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.

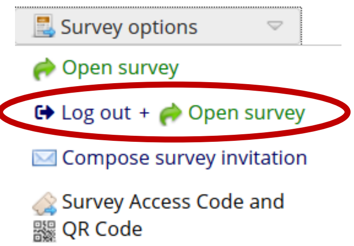
Administering eConsent: In-Person/Onsite

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.

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.

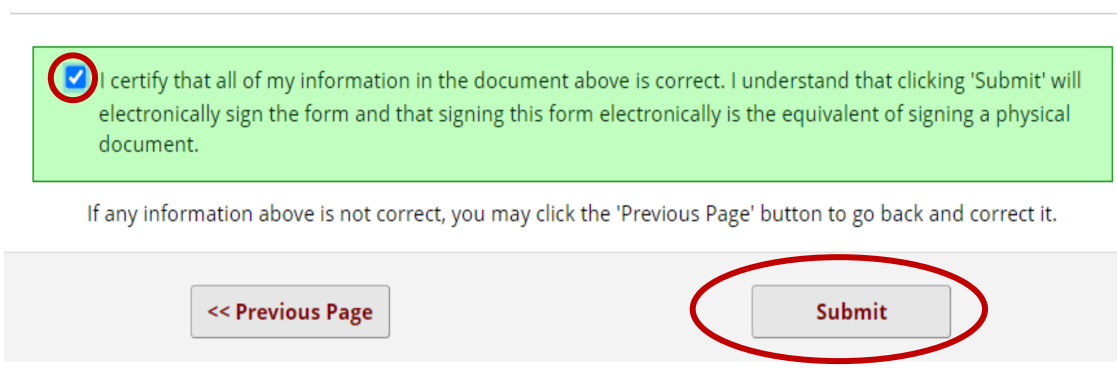
   c. Provide the mobile device to the participant with eConsent opened as a survey.

   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.



      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.

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.

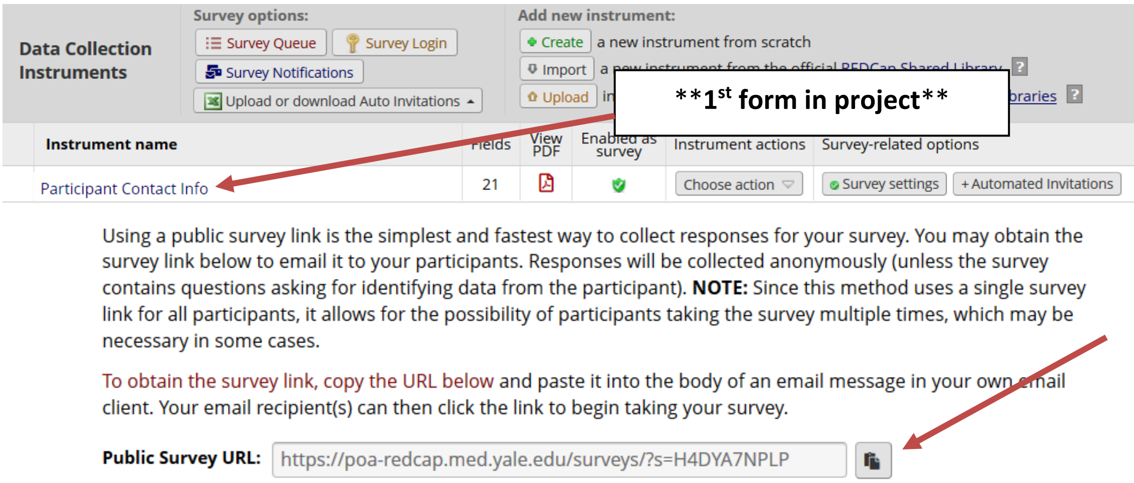
Public Hyperlink

If you opt to use a public hyperlink, you will use one hyperlink for <u>all</u> 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 <u>not</u> 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).

To use a public link:

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



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

i. 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.

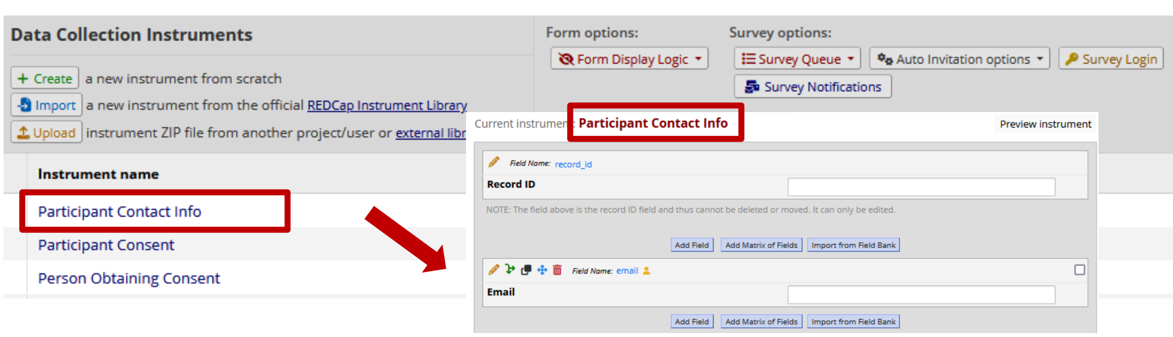
Private Hyperlink (record-specific link)

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:

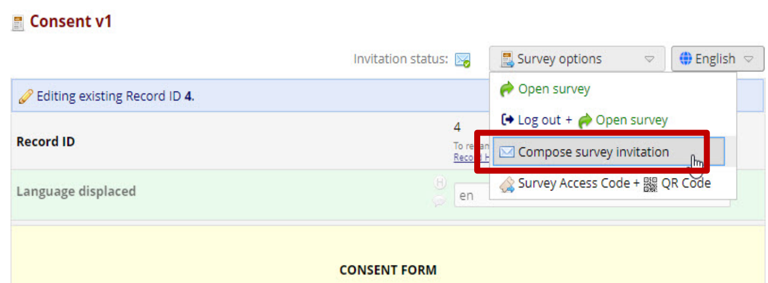
1. Designate an email field for sending survey invitations:

   - 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.

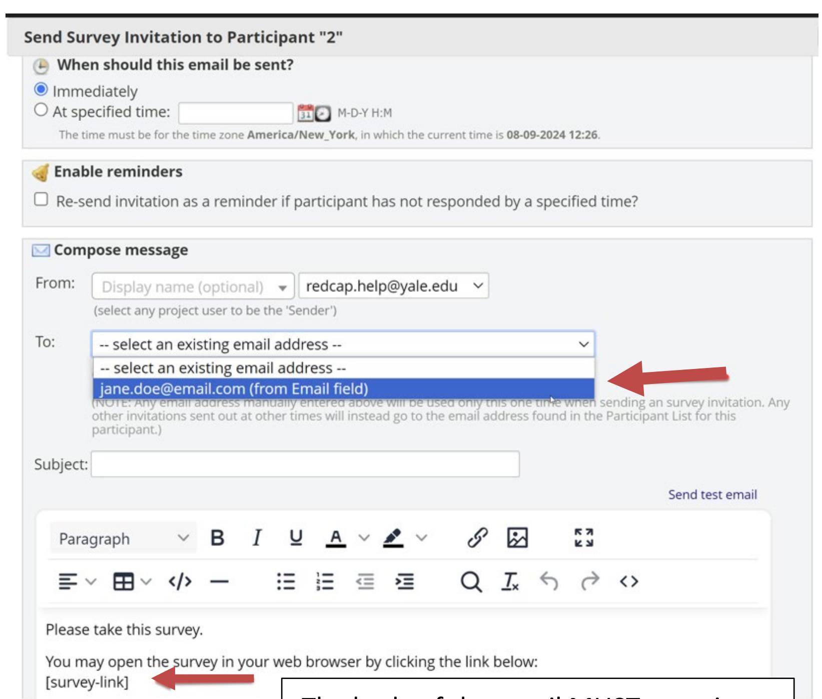


- Once the Participant Contact Info form is created with the participant email field, you can designate this email for sending survey invitations. To do that, go to the **Project Setup -> Enable optional modules and customizations -> Designate the email field for sending survey invitation**. Only text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

    i. **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**

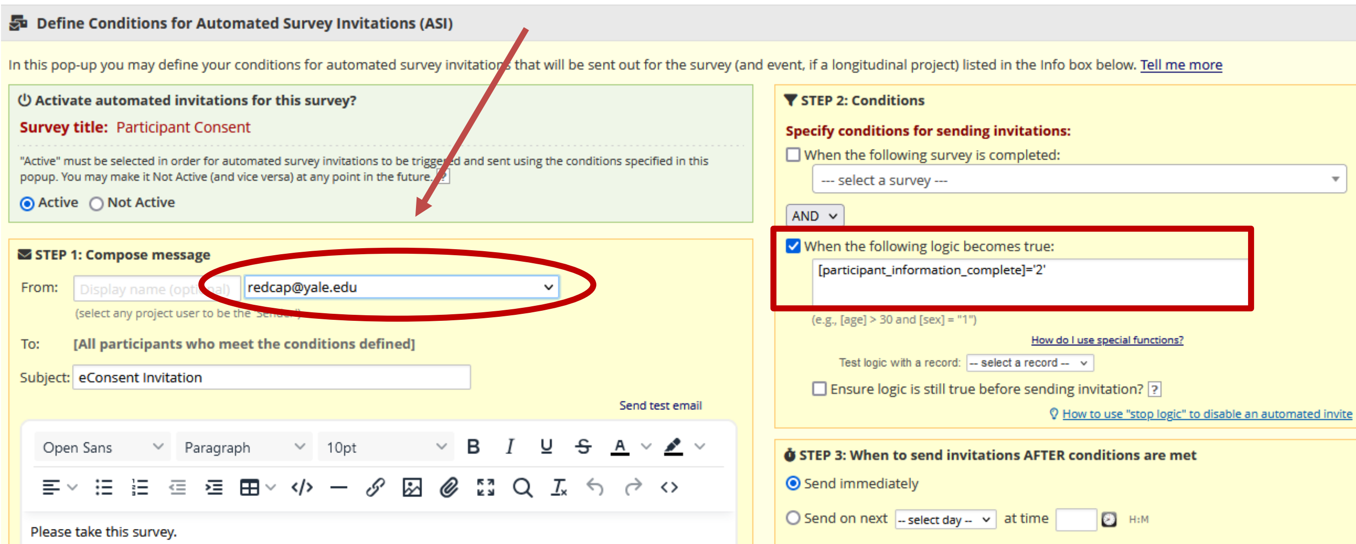


- If the email is designated and saved in the record, it will appear in the '*select existing email address*' dropdown option. Select the participant email.



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

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.



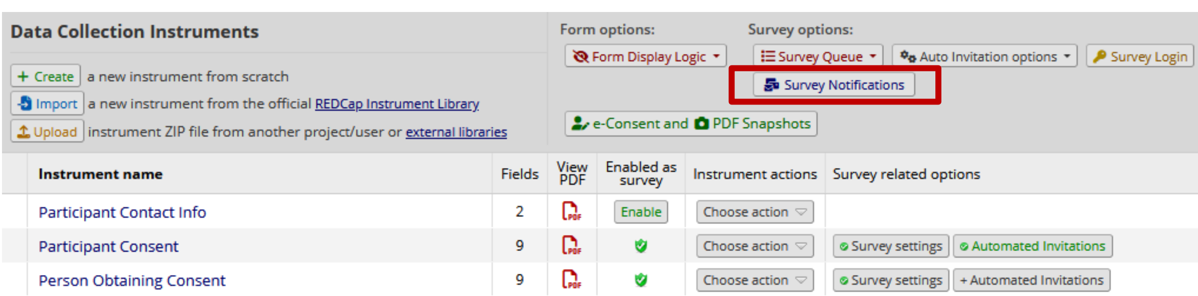
Refer to ***FAQ: Automatic Survey Invitation*** to learn more about ASI.

Survey Notifications

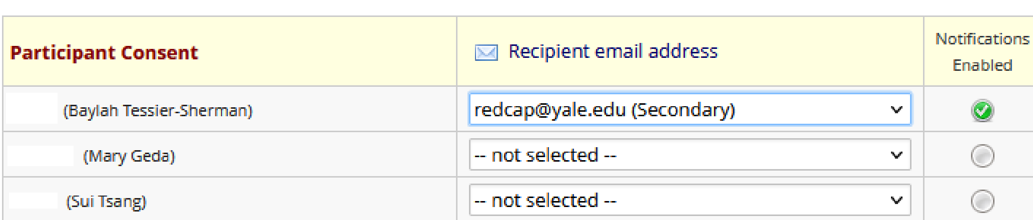
Survey notifications allow you to receive a notification when an eConsent survey is completed. (Note: for other ways to set up automatic notifications see Alerts and Notifications in REDCap Help page)

<u>To setup automatic notifications</u>:

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

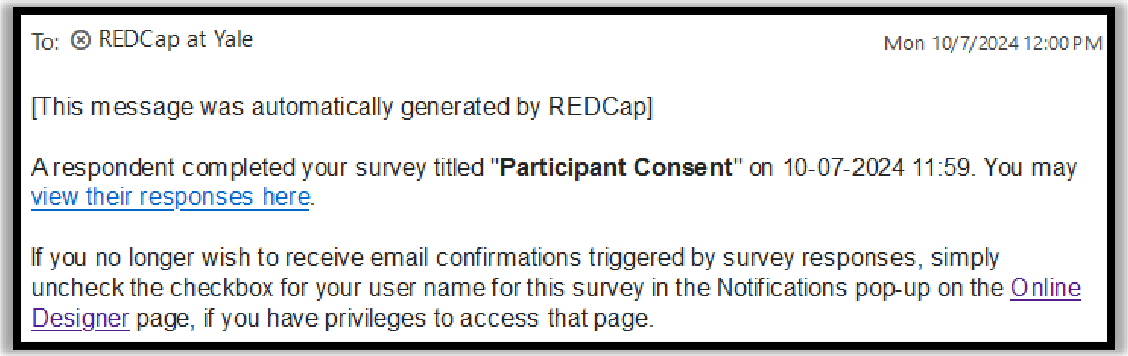


2. Under the eConsent form, select the person(s) who will receive the notification.



3. Click ‘**Close**’.

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



To: REDCap at Yale Mon 10/7/2024 12:00 PM

[This message was automatically generated by REDCap]

A respondent completed your survey titled "**Participant Consent**" on 10-07-2024 11:59. You may view their responses here.

If you no longer wish to receive email confirmations triggered by survey responses, simply uncheck the checkbox for your user name for this survey in the Notifications pop-up on the Online Designer page, if you have privileges to access that page.

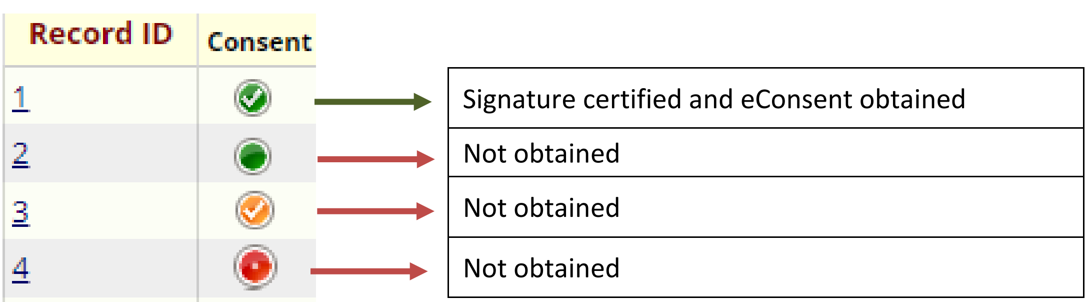
Verify Consent

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.

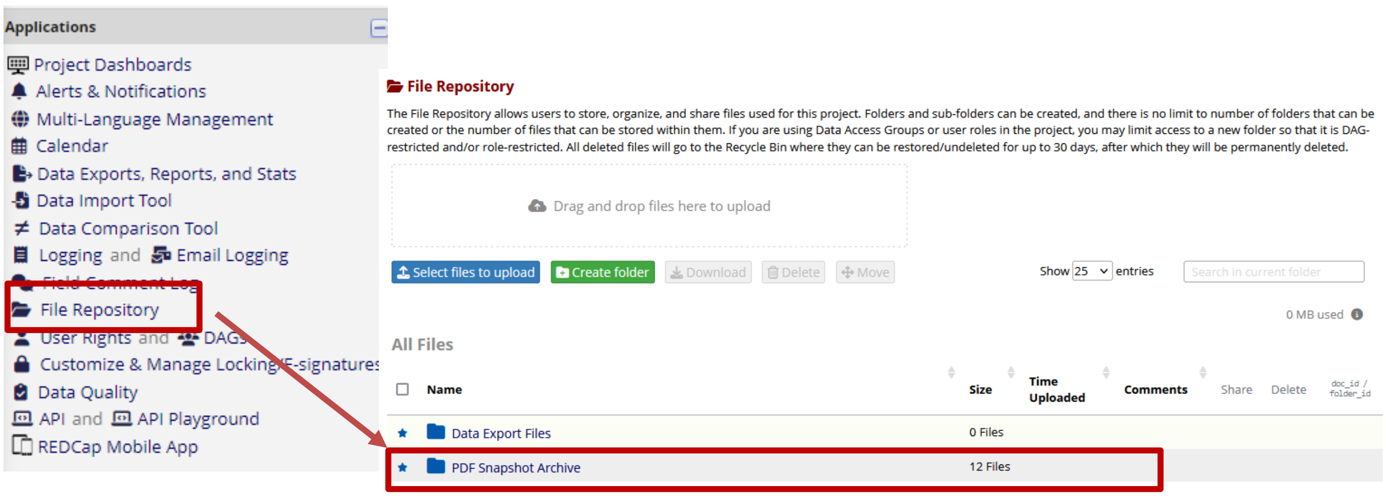
Verifying Signatures

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.

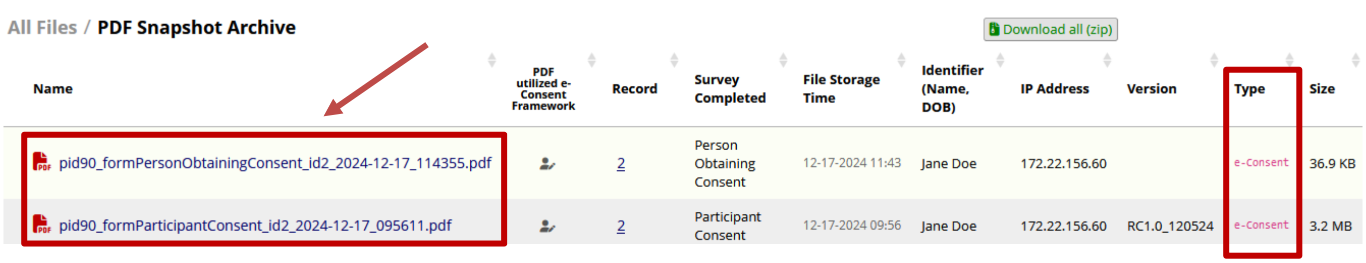


Accessing eConsents: The PDF Snapshot Archive

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.



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**

Download all (zip)

Name	PDF utilized e-Consent Framework	Record	Survey Completed	File Storage Time	Identifier (Name, DOB)	IP Address	Version	Type	Size
pid90_formPersonObtainingConsent_id2_2024-12-17_114355.pdf		2	Person Obtaining Consent	12-17-2024 11:43	Jane Doe	172.22.156.60		e-Consent	36.9 KB
pid90_formParticipantConsent_id2_2024-12-17_095611.pdf		2	Participant Consent	12-17-2024 09:56	Jane Doe	172.22.156.60	RC1.0_120524	e-Consent	3.2 MB

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

Example of valid, certified consent:

First Name	Jane
Last Name	Doe
Signature	
Participant Consent Survey Completion Date and Time	2024-12-17 11:55:14
REDCap Consent Version	RC1.0_120524

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

12-17-2024 11:55 Jane Doe, Version: RC1.0_120524 projectredcap.org REDCap

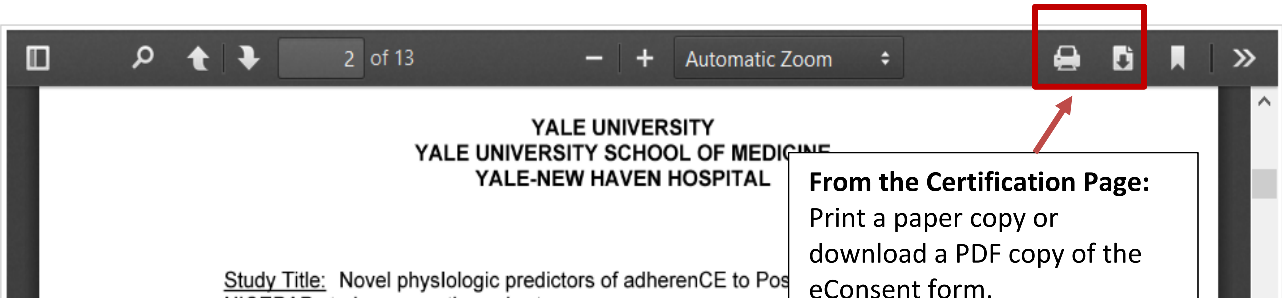
Provide copies of the eConsent form

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.

To Share a Paper Copy

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



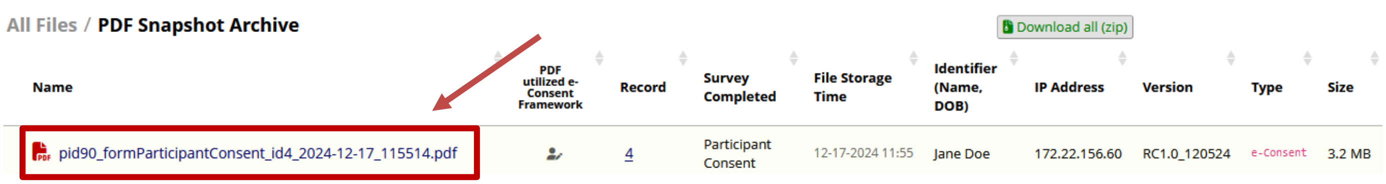
From the Certification Page: Print a paper copy or download a PDF copy of the eConsent form.

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.



a. **IMPORTANT**: Because signed consent documents can contain Protected Health Information (PHI) or Private Identifiable Information (PII), the email must be encrypted.

b. To send encrypted emails from the Yale or YNHH 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

Revision History

Version	Effective Date	Section	Page	Description/Rational
5.0	03/24/25	*Accessing eConsents: The PDF Snapshot Archive*	8-10	Updated screenshots.