

Frequently Asked Question (FAQ) Library

How do I administer eConsent? I received IRB approval and am ready to use my eConsent.

These instructions will explain how to: (1.) administer the eConsent by setting up signature fields and using the eConsent with participants, (2.) set up automatic notifications when an eConsent form is submitted, (3.) access the signed eConsent forms, and (4.) share copies of the signed eConsent forms. Because the eConsent can be administered in-person or remotely, both scenarios will be addressed in this FAQ.

Please refer to [FAQ: How do I build an eConsent?](#) for instructions on creating and enabling the eConsent framework.

Administering eConsent In-Person

In-Person: Signature Setup

For an in-person consent process requiring a signature, the participant and the person obtaining consent are together and will sign the electronic consent form at the same time. In this case, both the signature of the participant and the signature of the person obtaining consent will be captured on the same REDCap form as shown below.

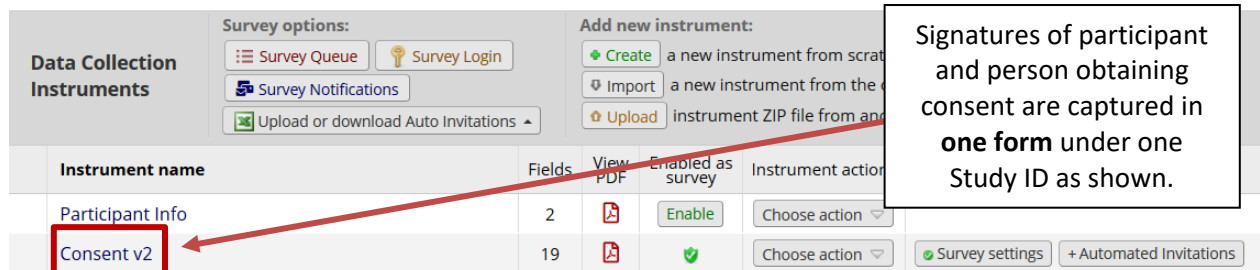
For example:

Date Consent Form Signed		<input type="text"/>	Today	M-D-Y
* must provide value				
Participant				
Participant First Name	<input type="text"/>			
* must provide value				
Participant Last Name	<input type="text"/>			
* must provide value				
Participant Signature	<input type="text"/>			Add signature
* must provide value				
Person Obtaining Consent				
First Name of Person Obtaining Consent	<input type="text"/>			
* must provide value				
Last Name of Person Obtaining Consent	<input type="text"/>			
* must provide value				
Signature of Person Obtaining Consent	<input type="text"/>			Add signature
* must provide value				

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To administer eConsent in-person, you will add the fields for the participant and the person obtaining signature to one form and enable eConsent Framework on that form.

To enable the eConsent Framework, enable the form as survey and select eConsent Framework in the survey settings.



Survey options: Survey Queue, Survey Login, Survey Notifications, Upload or download Auto Invitations

Add new instrument: Create, Import, Upload

Instrument name	Fields	View PDF	Enabled as survey	Instrument action
Participant Info	2		Enable	Choose action
Consent v2	19			Choose action

Signatures of participant and person obtaining consent are captured in **one form** under one Study ID as shown.

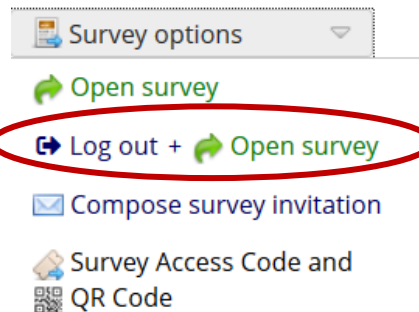
In-Person: Consenting

IMPORTANT: To consent a participant, the eConsent form in REDCap must be administered as a survey.

The eConsent process will involve the use of an electronic device in lieu of paper, as outlined in your IRB protocol. Although the consent process will differ from study-to-study, a **typical** in-person eConsent involves some variation of the following: (1.) identifying an electronic device to access REDCap, (2.) opening the eConsent as a survey, (3.) reviewing the research study with the participant, (4.) providing the participant with time to review the content and explore hyperlinks, (5.) answering questions, (6.) obtaining participant signature, (7.) reviewing the eConsent form to confirm it is filled out correctly and (8.) signing the eConsent as the 'person obtaining consent'.

To sign the eConsent (#6-8 above), research staff will:

- Login to REDCap.
- Open the eConsent form.
- Use the '**Log out + Open Survey**' survey option to open the form as survey.
- Give the device to the participant. Explain the details of the consent form while allowing the participant to review the consent form on screen.
- After participant signs the eConsent form, the participant will hand the device back to the research staff who can review, fill out and sign as '*the person obtaining consent.*'
- Click submit after the consent form is signed by both the participant and study staff.



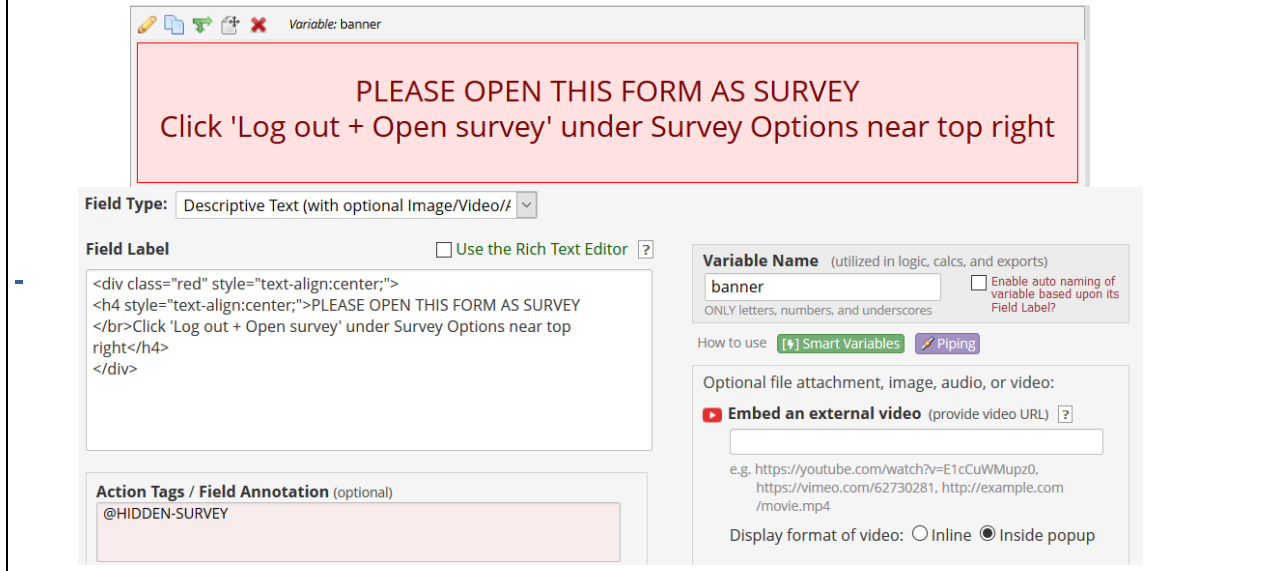
Survey options

- Open survey
- Log out + Open survey**
- Compose survey invitation
- Survey Access Code and QR Code

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Pro Tip: Remind study staff to open the form as survey.
Add an **instruction banner** by inserting a descriptive field on the top of the eConsent form.

Example of instruction banner:



The screenshot shows the REDCap form editor interface for a variable named 'banner'. A red box highlights the instruction banner text: "PLEASE OPEN THIS FORM AS SURVEY" and "Click 'Log out + Open survey' under Survey Options near top right". Below the banner, the configuration options are visible:

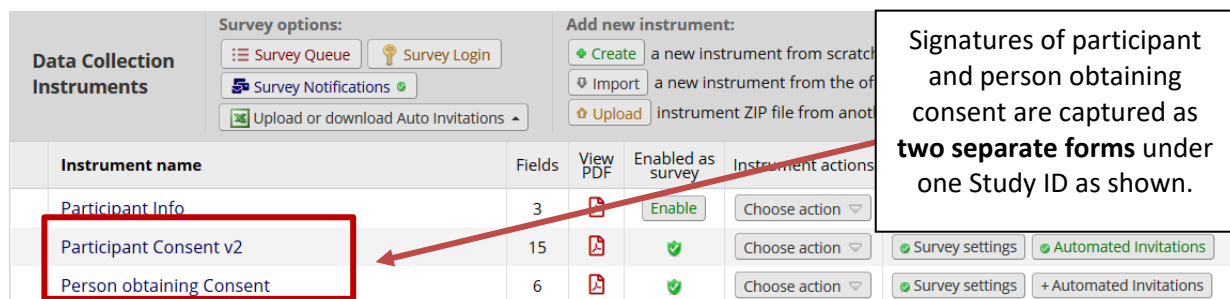
- Field Type:** Descriptive Text (with optional Image/Video/)
- Field Label:** Use the Rich Text Editor
- Variable Name:** banner (utilized in logic, calcs, and exports)
- How to use:** Smart Variables, Piping
- Optional file attachment, image, audio, or video:** Embed an external video (provide video URL)
- Action Tags / Field Annotation (optional):** @HIDDEN-SURVEY

Administering eConsent Remotely

Remote: Signature Setup

For remote eConsent, the participant and the person obtaining consent will sign the consent form in different locations. In this case, the signature of the person obtaining consent signature should be captured on a separate REDCap form as shown below.

For example:



The screenshot shows the REDCap Instruments table with the following data:

Instrument name	Fields	View PDF	Enabled as survey	Instrument actions
Participant Info	3		Enable	Choose action
Participant Consent v2	15			Choose action
Person obtaining Consent	6			Choose action

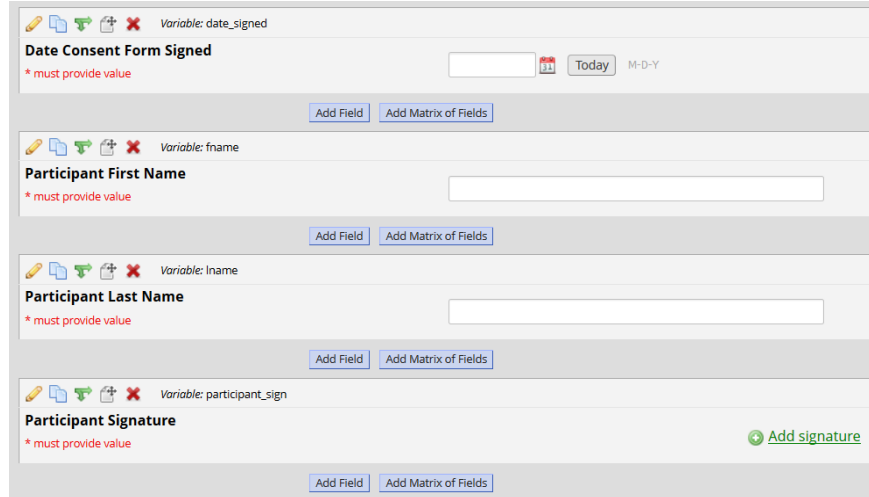
A red box highlights the 'Participant Consent v2' and 'Person obtaining Consent' rows. A red arrow points from a text box to the 'Participant Consent v2' row. The text box contains the following text:

Signatures of participant and person obtaining consent are captured as **two separate forms** under one Study ID as shown.

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In signature setup example above:

The Form “Participant Consent v2” will contain the participant signature as shown below:



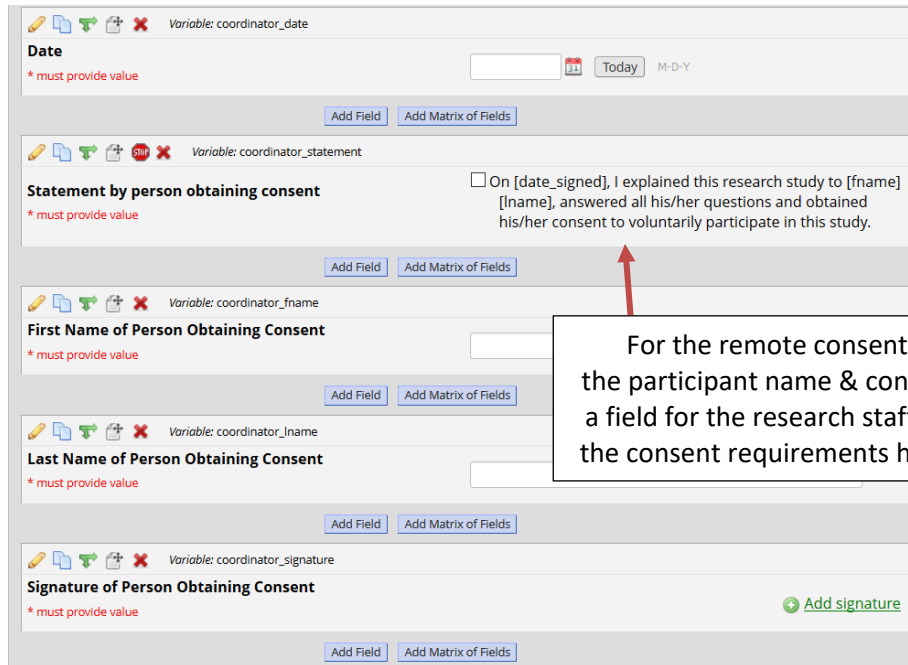
Variable: date_signed
Date Consent Form Signed
* must provide value

Variable: fname
Participant First Name
* must provide value

Variable: lname
Participant Last Name
* must provide value

Variable: participant_sign
Participant Signature
* must provide value

The Form “Person obtaining Consent” will contain the research staff signature as shown below:



Variable: coordinator_date
Date
* must provide value

Variable: coordinator_statement
Statement by person obtaining consent
* must provide value

Variable: coordinator_fname
First Name of Person Obtaining Consent
* must provide value

Variable: coordinator_lname
Last Name of Person Obtaining Consent
* must provide value

Variable: coordinator_signature
Signature of Person Obtaining Consent
* must provide value

On [date_signed], I explained this research study to [fname] [lname], answered all his/her questions and obtained his/her consent to voluntarily participate in this study.

For the remote consent process, show the participant name & consent date with a field for the research staff to verify that the consent requirements have been met.

Pro Tip: To verify the identity of the participant and prevent errors, piping can be used to display the participant name and consent date on the form. To learn more, refer to [FAQ: Piping](#).

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Reminder: The eConsent Framework will be enabled for the “Participant Consent” form AND for the “Person Obtaining Consent” form in REDCap. To enable the eConsent Framework, enable the form as survey and select eConsent Framework in the survey settings.

Instrument name	Fields	View PDF	Enabled as survey	Instrument actions	Survey-related options
Participant Info	3		Enable	Choose action	
Participant Consent v2	15			Choose action	Survey settings Automated Invitations
Person obtaining Consent	6			Choose action	Survey settings + Automated Invitations

IMPORTANT: When enabling the “Person Obtaining Consent”, select the **participant name** for the First and Last name field, NOT the name of the person obtaining consent.

e-Consent Framework
- and -
PDF Auto-Archiver

Upon survey completion, a compact PDF copy of the survey response will be automatically stored in the project's File Repository, from which the archived PDFs can be downloaded at any time.

Disabled
 Auto-Archiver enabled
 Auto-Archiver + e-Consent Framework [What is the e-Consent Framework?](#)
(includes end-of-survey certification & archival of PDF consent form)

e-Consent Framework Options:
For e-Consent it is sometimes required to include the consenting participant's name (and date of birth in some cases) on the final consent form as extra documentation of their identity. Below you may select fields used to capture that info. You may enter the current e-Consent version and e-Consent type for this form. The value of the fields below will be automatically inserted into the footer of the PDF consent form that the participant will review at the end of the survey, after which that PDF 'hard-copy' will be archived in the File Repository. [Read more](#)

Allow e-Consent responses to be edited by users?

e-Consent version: e.g., 4

First name field:

Last name field:

Note: If you are using a single field to capture both names, please select either first/last name above while leaving the other name field unselected.

These fields will be printed on the footer of the 'Person Obtaining Consent' form and should reference the participant.

Remote: Consenting

IMPORTANT: To consent, the eConsent form in REDCap must be administered as a survey.

The eConsent process will involve the use of an electronic device in lieu of paper, as outlined in your IRB protocol. Although the consent process will differ from study-to-study, a **typical** remote eConsent includes some variation of the following: (1.) sending a link to the eConsent form via email or text, (2.) providing the participant with time to review the content and explore hyperlinks, (3.) contacting the participant to review the research study, eConsent form, and answer questions, (4.) receiving a notification when a participant has signed and submitted the eConsent form, (5.) reviewing the form to confirm it is filled out correctly, and (6.) opening the corresponding ‘Person Obtaining Consent’ form as a survey and electronically signing.

To learn about REDCap’s secure options for outgoing emails, refer to [FAQ: Protected Email Mode](#).

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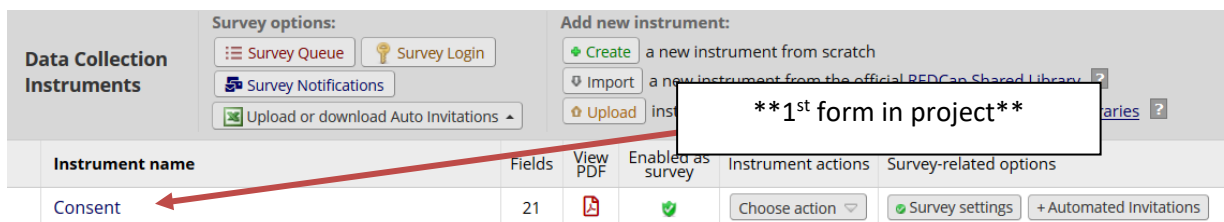
The REDCap features found in the survey setup will allow you to (1.) *send a link* and (4.) *receive a notification* as described below. The eConsent may be distributed as a public or private hyperlink. You must describe the plan in your study protocol.

Public Hyperlink

If you opt to use a public hyperlink, you will use one hyperlink for all study participants. A unique record will be created AFTER a participant submits a consent form. Public links are useful for contacting in mass (i.e. email distribution lists, public website, or other forums). Public links are more commonly used on studies classified as exempt. Because you are only notified of submitted consents, you will not have a record of non-respondents.

To use a public link:

- a. The eConsent must be the first form in your project.



Survey options: Survey Queue, Survey Login, Survey Notifications, Upload or download Auto Invitations

Add new instrument: Create, Import, Upload

Instrument name	Fields	View PDF	Enabled as survey	Instrument actions	Survey-related options
Consent	21			Choose action	Survey settings, + Automated Invitations


- b. You can obtain the public link from the **Survey Distribution Tool** -> **Public Survey Link** page.

Survey Distribution Tools

Public Survey Link | Participant List | Survey Invitation Log

Using a public survey link is the simplest and fastest way to collect responses for your survey. You may obtain the survey link below to email it to your participants. Responses will be collected anonymously (unless the survey contains questions asking for identifying data from the participant). **NOTE:** Since this method uses a single survey link for all participants, it allows for the possibility of participants taking the survey multiple times, which may be necessary in some cases.

To obtain the survey link, copy the URL below and paste it into the body of an email message in your own email client. Your email recipient(s) can then click the link to begin taking your survey.

Public Survey URL: 

- c. The public link can be copied and pasted into communications.

Pro Tip: If you plan to contact the participant via email after enrollment, you will need to include an email field on your eConsent form or accompanying survey.

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Private Hyperlink

If you opt to use a private hyperlink, each study participant will have a unique hyperlink. Generally, private links are used for targeted recruitment efforts. To send a private link, you will need to collect emails from your target population. Because each email will have a unique link, you will have a record of respondents and non-respondents.

To use private links:

1. Designate an email field for sending survey invitations:
 - a. This method allows for tracking of respondents and non-respondents. The eConsent link can also be configured to be sent automatically after a condition is met (e.g. the Participant Info form is saved).
 - b. To use, create a form that precedes the eConsent form and add an email field to this form as shown below.

Instrument name	Fields	View PDF	Enabled as survey	Instrument actions	Survey-related options
Participant Info	3		Enable	Choose action	
Participant Consent v2	15			Choose action	Survey settings Automated Invitations
Person obtaining Consent	6			Choose action	Survey settings + Automated Invitations

Current instrument: **Participant Info** Preview instrument

Variable: subjectid

Subject 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](#)

Variable: study_id

Study ID

[Add Field](#) [Add Matrix of Fields](#)

Variable: email

Participant Email

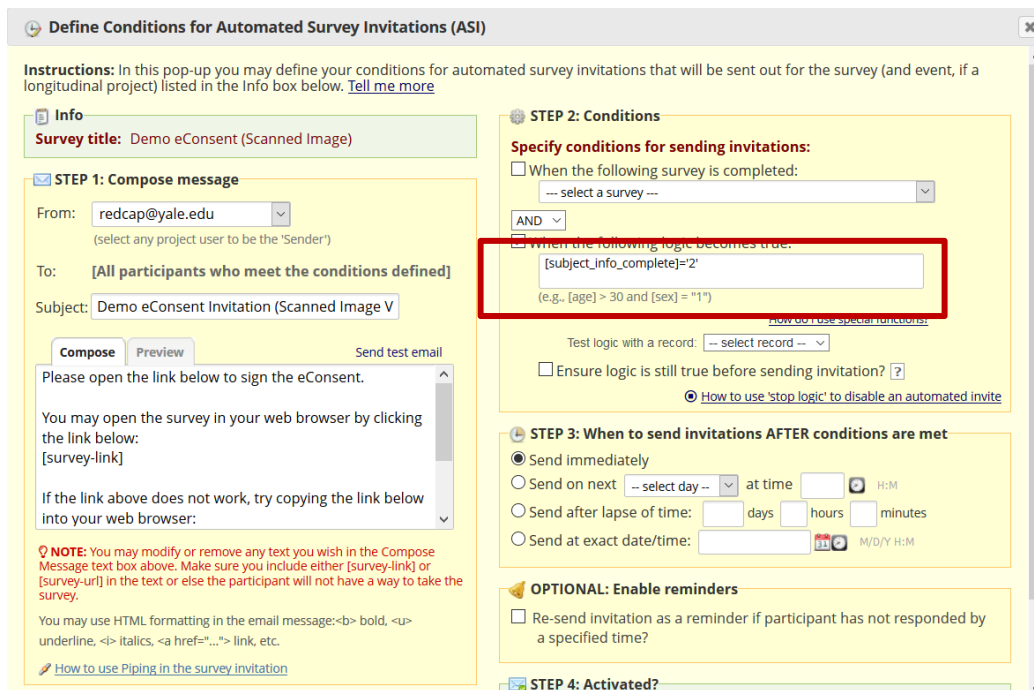
Must provide value

[Add Field](#) [Add Matrix of Fields](#)

- c. Once the Participant Info form is created with the participant email field, you can designate this email for sending survey invitations. To do that, go to the **Project Setup -> Enable optional modules and customizations -> Designate the email field for sending survey invitation**.

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- d. Once completed, you can set up an **automatic survey invitation** so the eConsent is sent to the participant when their email is entered, and the Participant Info form is saved with a 'Complete' status.
- i. Refer to [FAQ: Automatic Survey Invitation](#) to learn more about sending automatic survey invitations.



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: Demo eConsent (Scanned Image)

STEP 1: Compose message
From: redcap@yale.edu
To: [All participants who meet the conditions defined]
Subject: Demo eConsent Invitation (Scanned Image V)

STEP 2: Conditions
Specify conditions for sending invitations:
 When the following survey is completed:
-- select a survey --
AND
 When the following logic becomes true:
[subject_info_complete]=2
(e.g., [age] > 30 and [sex] = "1")

STEP 3: When to send invitations AFTER conditions are met
 Send immediately
 Send on next -- select day -- 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?

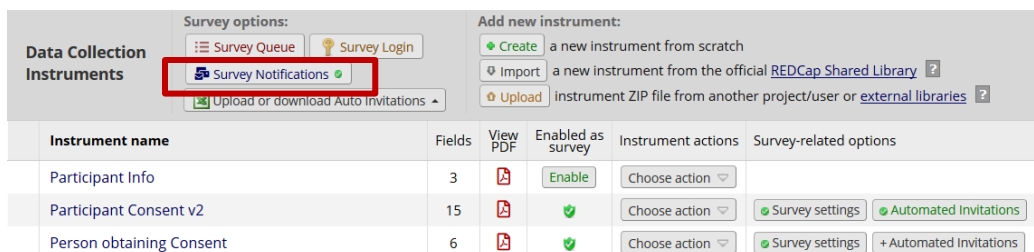
STEP 4: Activated?

Automatic Notifications

With REDCap, your study team can receive a notification when an eConsent is submitted.

To setup automatic notifications:

1. Click **'Survey Notifications'** in the online designer.



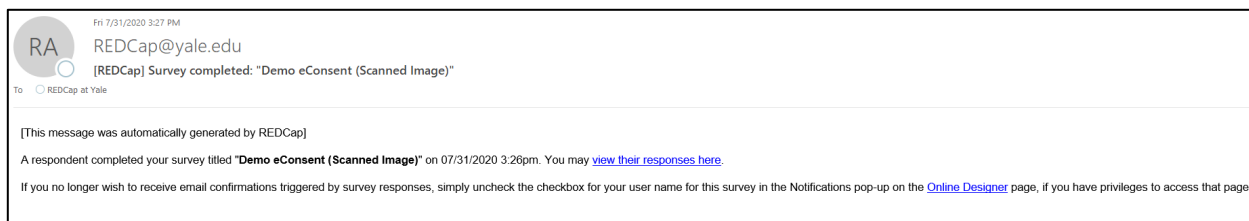
Instrument name	Fields	View PDF	Enabled as survey	Instrument actions	Survey-related options
Participant Info	3		Enable	Choose action	
Participant Consent v2	15			Choose action	Survey settings Automated Invitations
Person obtaining Consent	6			Choose action	Survey settings Automated Invitations

2. Under the eConsent form, select the person(s) who will receive the notification.

Demo eConsent (Scanned Image)	Recipient email address	Notifications Enabled
(Janet Miceli)	-- not selected --	
(Mary Geda)	-- not selected --	
(Sui Tsang)	REDCap@yale.edu (Tertiary)	

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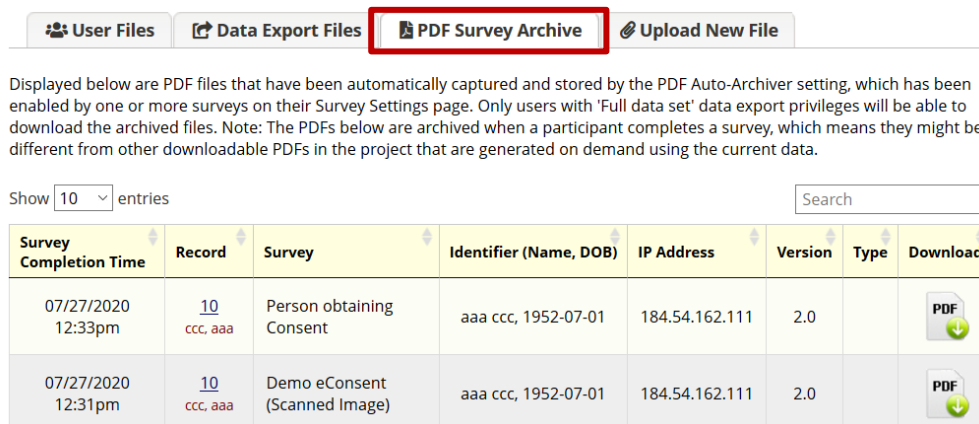
3. Click 'Close'.
4. The selected person(s) will receive an email notification each time an eConsent is submitted.



Accessing eConsents: The PDF Archive

With the eConsent Framework enabled, a compact PDF copy of the signed eConsent will be automatically stored in your project's File Repository. The archived PDFs can be viewed and downloaded by the study team. Downloaded files should be stored to a secure, protected location in compliance with your IRB protocol.

You can access the archive in **File Repository -> PDF Survey Archive** as shown below.



Displayed below are PDF files that have been automatically captured and stored by the PDF Auto-Archiver setting, which has been enabled by one or more surveys on their Survey Settings page. Only users with 'Full data set' data export privileges will be able to download the archived files. Note: The PDFs below are archived when a participant completes a survey, which means they might be different from other downloadable PDFs in the project that are generated on demand using the current data.

Show entries

Survey Completion Time	Record	Survey	Identifier (Name, DOB)	IP Address	Version	Type	Download
07/27/2020 12:33pm	10 ccc, aaa	Person obtaining Consent	aaa ccc, 1952-07-01	184.54.162.111	2.0		
07/27/2020 12:31pm	10 ccc, aaa	Demo eConsent (Scanned Image)	aaa ccc, 1952-07-01	184.54.162.111	2.0		

Sharing the Signed eConsent

You can provide a copy of the signed eConsent to the participant as a paper or electronic document. Regardless, you will need to describe the plan in your protocol and follow data protection and security measures. This includes downloading the eConsent form to a secure location when sharing.

To Share a Paper Copy

1. **In-Person:** If a printer is available, print a copy of the signed eConsent form on the signature **certification page** and provide it to the participant at the time of consent.
2. **Remote:** If a printer is not available, download the PDF files from the **PDF Survey Archive** when a printer is available, print the signed eConsent form, and mail it to the participant.

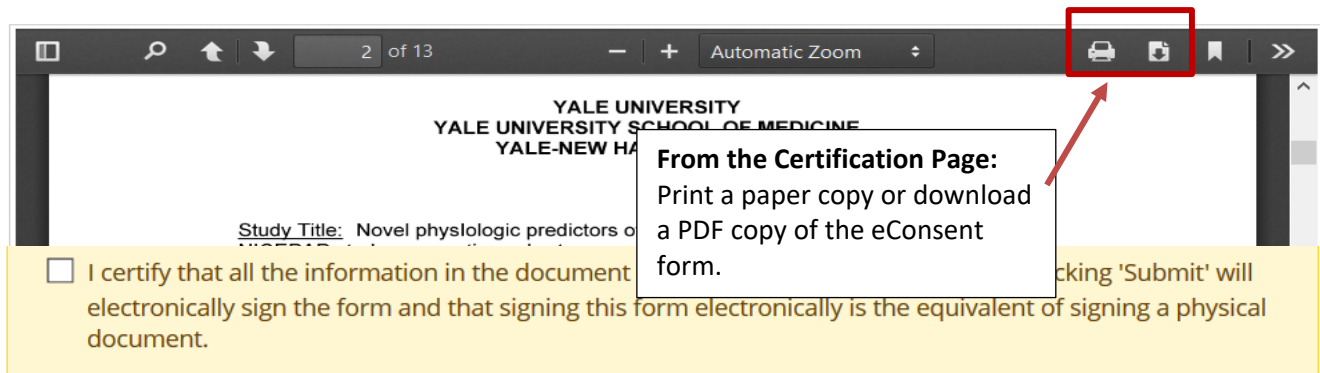
Frequently Asked Question (FAQ) Library

To Share an Electronic Copy

1. **In-Person:** If the participant signs the eConsent form on their personal device, they can download it from the signature **certification page** and save it to their device.
2. **Remote:** To email the signed eConsent, download the PDF files from the **PDF Survey Archive** and send it as attachment to your email.
 - a. **IMPORTANT:** Because signed consent documents can contain Protected Health Information (PHI) or Private Identifiable Information (PII), the email must be encrypted.

Refer to ITS's website for instructions on encrypted email:


<https://cybersecurity.yale.edu/encryption>



User Files | Data Export Files | PDF Survey Archive | Upload New File

Displayed below are PDF files that have been automatically captured and stored by the PDF Auto-Archiver setting, which has been enabled by one or more surveys on their Survey Settings page. Only users with 'Full data set' data export privileges will be able to download the archived files. Note: The PDFs below are archived when a participant completes a survey, which means they might be different from other downloadable PDFs in the project that are generated on demand using the current data.

Show 10 entries

Survey Completion Time	Record	Survey	Identifier (Name, DOB)	IP Address	Version	Type	Download
07/27/2020 12:33pm	10 ccc. aaa	Person obtaining Consent	aaa ccc, 1952-07-01	184.54.162.111	2.0	PDF	

From the PDF Survey Archive:
Download the eConsent form to securely email or print & mail to the participant.