

Frequently Asked Question (FAQ) Library

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

These instructions explain how to:

- (1.) Administer an eConsent tool.
 - a. In-Person/Onsite
 - b. Remote
 - i. Compose Survey Invitation
 - ii. Set up Automatic Survey Invitations (ASI)
- (2.) Verify Consent.
- (3.) Provide copies of the eConsent form.

Please refer to [FAQ: eConsent Build PDF Upload](#) for instructions on creating an eConsent.

The procedures for obtaining, administering, and monitoring consent will be described in your study protocol. You may use these instructions to inform the development of study-specific materials and Standard Operating Procedures as required by Good Clinical Practice (GCP) guidelines and federal regulations. For more information, refer to the [Yale Human Research Protection Program \(HRPP\) eConsent Guidance](#).

Administer eConsent

The eConsent process involves the use of an electronic device in lieu of paper.

Administering eConsent: In-Person/Onsite

The instructions below explain how to administer the REDCap eConsent in-person/onsite. Although the consent process will differ from study-to-study, a **typical** in-person process involves some variation of the following: (1.) verifying the participant's identity, (2.) using a computer or mobile device to access REDCap, (3.) opening the eConsent as a survey, (4.) reviewing the elements of informed consent with the participant, (5.) providing the participant with time to read the consent, (6.) gauging comprehension and answering questions, (7.) obtaining participant signature, (8.) confirming the participant correctly signed, dated, and submitted the eConsent, (9.) opening the 'Person Obtaining Consent' form as a survey and signing the eConsent, and (10.) providing a copy of the informed consent.

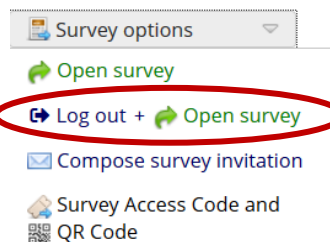
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IMPORTANT: To consent a participant, the eConsent form in REDCap **must** be administered as a **survey**.

To administer the eConsent

1. Research staff will:

- a. Login to REDCap and open the eConsent form in a mobile device.
- b. Use the **'Log out + Open Survey'** survey option to open the form as survey.



Pro Tip: Prevent a security breach.

The person obtaining consent must never provide a participant access to device (computer, tablet) that has a logged-in REDCap session running. Always log-out and open as a survey before providing your mobile device (tablet, laptop, etc.) to participants.

- c. Provide the mobile device to the participant with eConsent opened as a survey.
 - d. Consent the participant.
2. Once the consent discussion is completed, the participant will:
- a. Sign the consent form
 - i. Certify and click submit to save their signature.

I certify that all of my information in the document above is correct. I understand that clicking 'Submit' will electronically sign the form and that signing this form electronically is the equivalent of signing a physical document.

If any information above is not correct, you may click the 'Previous Page' button to go back and correct it.

<< Previous Page
Submit

- ii. Return the mobile device to the research staff.

Pro Tip: After the participant signs the eConsent form, verify that the box *"I certify that..."* was checked and submitted. Otherwise, the signature will not be saved, a PDF snapshot of the consent will not be generated, and the consent will be invalid.

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- b. Research staff will:
 - i. Open the **Person Obtaining Consent Form**.
 - ii. Use the '**Log out + Open Survey**' survey option to open the form as a survey.
 - iii. Sign the person obtaining consent section of the consent form.
 - iv. Certify and click submit to save their signature.
- c. Remember to verify consent and provide copies of consent as described below.

Administering eConsent: Remote

The instructions below explain how to administer the REDCap eConsent remotely. Although the consent process will differ from study-to-study, a **typical** remote process involves some variation of the following: (1.) verifying the participant's identity, (2.) reviewing the elements of informed consent with the participant, (3.) sending the eConsent to the participant as a survey, (4.) gauging comprehension and following up as necessary to answer any questions, (5.) confirming the participant correctly signed, dated, and submitted the eConsent, (6.) opening the '*Person Obtaining Consent*' form as a survey and signing the eConsent, and (7.) providing an electronic copy of the informed consent.

The survey setup will allow you to (1.) *send a hyperlink* and (2.) *receive a notification* as described below.

Sending the eConsent: Hyperlinks

The eConsent may be distributed as a public or private hyperlink (as described in your study protocol).

Pro Tip: Recruitment language, which includes eConsent email communications, must be approved by the IRB prior to distribution.

Public Hyperlink

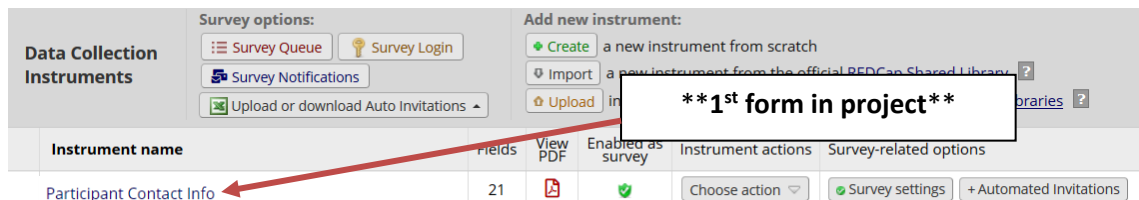
If you opt to use a public hyperlink, you will use one hyperlink for all study participants. Public hyperlinks cannot be used on studies that are FDA-regulated and subject to 21 CFR Part 11 requirements or for any greater than minimal risk research where the identity of the participant must be verified prior to consent. A unique record will be created AFTER a participant submits a consent form. Public links are useful for mass distribution (i.e. email distribution lists, public website, or other forums); however, they are vulnerable to fraudulent responses. Because you are only notified of submitted consents, you will not have a record of non-respondents.

Public hyperlinks are more commonly used to distribute eConsents on survey-based research that is classified as exempt (AND includes the collection of identifiers).

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To use a public link:


- The eConsent must be the first form in your project.
- You can obtain the public link from the **Survey Distribution Tool** -> **Public Survey Link** page.



The screenshot shows the 'Survey Distribution Tool' interface. A red arrow points from a text box containing '**1st form in project**' to the 'Participant Contact Info' instrument in the list below. The interface includes sections for 'Survey options' (Survey Queue, Survey Login, Survey Notifications, Upload or download Auto Invitations) and 'Add new instrument:' (Create, Import, Upload).

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: 

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

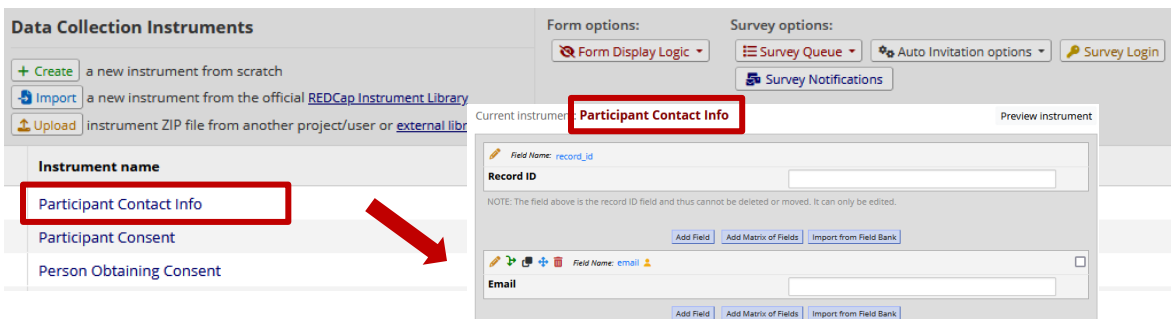
Pro Tip: If you plan to contact the participant via email after enrollment, you will need to include an email field on your eConsent form or accompanying survey. Remember to obtain IRB approval for collecting identifiers.

Private Hyperlink (record-specific link)

If you opt to use a private hyperlink, each participant will receive a survey invitation through a unique hyperlink associated with a specific REDCap record. To send a private link, email addresses are required. With this method, you will have a record of respondents and non-respondents.

To use private links:

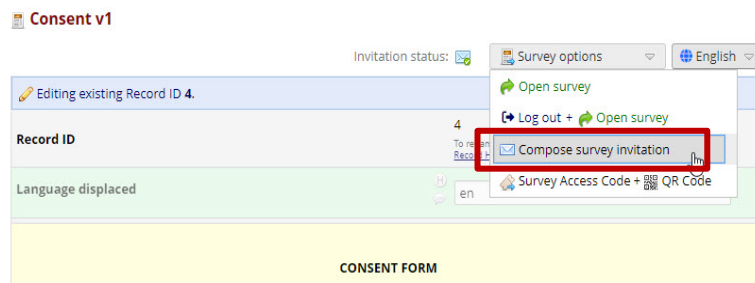
- Designate an email field for sending survey invitations:
 - To use, create a form that precedes the eConsent form and add an email field to this form as shown below. The field must be a text field that is validated as an email.



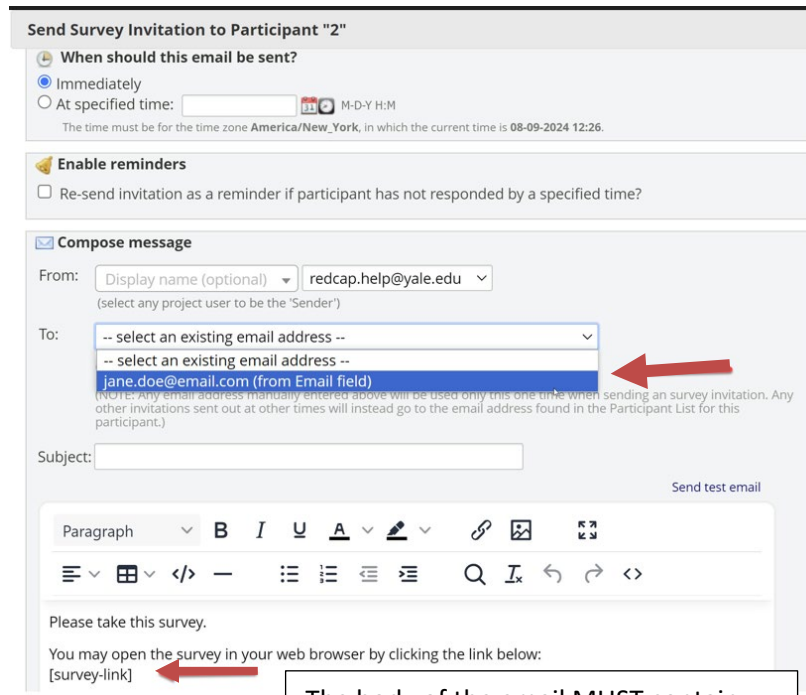
The screenshot shows the 'Participant Contact Info' instrument configuration. A red box highlights the instrument name 'Participant Contact Info' in the list on the left. A red arrow points from this box to the 'Form options' section on the right, where an 'Email' field is being added. The 'Form options' section includes 'Form Display Logic' and 'Survey options' (Survey Queue, Auto Invitation options, Survey Login, Survey Notifications).

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- Once the Participant Contact 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**. Only text fields with 'email' validation will appear as options.
- Once the participant email is designated, there are a few ways to send them a private link, including **'Compose Survey Invitation'** and **'Automatic Survey Invitation'**.
 - Compose Survey Invitations:** To send a survey invitation to a participant individually, open the participant's record and the consent form instrument you wish to send. In the top right corner select the "Survey Options" → **Compose Survey Invitations**



- If the email is designated and saved in the record, it will appear in the *'select existing email address'* dropdown option. Select the participant email.

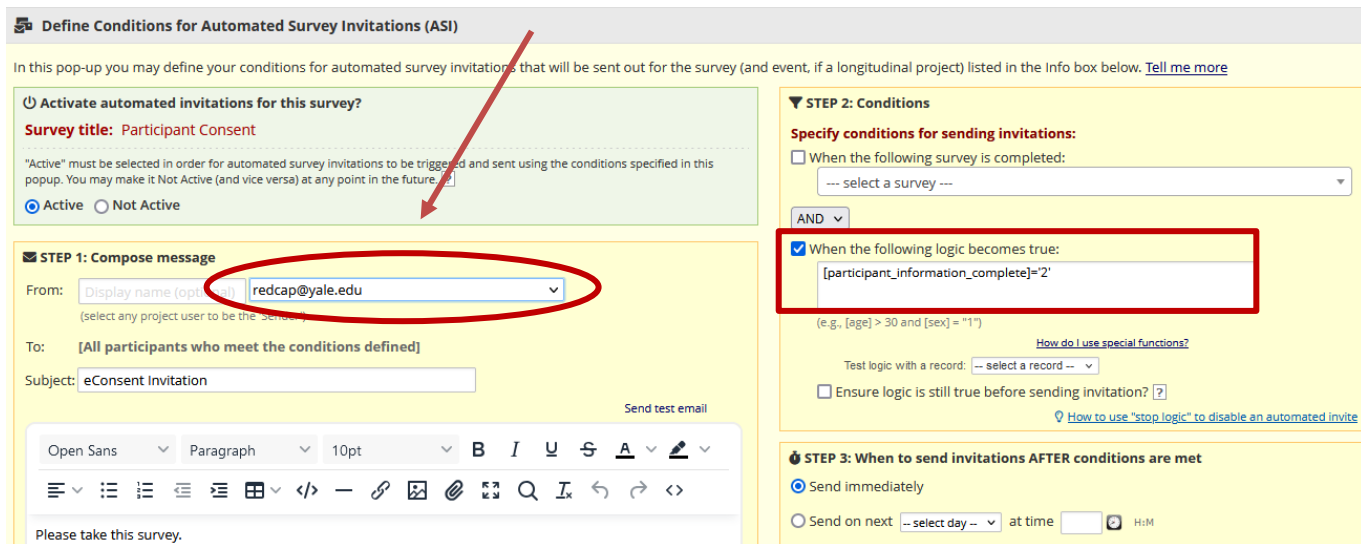


The screenshot shows the 'Send Survey Invitation to Participant "2"' form. The 'When should this email be sent?' section has 'Immediately' selected. The 'Enable reminders' section has 'Re-send invitation as a reminder if participant has not responded by a specified time?' unchecked. The 'Compose message' section shows the 'From' field as 'redcap.help@yale.edu'. The 'To' field dropdown is open, showing 'jane.doe@email.com (from Email field)' selected, with a red arrow pointing to it. The 'Subject' field is empty. Below the form is a rich text editor with a 'Send test email' button. The body of the email contains the text: 'Please take this survey. You may open the survey in your web browser by clicking the link below: [survey-link]' with a red arrow pointing to the '[survey-link]' placeholder.

The body of the email MUST contain the smart variable "[survey-link]" (in brackets with a dash) to populate the private survey link.

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- ii. **Automatic Survey Invitations (ASI):** You can also set up an automatic survey invitation so the eConsent link is sent to the participant when their email is entered, and the Participant Contact Info form is saved with a 'Complete' status. Note: the logic criteria specified in 'When the following logic becomes true' is not evaluated until the form is saved.



Define Conditions for Automated Survey Invitations (ASI)

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](#)

Activate automated invitations for this survey?
Survey title: Participant Consent
 "Active" must be selected in order for automated survey invitations to be triggered and sent using the conditions specified in this popup. You may make it Not Active (and vice versa) at any point in the future. [?]
 Active Not Active

STEP 1: Compose message
From: Display name (optional) **redcap@yale.edu**
 (select any project user to be the sender)
To: [All participants who meet the conditions defined]
Subject: eConsent Invitation
 Send test email

STEP 2: Conditions
Specify conditions for sending invitations:
 When the following survey is completed:
 --- select a survey ---
 AND
 When the following logic becomes true:
 [participant_information_complete]=2
 (e.g., [age] > 30 and [sex] = "1")
[How do I use special functions?](#)
 Test logic with a record: -- select 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 -- select day -- at time [] H:M

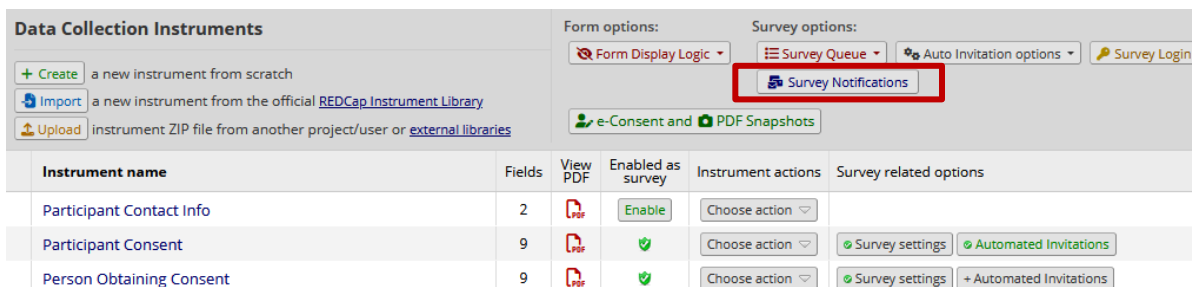
Refer to [FAQ: Automatic Survey Invitation](#) to learn more about ASI.

Survey Notifications

Survey notifications allow you to receive a notification when an eConsent survey is completed. (Note: for other ways to set up automatic notifications see Alerts and Notifications in REDCap Help page)

To setup automatic notifications:

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



Data Collection Instruments

+ 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 options: Form Display Logic Survey Queue Survey Notifications Auto Invitation options Survey Login

e-Consent and PDF Snapshots

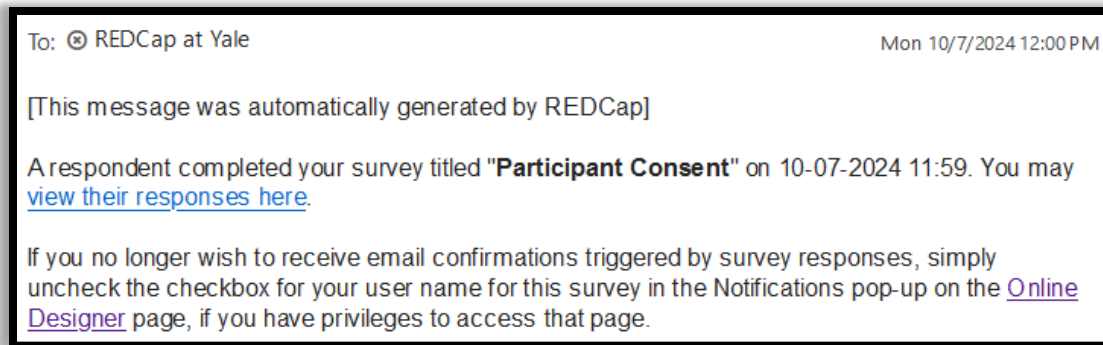
Instrument name	Fields	View PDF	Enabled as survey	Instrument actions	Survey related options
Participant Contact Info	2		Enable	Choose action	
Participant Consent	9			Choose action	Survey settings Automated Invitations
Person Obtaining Consent	9			Choose action	Survey settings + Automated Invitations

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

Participant Consent	Recipient email address	Notifications Enabled
(Baylah Tessier-Sherman)	redcap@yale.edu (Secondary)	
(Mary Geda)	-- not selected --	
(Sui Tsang)	-- not selected --	

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







Verify Consent

To certify the eConsent process, REDCap's eConsent Framework captures the IP address of study participants when they submit the eConsent. The IP addresses is a personal identifier. The IP address can be found in **File Repository -> PDF Snapshot Archive**.

IMPORTANT: Researchers will need IRB approval to collect IP addresses as part of the eConsent process. This should be included in the study protocol and data protection plan.

Verifying Signatures

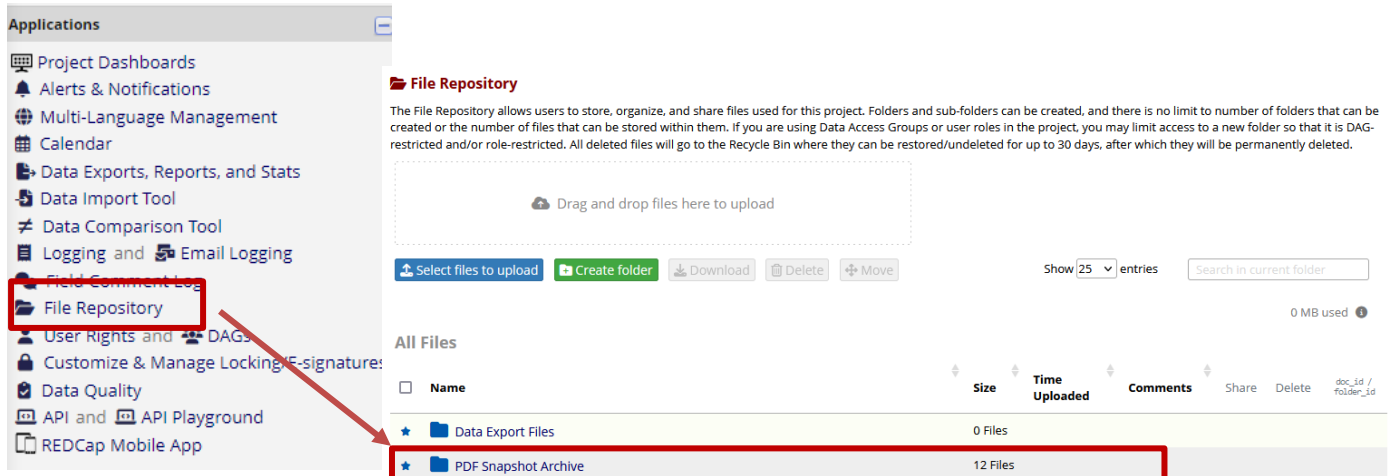
To verify eSignatures have been obtained, open the **Record Status Dashboard**. A green checkbox indicates the signature was obtained and the eConsent certified. Any other indicator status requires additional follow-up. Revisit the [Administer eConsent](#) section to re-administer the consent.

Record ID	Consent	
<u>1</u>		→ Signature certified and eConsent obtained
<u>2</u>		→ Not obtained
<u>3</u>		→ Not obtained
<u>4</u>		→ Not obtained

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Accessing eConsents: The PDF Snapshot Archive

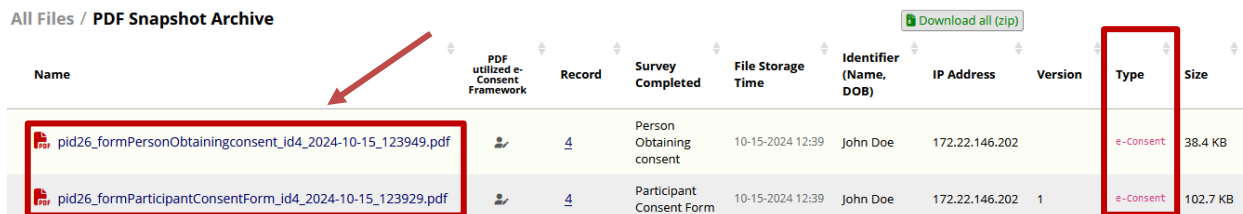
With the eConsent Framework enabled, a compact PDF copy of the signed eConsent and signed Person Obtaining Consent form will be automatically stored in your project's File Repository. The PDF snapshot can be viewed and downloaded by the study team. Downloaded files should be stored in a secure, protected location in compliance with your IRB protocol. You can access the archive in **File Repository -> PDF Snapshot Archive** as shown below.



The screenshot shows the REDCap File Repository interface. On the left, the 'Applications' sidebar has 'File Repository' highlighted. The main area shows a 'File Repository' section with a description and a table of folders. The 'PDF Snapshot Archive' folder is highlighted with a red box, showing it contains 12 files.

1. Upon completion of the consent process, open and review the consent in the PDF Snapshot Archive to verify consent was obtained and properly documented. Note that the column "Type" will confirm that the PDF is an eConsent.

All Files / PDF Snapshot Archive

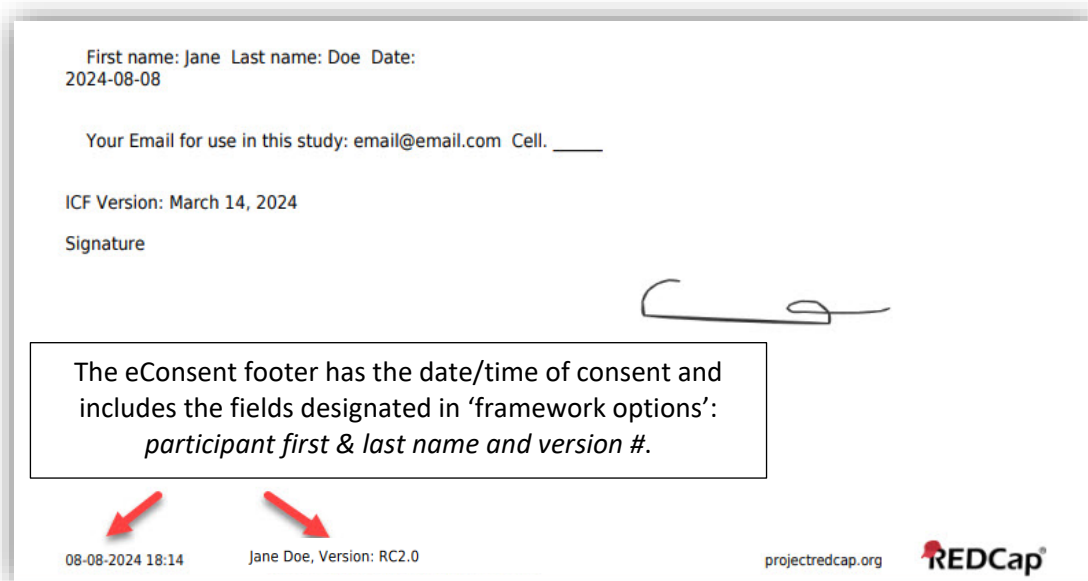


Name	PDF utilized e-Consent Framework	Record	Survey Completed	File Storage Time	Identifier (Name, DOB)	IP Address	Version	Type	Size
pid26_formPersonObtainingconsent_id4_2024-10-15_123949.pdf		4	Person Obtaining consent	10-15-2024 12:39	John Doe	172.22.146.202		e-consent	38.4 KB
pid26_formParticipantConsentForm_id4_2024-10-15_123929.pdf		4	Participant Consent Form	10-15-2024 12:39	John Doe	172.22.146.202	1	e-consent	102.7 KB

Pro Tip: Are you missing the option to download the eConsent? Make sure you have user rights to 'Download full data'.

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Example of valid, certified consent:



First name: Jane Last name: Doe Date:
2024-08-08

Your Email for use in this study: email@email.com Cell. ____

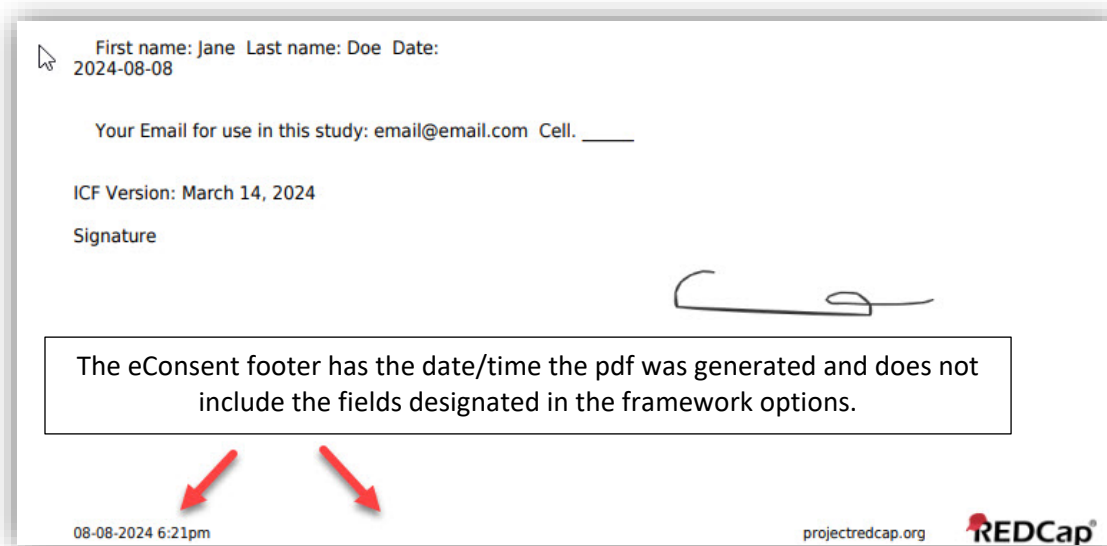
ICF Version: March 14, 2024

Signature

The eConsent footer has the date/time of consent and includes the fields designated in 'framework options':
participant first & last name and version #.

08-08-2024 18:14 Jane Doe, Version: RC2.0 projectredcap.org REDCap®

Example of invalid, uncertified eConsent:



First name: Jane Last name: Doe Date:
2024-08-08

Your Email for use in this study: email@email.com Cell. ____

ICF Version: March 14, 2024

Signature

The eConsent footer has the date/time the pdf was generated and does not include the fields designated in the framework options.

08-08-2024 6:21pm projectredcap.org REDCap®

Provide copies of the eConsent form

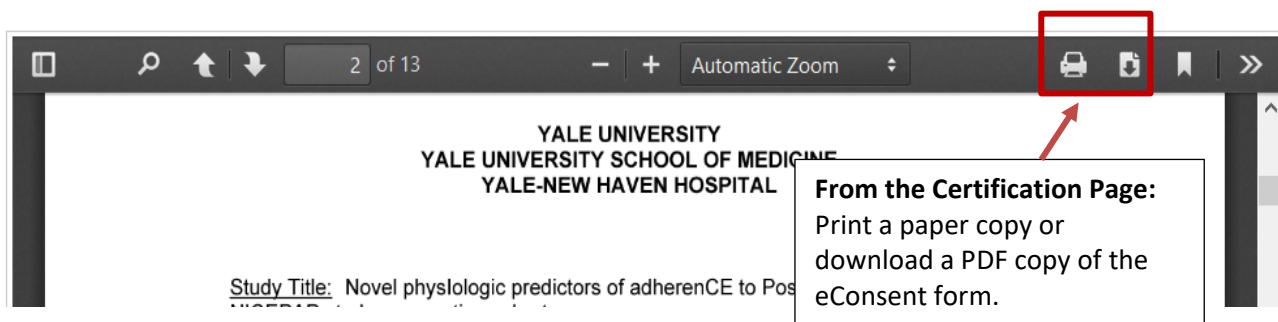
You can provide a copy of the eConsent to the participant as a paper or an electronic document. Regardless, you will need to describe your consent process in the study protocol.

If you are downloading and storing the eConsent form to share it with your participant, describe the storage location in the data security and protection section of your study protocol.

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To Share a Paper Copy

Print the signed eConsent form on the signature **certification page** to provide a copy to the participant.



To Share an Electronic Copy


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

1. If the participant signs the eConsent form on their personal device, you can instruct the participant to download it from the signature **certification page** and save it to their personal device.
2. To email the signed eConsent, download the PDF files from the **PDF Snapshot Archive** and send it as attachment to your email.

From the PDF Snapshot Archive: You can download the eConsent form to share with the participant. When downloading, save the file to a secure location.

All Files / PDF Snapshot Archive

Download all (zip)

Name	Record	Survey Completed	File Storage Time	Identifier (Name, DOB)	IP Address	Version	Type	Size
 pid26_formParticipantConsentForm_id2_2024-10-07_121428.pdf	2	Participant Consent Form	10-07-2024 12:14	John Doe	172.25.184.9	2	e-Consent	114.3 KB

- IMPORTANT:** Because signed consent documents can contain Protected Health Information (PHI) or Private Identifiable Information (PII), the email must be encrypted.
- To send encrypted emails from the Yale or YNH email domain, include [encrypt] at the beginning of the email subject line. Refer to ITS's website for instructions on encrypted email: <https://cybersecurity.yale.edu/emailencryption>