form will GO LIVE IMMEDIATELY on the e-Consent survey.**

Consent form version: 2025-01-01
It is required to version each consent form (e.g., "1.1", "2.3.1 2024-06-01") so that you may manage any future changes and differentiate all versions of the consent form. It is recommended that you do not begin the version number with the letter "V".

Placement of consent form: consent_pdf
Choose a Descriptive field on the survey that will serve as the location of the consent form. The consent form will be displayed immediately below this field on the survey page. Note: The Descriptive field selected must be the same for all consent forms specified for this survey. If the field is changed, it will be changed for all consent forms for this survey.

Display for specific DAG: No data access groups exist
Only display this consent form when the record is assigned to the selected data access group. Note: The default option will be used if no DAG-specific consent forms exist.

Display for specific language: No languages defined on MLM page
Only display this consent form when viewing the survey in the selected language.

Consent Form (Rich Text) **Consent Form (Inline PDF)**

Provide your consent form as a PDF file that will be displayed inline on the page directly below the field selected for 'Location of consent form' on the instrument/survey.

Upload your PDF consent form: Choose File Sample Res...._English.pdf Reset

Add new consent form Cancel

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.

Settings for e-Consent & PDF Snapshots VIDEO: e-Consent Framework and PDF Snapshots

Back to Online Designer e-Consent Framework PDF Snapshots of Records **ENABLE E-CONSENT FOR NEW SURVEYS**

Electronic Consent (e-Consent) is a platform for consenting patients or research subjects either on site or at home using a computer-based consent form rather than traditional paper documentation. Consent forms can be implemented in a REDCap survey via computer, mobile phone, or tablet. The REDCap e-Consent Framework provides standardized tools to obtain consent and store consent documentation with a certification screen and a storage function which automatically generates a "hard-copy" PDF of the signed form. The e-Consent Framework offers many options to allow customization to your specific needs. The e-Consent Framework can be enabled for any survey in this project. You may optionally provide consent forms as either an inline PDF or rich text that will be displayed on the consent survey itself. The consent forms can be context-specific if you are using MLM languages and/or Data Access Groups so that it displays the correct consent form for a participant with a specific language set and/or assigned to a specific DAG. See the "Add consent form" link for more details after enabling e-Consent for a survey. [Read more](#)

e-Consent Framework Settings **+ Enable the e-Consent Framework for a survey** Hide inactive Search

e-Consent active?	Edit settings	Survey	Location(s) to save the signed consent snapshot	Custom tag/category	Notes
<input checked="" type="checkbox"/>		ADD NEW VERSIONS FOR EXISTING E-CONSENT SURVEYS "Consent Form (participant and study personnel) v1.0" (consent_form_participant_and_study_personnel_v10) + Add consent form	File Repository		
<input checked="" type="checkbox"/>		"Participant Consent Form v1.0" (participant_consent_form_v10) Consent form v1.0.XXX + Add consent form View all versions	File Repository		
<input checked="" type="checkbox"/>		"Study Personnel Consent Form v1.0" (study_personnel_consent_form_v10) + Add consent form	File Repository		

Showing 1 to 3 of 3 entries Previous 1 Next

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'

Settings for e-Consent & PDF Snapshots VIDEO: e-Consent Framework and PDF Snapshots

Back to Online Designer e-Consent Framework **PDF Snapshots of Records**

This page can be used to set up triggers for capturing PDF Snapshots of records. A PDF Snapshot is a REDCap-generated PDF file of a single instrument/survey, multiple instruments, or all the instruments of a given record. PDF Snapshots can be triggered when 1) a survey is completed, or 2) when specified conditional logic evaluates as True. When triggered, snapshots can be stored in the PDF Snapshot Archive folder in the File Repository and/or stored in a specified File Upload field. You may create as many triggers as you wish for capturing snapshots.

Triggers for PDF Snapshots **+ Add new trigger** Hide inactive Search

Active?	Edit settings	Name	Type of trigger	Save snapshot when...	Scope of the snapshot	Location(s) to save the snapshot	Snapshot ID
<input checked="" type="checkbox"/>		Governed by e-Consent	Survey completion	Complete survey "Consent Form (participant and study personnel) v1.0" (consent_form_participant_and_study_personnel_v10)	Single survey response	File Repository	4132
<input checked="" type="checkbox"/>		Governed by e-Consent	Survey completion	Complete survey "Participant Consent Form v1.0" (participant_consent_form_v10)	Single survey response	File Repository	4130
<input checked="" type="checkbox"/>		Governed by e-Consent	Survey completion	Complete survey "Study Personnel Consent Form v1.0" (study_personnel_consent_form_v10)	Single survey response	File Repository	4131
<input checked="" type="checkbox"/>		Merged Participant-Study Staff Consent	Survey completion	Complete survey "Study Personnel Consent Form v1.0" (study_personnel_consent_form_v10)	Selected instruments	File Repository Specified field: signed_pdf	4133

Showing 1 to 4 of 4 entries Previous 1 Next

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'.

Add/Edit Trigger for PDF Snapshot

Use the options below to create a trigger for capturing a PDF Snapshot of a record. The snapshot can be triggered by a survey being completed *or* when specified conditional logic becomes true (but not by both). You may provide the scope of the snapshot, which is simply which instruments/events you wish to include in the snapshot (one instrument, multiple instruments, or all instruments). When triggered, snapshots can be saved to the File Repository and/or a single File Upload field. Additionally, you may specify a custom prefix for the snapshot's file name when it is saved. You may create as many triggers as you wish, and you can deactivate/reactivate them at any time.

Name of trigger:

Merged Participant-Study Staff Consent

STEP 1: Trigger conditions - Define when the snapshot will be triggered.

Every time the following survey is completed:

"Study Personnel Consent Form v1.0"

-- OR --

When the following logic becomes true (only once per record):

How to use this

(e.g., [age] > 30 and [sex] = "1")

STEP 2: Scope of the snapshot

Click the pencil in the text box below to select specific instruments/events to be included in the PDF.

[participant_consent_form_v10].[study_personnel_consent_form_v10]

TIP: Leave blank to include all instruments/events (i.e., the entire record's data).

☒ Save as Compact PDF (includes only fields with saved data)
 ☒ Store the translated version of the PDF (if using Multi-language Management)

STEP 3: Location(s) to save the snapshot

☒ Save to File Repository*
 ☒ Save to specified field: signed_pdf "Complete and Signed Consent Form"

* If the PDF Snapshot contains a completed e-Consent survey response, the snapshot will additionally be saved to an External Storage server managed by your institution.

STEP 4: Snapshot file name

Use static text or piping to customize the prefix of the snapshot file's name when it gets stored. Note: The file name will always be appended with the date/time when the snapshot was saved.

File name:

[first_name].[last_name].pid[project-id].id[record-name]

_YYYY-MM-DD_HHMMSS.pdf


e.g., [last_name].[first_name].[dob].record[record-name]

Save

Cancel

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.




Not started

I'm done!

Test your project thoroughly

It is important to test the essential components of your project before moving it into production. Try creating a few test records and entering some data for each to ensure that your data collection instruments look and behave how you expect, especially branching logic and calculations. Then review your test data by creating reports and exporting your data to view in Excel or a statistical analysis package. If you have surveys, complete the surveys as if you were a participant by using the Public Survey Link or Participant List by sending a survey invitation to yourself. If other project modules will be used regularly, test them out a bit too. The best way to test your project is to use it as if you were entering real production data, and it is always helpful to have colleagues (especially team members) take a look at your project to get a fresh set of eyes looking at it.

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



Not started

Move your project to production status

Move the project to production status so that real data may be collected. Once in production, you will not be able to edit the project fields in real time anymore. However, you can make edits in Draft Mode, which will be auto-approved or else might need to be approved by a REDCap administrator before taking effect.

Go to [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.**

Settings for e-Consent & PDF Snapshots VIDEO: e-Consent Framework and PDF Snapshots

Back to Online Designer e-Consent Framework PDF Snapshots of Records **ENABLE E-CONSENT FOR NEW SURVEYS**

Electronic Consent (e-Consent) is a platform for consenting patients or research subjects either on site or at home using a computer-based consent form rather than traditional paper documentation. Consent forms can be implemented in a REDCap survey via computer, mobile phone, or tablet. The REDCap e-Consent Framework provides standardized tools to obtain consent and store consent documentation with a certification screen and a storage function which automatically generates a "hard-copy" PDF of the signed form. The e-Consent Framework offers many options to allow customization to your specific needs. The e-Consent Framework can be enabled for any survey in this project. You may optionally provide consent forms as either an inline PDF or rich text that will be displayed on the consent survey itself. The consent forms can be context-specific if you are using MLM languages and/or Data Access Groups so that it displays the correct consent form for a participant with a specific language set and/or assigned to a specific DAG. See the "Add consent form" link for more details after enabling e-Consent for a survey. [Read more](#)

e-Consent Framework Settings + Enable the e-Consent Framework for a survey Hide inactive Search

e-Consent active?	Edit settings	Survey	Location(s) to save the signed consent snapshot	Custom tag/category	Notes
<input checked="" type="checkbox"/>		"Consent Form (participant and study personnel) v1.0" (consent_form_participant_and_study_personnel_v10) + Add consent form	File Repository		
<input checked="" type="checkbox"/>		"Participant Consent Form v1.0" (participant_consent_form_v10) Consent form vX.XX + Add consent form View all versions	File Repository		
<input checked="" type="checkbox"/>		"Study Personnel Consent Form v1.0" (study_personnel_consent_form_v10) + Add consent form	File Repository		

Showing 1 to 3 of 3 entries Previous 1 Next

Turning on Automated Survey Invitations (ASI)

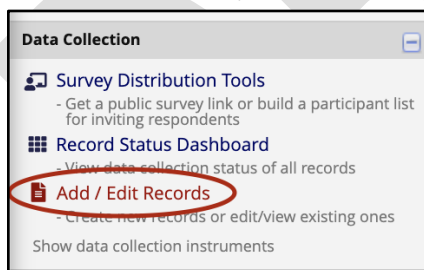
Automated survey invitations allow REDCap to automatically email the participant a link to their individual eConsent form. The six steps below cover how to turn on ASI and the following section called 'Sending the eConsent Invitation Email' covers adding a new participant record to trigger the ASI.

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 rhelp@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'.

Survey Distribution Tools

[Public Survey Link](#)
[Participant List](#)
[Survey Invitation Log](#)

The Participant List allows you to **send a customized email** to anyone in your list and **track who responds to your survey**. It is also possible to identify an individual's survey answers, if desired, by providing an Identifier for each participant (this feature must first be enabled by clicking the 'Enable' button in the table below). [More details](#)

Survey Response Status: Not Anonymous

Participant List belonging to "Participant Consent Form v1.0"

Displaying 1 - 2 of 2
 [Add participants](#)
[Compose Survey Invitations](#)
[Export list](#)

Email	Record	Participant Identifier	Responded?	Invitation Scheduled?	Invitation Sent?	Link	Survey Access Code and QR Code
1) mnegggers@bu.edu	1	Disabled		-		-	-
2) mnegggers@bu.edu	4	Disabled		-			

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.

Participant List belonging to "Participant Consent Form v1.0"							
Displaying 1 - 3 of 3		Add participants		Compose Survey Invitations		Export list	
Email	Record	Participant Identifier	Responded?	Invitation Scheduled?	Invitation Sent?	Link	Survey Access Code and QR Code
1) mneeggars@bu.edu	4	Disabled		-			

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.

Create new alert

You may define the settings for your alert in Steps 1-3 below. After clicking the Save button at the bottom, your alert will immediately become active and may be triggered at any time thereafter. If you would like to remove or stop using an alert, it may be deactivated at any time. You may modify an existing alert at any time, even after some notifications have already been sent or scheduled.

Title of this alert:

STEP 1: Triggering the Alert

A) How will this alert be triggered?

☒ When a record is saved on a specific form/survey*

☐ If conditional logic is *TRUE* when a record is saved on a specific form/survey*

☐ When conditional logic is *TRUE* during a data import, data entry, or as the result of time-based logic ⓘ

B) Trigger the alert...

when is saved with any form status (excludes data imports)

C) Trigger Limit: Trigger the alert...

(The trigger limit determines where and to what extent within a record that the alert will be triggered.)

* The alert will not be re-triggered if the form/survey is saved again, unless it is set to send Every time in Step 2 below.

- 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.

STEP 2: Set the Alert Schedule

When to send the alert?

☒ Send immediately

☐ Send on next at time H:M

☐ Send the alert days hours minutes

the exact time that the alert was triggered ⓘ

☐ Send at exact date/time: ⓘ

Send it how many times?

☒ Just once

☐ Every time the form/survey in Step 1B is (excludes data imports)

☐ Multiple times on a recurring basis:

☒ Send every days after initially being sent.

☐ Send up to times total (including the first time sent). *Leave blank to continue sending forever.*

Alert expiration: (optional) ⓘ

This alert will be auto-deactivated at the specified date/time above. Note: This will cause any already-scheduled notifications not to be sent after the expiration time.

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

Message Attachments
(Max file size: 10MB)

File Upload fields:
You may utilize files attached to records that have been uploaded into File Upload or Signature fields.
-- and/or --
Attachment #1:

Choose File
No file chosen

+ Add another attachment

× [signed_pdf] "Complete and Signed Consent Form"

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.

DRAFT

Appendix B: eConsent for Non-Exempt Research Template

Data Collection Instruments				Form options:	Survey options:
+ 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				Form Display Logic	Survey Queue Auto Invitation options Survey Login Survey Notifications
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.
 - 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.

Current instrument: **Participant Information** [Preview Instrument](#)

Variable: record_id
Record ID

NOTE: The field above is the record ID field and thus cannot be deleted or moved. It can only be edited.

[Add Field](#) [Add Matrix of Fields](#) [Import from Field Bank](#)

Variable: email
Participant's email

[Add Field](#) [Add Matrix of Fields](#) [Import from Field Bank](#)

Variable: code
e-Consent Code

[Add Field](#) [Add Matrix of Fields](#) [Import from Field Bank](#)

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 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.
 - 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.

Current instrument: Signed Consent Copy

Preview instrument

Add Field

Add Matrix of Fields

Import from Field Bank

Variable: merge_info

Completed e-Consent PDF (combined PDFs for two e-Consent COMPLETED surveys)

Add Field

Add Matrix of Fields

Import from Field Bank

Variable: signed_pdf

Complete and Signed Consent Form

Upload file

Add Field

Add Matrix of Fields

Import from Field Bank