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:
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.

**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:**

- a) Login to REDCap.
- b) Open the eConsent form.
- c) Use the ‘Log out + Open Survey’ survey option to open the form as survey.
- d) Give the device to the participant. Explain the details of the consent form while allowing the participant to review the consent form on screen.
- e) 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.’
- f) Click submit after the consent form is signed by both the participant and study staff.
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:**

![Instruction Banner Example]

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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:

![Remote Signature Setup Example]
In signature setup example above:

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

![Participant Consent Form](image)

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

![Research Staff Consent Form](image)

**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](#).

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.
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.

**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.

**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**.
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:**

1. The eConsent must be the first form in your project.
2. You can obtain the public link from the **Survey Distribution Tool -> Public Survey Link** page.
3. 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.
**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.

   ![Image of form](image1)

   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.**
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.

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### 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.

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

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**Tags: eConsent, Administer eConsent**
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.

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.
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/emailencryption](https://cybersecurity.yale.edu/emailencryption)