

REDCap e-Consent

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Outline

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3. Overview of Setup of REDCap e-Consent

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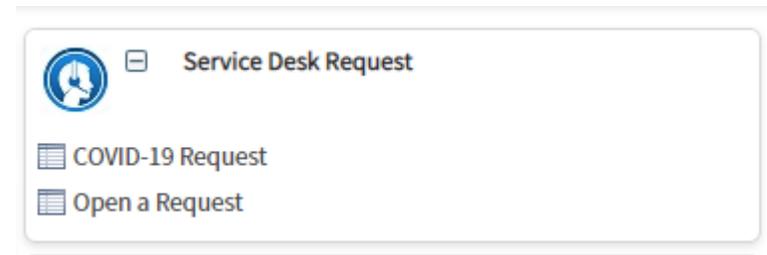
5. Method of e-Consent Distribution

6. Updating e-Consent

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1. Quick overview of DocuSign

- Limited access!
- Available for FDA-regulated research studies (drugs/devices studies) that are enrolling COVID-19 patients at BMC
- Process:
 - ICF is sent to participant via email from DocuSign.
 - Participant first must agree to sign electronically before accessing the form and then signs form
 - Investigator receives email with signed document attached and proceeds to sign the document
 - Copy of fully signed/completed consent form is emailed to both parties
- To get started:
 - Log into ServiceNow's Service Catalog
 - Under Service Desk Requests, click COVID-19 Request
 - Complete the form and check the "Research" checkbox



1. Terminology

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

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

Survey – An instrument in which a research participant can enter data or answer questions without a REDCap account. Instrument is accessed through a URL. (viewing method)

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

Record ID – A unique identifier for each record in a project.

Survey Login – A way to increase security on private surveys by requiring participants to enter 1 to 3 specified login credentials in order to begin a survey. The credentials must already exist in the system for the survey login feature to be utilized, either by pulling them from a survey that has already been completed or by entering them on a form.

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 project. An alternative to the Online Designer for building or editing projects. Mainly use to save the project for future reference or project duplication.

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.

2. Overview of Setup of REDCap e-Consent

- Approved e-consent form
- Entry fields for name, signature, and date
- Survey settings
- Consent documentations to consider:
 - Confirmation that a copy of informed consent was given to participant
 - Verbally instruct participant to download a copy of the completed ICF and document this in comment field
 - Automate sending of completed ICF to participant

2. Overview of Setup of REDCap e-Consent

1. Create a project in REDCap using the e-Consent template which goes along with the REDCap e-Consent Guidance (“default setup”)

+ 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:
Title to be displayed on project webpage

Purpose of this project: How will it be used?

Assign project to a Project Folder?

Project notes (optional): Comments describing the project's use or purpose that are displayed on the My Projects page.

Start project from scratch or begin with a template?

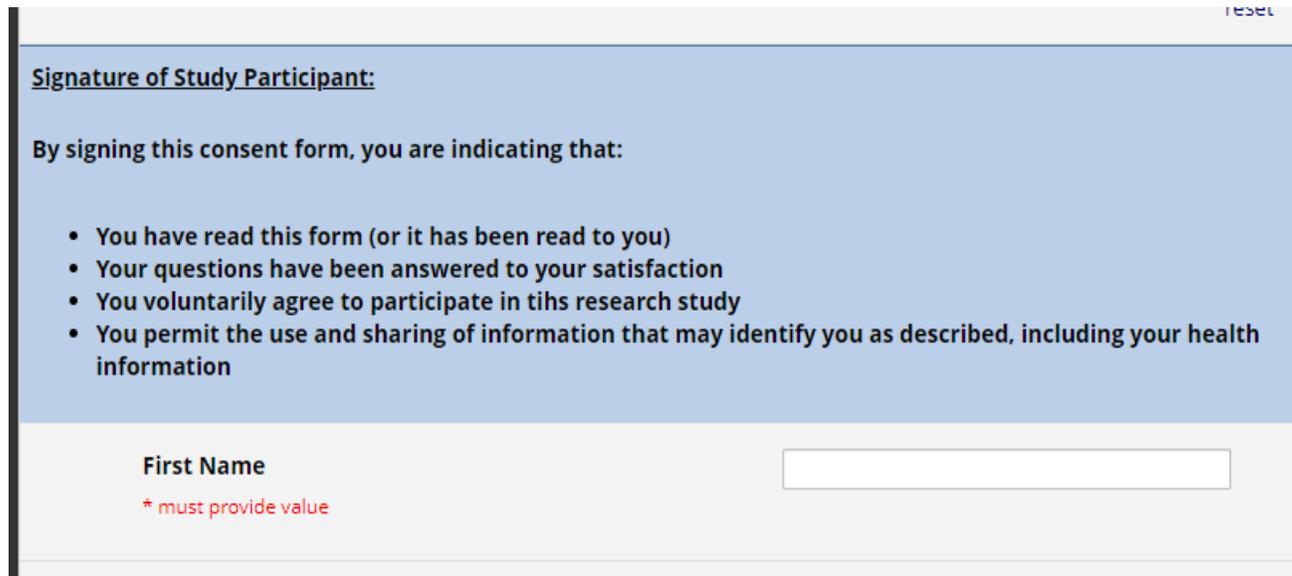
- Create an empty project (blank slate)
- Upload a REDCap project XML file (CDISC ODM format) [?](#)
- Use a template (choose one below)

★ Choose a project template (comes pre-filled with fields, forms/surveys, and other settings)

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 type="radio"/>	e-Consent for Non-Exempt Research	CRRO Guidance
<input type="radio"/>	Field Embedding Example: Baseline	Contains a single data collection instrument to demonstrate the Field Embedding feature.

2. Overview of Setup of e-Consent

1. Create a project in REDCap using the e-Consent template (“default setup”)
2. Modify the consent form based on the approved research study:
 - i. Convert approved ICF to JPEG files
 - ii. Edit default text for REDCap signing language to match approved language in ICF



The screenshot shows a portion of a REDCap e-consent form. The top section is a blue box with the heading **Signature of Study Participant:**. Below this heading, the text reads: **By signing this consent form, you are indicating that:** followed by a bulleted list of four items:

- You have read this form (or it has been read to you)
- Your questions have been answered to your satisfaction
- You voluntarily agree to participate in tihs research study
- You permit the use and sharing of information that may identify you as described, including your health information

Below the blue box is a white input field for the **First Name**. A red asterisk and the text *** must provide value** are located below the input field. A small **reset** link is visible in the top right corner of the form area.

2. Overview of Setup of e-Consent

1. Create a project in REDCap using the e-Consent template (“default setup”)
2. Modify the consent form based on the approved research study:
 - i. Convert approved ICF to JPEG files
 - ii. Edit default text for REDCap signing language to match approved language in ICF
 - iii. Modify default checkbox section (re-contact, sub-study, repository etc.)

Optional sub-study/recontact section:

Variable: re_contact

Recontact
* must provide value

Yes, you may contact me again to let me know about a different research study.

No, you may not contact me to let me know about a different research study.

reset

Optional sub-study/recontact section:			
	Yes	No	
You may contact me again to ask for additional information related to this study * must provide value	<input type="radio"/>	<input type="radio"/>	reset
You may contact me again to ask for additional biological samples related to this study * must provide value	<input type="radio"/>	<input type="radio"/>	reset
You may contact me again to let me know about a different research study * must provide value	<input type="radio"/>	<input type="radio"/>	reset
You may contact me again to list reason - or delete line * must provide value	<input type="radio"/>	<input type="radio"/>	reset

2. Overview of Setup of e-Consent

1. Create a project in REDCap using the e-Consent template (“default setup”)
2. Modify the consent form based on the approved research study:
 - i. Convert approved ICF to JPEG files
 - ii. Edit default text for REDCap signing language to match approved language in ICF
 - iii. Modify checkbox section (re-contact, sub-study, repository etc.)
3. Setup survey settings
 - i. Add survey instructions and survey completion text
 - ii. Enable option for participants to download a PDF of completed e-Consent at end of survey
 - iii. Enable e-Consent framework - this adds two extra things to the survey format:
 - Certification step: Adds extra certification page to end of the survey in which participants will be asked to confirm that all information in the document is correct.
 - Auto-archive step: Completed e-Consent survey will be stored as a PDF in the project’s File Repository.

3. In-Person vs. Remote e-Consent

- In-Person e-Consent Form:
 - Study teams need to create 1 instrument
 - Participant and Study Personnel signature section exist on the same instrument
- Remote e-Consent Form
 - Study teams need to create 2 instruments
 - Participant e-Consent and Study Personnel e-Consent forms are two separate instruments
 - The 2 e-Consents are linked by the same Record ID

4. Method of e-Consent Distribution

➤ E-mail

- Enable module to designate an email field for sending survey invitations
- Invitation can be automated
- Use Survey Login for added security (e-mail alone is not a secure form of communication)

➤ Twilio

- Survey as webpage – survey URL provided by SMS (similar to invitation via email)
- Study teams must submit this form to enable Twilio in their REDCap project:
<https://redcap.bumc.bu.edu/surveys/?s=HJPXWCME7H>

➤ Hospital patient communication portal

➤ Video conference chat

**Make sure you state in your IRB application your method of e-Consent distribution and get appropriate IRB approval

4. Method of e-Consent Distribution

➤ Utilizing Survey Login

1. Create a “Participant Information” instrument to enter participant’s email and e-Consent code
 - i. Study staff can create a (easy) unique code

 **Participant Information**

 Editing existing Record ID 1

Record ID	1
Participant's email	<input type="text" value="jung@bu.edu"/>
e-Consent Code	<input type="text" value="test123"/>
Form Status	
Complete?	<input type="text" value="Complete"/>

4. Method of e-Consent Distribution

- Utilizing Survey Login
 - Create a “Participant Information” instrument to enter participant’s email and e-Consent code
 - Study staff can create a (easy) unique code
- Manually send survey invitation

🔧 Survey Distribution Tools

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

The Participant List option 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](#)

Participant List belonging to "Participant e-Consent Form" ▼

Displaying 1 - 1 of 1 + Add participants ✉ Compose Survey Invitations 📄 Export list

Email	Record	Participant Identifier	Responded?	Invitation Scheduled?	Invitation Sent?	Link	Survey Access Code and QR Code
jung@bu.edu	1	Disabled	●	-	✉	🔗	📄

4. Method of e-Consent Distribution

➤ Automated Survey Invitation

- study teams can specify conditions for sending invitation
 - create a Yes/No field where staff will confirm whether or not to email the consent survey and specify which e-consent instrument version to email to the participant

Define Conditions for Automated Survey Invitations (ASI)

Instructions: In this pop-up you may define your conditions for automated survey invitations that will be sent out for the survey (and event, if a longitudinal project) listed in the Info box below. [Tell me more](#)

Info
Survey title: Participant Consent Form v1.0

STEP 1: Compose message

From:
(select any project user to be the 'Sender')

To: **[All participants who meet the conditions defined]**

Subject:

Please take this survey.

You may open the survey in your web browser by clicking the link below:

If the link above does not work, try copying the link below into your web browser:

NOTE: You may modify or remove any text you wish in the Compose Message text box above. Make sure you include either `[survey-link]` or `[survey-url]` in the text or else the participant will not have a way to take the survey.

You may use HTML formatting in the email message: `` bold, `<u>` underline, `<i>` italics, `` link, etc.

STEP 2: Conditions

Specify conditions for sending invitations:

When the following survey is completed:

AND

When the following logic becomes true:

(e.g., [age] > 30 and [sex] = "1")
[How do I use special functions?](#)

Test logic with a record:

Ensure logic is still true before sending invitation? [?](#)

[How to use 'stop logic' to disable an automated invite](#)

STEP 3: When to send invitations AFTER conditions are met

Send immediately

Send on next at time H:M

Send after lapse of time: days hours minutes

Send at exact date/time: M/D/Y H:M

OPTIONAL: Enable reminders

Re-send invitation as a reminder if participant has not responded by a specified time?

5. Updating e-Consent

- Are you utilizing an Automated Survey Invitation feature?
 - Then you need to carefully think about what exactly you should set as your conditional field that will trigger this invitation
 - So our recommendation is that you utilize a Version Tracking instrument
- If you are not utilizing ASI, then you don't have to worry about this step
 - You can select which instrument to email to the participant via Survey Distribution Tool

5. Updating e-Consent

- Version tracking instrument
 - Use this to keep track of informed consent versions
 - Create a Yes/No field in this instrument to set up the Automated Survey Invitation trigger
 - Create a ICF version field to specify which ICF version you are going to email out
 - Make a repeatable instrument

The screenshot shows the configuration interface for an instrument named "Version Tracking". At the top left, there is a blue button labeled "Return to list of Instruments". To the right of the instrument name, there is a "Preview instrument" button. Below the instrument name, there are two sections for adding fields:

- The first section is for the variable "version". It contains a text input field labeled "Version number" with a placeholder "#.#". Above the input field are "Add Field" and "Add Matrix of Fields" buttons.
- The second section is for the variable "email_consent". It contains a radio button group labeled "Email consent form" with options "Yes" and "No". A "reset" button is located at the bottom right of this section. Above the radio buttons are "Add Field" and "Add Matrix of Fields" buttons.

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Info

Survey title: Participant Consent Form v1.0

STEP 1: Compose message

From:

(select any project user to be the 'Sender')

To: **[All participants who meet the conditions defined]**

Subject:

Compose

Preview

Send test email

Please take this survey.

You may open the survey in your web browser by clicking the link below:
[survey-link]

If the link above does not work, try copying the link below into your web browser:

NOTE: You may modify or remove any text you wish in the Compose Message text box above. Make sure you include either [survey-link] or [survey-url] in the text or else the participant will not have a way to take the survey.

You may use HTML formatting in the email message: bold, <u> underline, <i> italics, link, etc.

[How to use Plain in the survey invitation](#)

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Specify conditions for sending invitations:

When the following survey is completed:

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When the following logic becomes true:

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

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Send on next at time H:M

Send after lapse of time: days hours minutes

Send at exact date/time: M/D/Y H:M

OPTIONAL: Enable reminders

Re-send invitation as a reminder if participant has not responded by a specified time?

5. Updating e-Consent

- Create a NEW e-consent survey for your updated (newly approved) informed consent form
 - Simple method: create a copy of the Participant e-Consent survey and Study Personnel e-Consent survey and updates the fields accordingly
- Fill out the Version Tracking instrument (if re-consenting, you will utilize that repeatable instrument feature and create a new instance of the Version Tracking instrument)

 Editing existing Record ID **16** (Instance #2)

Record ID	16
Version number	<input type="text" value="2.0"/> =,=
Email consent form	<input checked="" type="radio"/> Yes <input type="radio"/> No

reset

6. Exempt Research: Information Sheet and HIPAA Authorization Form

- Also applies to Non-Exempt Research that have a waiver of documentation
- Utilize the Template available in REDCap: “e-Consent for Exempt Research”
- Survey format option:
 - Use JPEG image of the Information sheet and HIPAA Authorization Form OR
 - Copy and paste text directly onto REDCap fields

Questions?