

REDCap eConsent

eConsent is available via REDCap. This functionality provides the ability to consent remote participants or participants in clinic via tablets or touchscreen device. Participants will have the capability to sign electronically with a stylus, mouse, or finger. Once the consent form is submitted, participants will receive an email that includes a PDF attachment with a copy of the signed consent form.

Can eConsent be used on all projects?

In order to use eConsent, the IRB must first approve the consent for the study. Provide the IRB with details in the protocol related to the consent process, such as:

- How will consent be collected?
- Will consent be self-guided or led by a coordinator?
- How will participants get questions answered before consent?
- Will a consent assessment be included?
- How will the participant get a copy of the signed consent?

The IRB will approve more than minimal risk studies on a case-by-case basis.

Also, include language in the consent document notifying the participants they will receive a signed copy of their consent via the email address they provide. Email is not a secure means of communication so this should be disclosed as a potential risk for loss of confidentiality, and participants should be aware when they provide consent.

eConsent needs to be set up on a per project basis. This can be setup by anyone with builder access to a specific REDCap project. If your study is subject to FDA oversight, you need to consider 21 CFR Part 11 requirements. See 'Can REDCap be used for studies requiring 21 CFR part 11 compliance?' section below for more information.

How is eConsent set up in REDCap?

Any REDCap builder can do the initial set-up. The University of Arizona REDCap team can build this project for you by contracting for a build. Refer to the 'Need help or want to contract for a build?' section, below.

1. Create an instrument including the consent language
 - This instrument must be enabled as a survey
2. Add descriptive fields with the consent language (see relevant video on how to set this up)
3. Add a field, a radio button with choices applicable to the project (i.e. I have read the consent document and I wish to participate in the study and I have read the consent document and I DO NOT wish to participate in the study, etc.)
 - ONLY if participant consents should the fields below be available (branching logic must be setup)
4. Add field to collect first name
5. Add field to collect last name
6. Add field to collect 'date of birth' (for some studies)
7. Add field to collect participant's email (be sure to validate this field as an e-mail field)

8. Add field to collect signature (signature can be drawn with mouse, stylus, or finger)
9. Add field to collect the date
 - Use Action Tags @DEFAULT to default date and @READONLY to make field un-editable
10. Add field which includes consent version date
 - Use Action Tags @DEFAULT to default date and @READONLY to make field un-editable
11. Add field which includes consent expiration date
 - Use Action Tags @DEFAULT to default date and @READONLY to make field un-editable
12. Add Descriptive text (with optional Image/Video/Audio/File Attachment) so participant can download a copy of the unsigned consent (optional)

How can I set up a confirmation email?

To send an automatic confirmation email with the signed PDF consent document attached, follow the steps below.

1. Click on 'Project Setup'
2. Under 'Main Project Settings', click on 'enable' to use surveys in the project.
3. Click on the Online Designer
4. Scroll down the page to the eConsent Framework section
5. Select Auto-Archiver + eConsent Framework
6. Under 'Force signature field(s) to be erased if participant clicks Previous Page button while on the certification page?', select the signature field for Signature field #1:
 - a. Select another signature field as needed if additional signatures are collected
7. Set "Send confirmation email" to 'Yes'
8. Customize the email message
 - a. Use an email address for your study team
 - b. Check 'Include PDF of completed survey as attachment'
9. Test to verify this is working correctly (i.e., copy of signed consent is automatically saved to the File Repository)

Note: Participants may be given the option to receive the consent form via a different method, but must receive a copy of their signed consent.

Is there an eConsent template available?

Yes, an eConsent template is available. This is a template only and must be updated to meet study needs and match IRB approved consent form. This template may be used through the creation of a new project and selecting the option to Use a template. Select the option button for eConsent from the Template titles, and then click on the Create Project button.

Is 'Person Obtaining Consent' required when using eConsent?

When consenting participants in a clinic, the 'Person Obtaining Consent' signature should be included on the instrument. For adapting to eConsent, this is not required and cannot be collected on the same instrument. Depending on the type of study, some teams have opted to sign on a different instrument once the participant has consented.

Can a copy of the signed consent form be sent to someone other than the participant and if so how?

Yes. To email a copy of the PDF to someone else you will use the “Save Survey to PDF External Module. Configuration of the module follows.

1. Create a ‘file upload’ field within your project, to save the pdf (The file will need to be saved in order to e-mail)
2. Enable the External Module Save Survey PDF to a Field
3. Once enabled, configure the external module:
 - a. On the left-hand side, under ‘Applications’, click ‘External Modules’
 - b. Click ‘Configure’ next to the ‘Save Survey PDF to a Field - v1.1.2’ module
 - c. Indicate the e-mail address that will receive generated PDF’s should the module be unable to save it
 - d. Indicate the name of the survey instrument that should generate the PDF(In this case, the consent form)
 - e. Indicate where the PDF of the survey should be saved (file upload field created in step #1)

Once the ‘Save Survey to PDF’ external module has been configured, ‘Alerts & Notifications’ can be set up to send the signed PDF to someone other than the participant.

The ‘Alerts & Notifications’ feature allows the ability to construct and send customized email notifications.

Create New Alert

1. **Triggering the Alert:**
 - a. On the left-hand side, under ‘Applications’, click ‘Alerts & Notifications’
 - b. Click ‘Add New Alert’
 - c. Title the alert
 - d. Identify how the alerts will be triggered.
 - i. When a record is saved on a specific form/survey
 - Indicate the specific instrument as well as the ‘form status’ that should be saved in order for the notification to be triggered
 - ii. When a record is saved on a specific form/survey with conditional logic:
 - Indicate the specific instrument, as well as the ‘form status’, that should be saved in order for the notification to be triggered AND specify the exact logic to be met in order for the notification to be triggered.**
 - iii. Using conditional logic during data import or data entry
 - Indicate the required logic for the notification to be triggered.
 - e. Indicate the specific instrument, as well as the ‘form status’, that should be saved in order for the notification to be triggered.

2. **Set the Alert Schedule:**

- a. Determine when the alert should be sent.
 - i. Send Immediately
 - Notification will be sent as soon as 'Step 1' logic has become true
 - ii. Send on next
 - Specify the exact day and time that the trigger should be sent (after the logic in 'Step 1' has become true).
 - iii. Send after lapse of time
 - Specify the exact number of days/hours/minutes that the trigger should be sent (after the logic in 'Step 1' has become true)
 - iv. Send at exact date/time
 - Specify the exact date/time that the trigger should be sent (after the logic in 'Step 1' has become true).
- b. Indicate the number of times the survey invitation should be sent
 - i. Just Once:
 - The invitation will only be sent once (note: will send on every instance for repeating instruments)
 - ii. Every time the form/survey in 'Step 1' is saved:
 - Every time 'saved' is clicked on the form indicated in 'Step 1'.
 - iii. Multiple times:
 - Send every set # of days after initially being sent

3. **Message Settings:**

- a. Indicate the e-mail addresses for the 'To:' and 'From:' fields. This can be done by selecting from the recipient list (or entered manually).
 - i. Add the subject of the e-mail in the Subject line.
 - ii. Include the appropriate verbiage into the body of the e-mail
 - iii. Add attachments:
 - Indicate the 'file upload' field variable that has the saved signed consent form
 - Attach a document by clicking 'browse' and selecting the appropriate document (optional)

How do I update the eConsent when there is change in my Consent language?

Once eConsent is set up for the project, a post-production change can be made to update the consent language. Changes to the consent language should be approved by the IRB before being made in REDCap. This is done via the normal post-production change method. Be aware some changes may require the REDCap team to review and approve. Please allow 1-2 business days for approval.

When the IRB has approved an amendment to the consent, and the REDCap project changes have not be approved, and a participant is consented on the old consent, this is a protocol deviation. Plan accordingly and have a contingency plan if REDCap changes have not be approved.

Do not change variable names in the consent form (especially the email address field) or the form name, as these changes could result in the eConsent no longer working correctly.

Can an eConsent be added to an existing REDCap project already in production?

Depending on the current workflow of the existing REDCap project, a post-production change may be made to add this functionality, but be aware of the timelines required to set this up in REDCap. In some cases, a better option is to create a stand-alone project for the eConsent process. For the best way to implement eConsent you may want to contact us at redcap@email.arizona.edu.

Can REDCap be used for studies requiring 21 CFR part 11 compliance?

REDCap is not, as an application, 21 CFR Part 11 compliant. Compliance must be met on a per project level. 21 CFR Part 11 also requires studies to validate the identity of the person providing an electronic signature, which may include a biometric method or two distinct identification components such as an identification code and password. Please consider if this will be possible for your project, and consult with your University of Arizona REDCap team if you have any questions before proceeding with the use of eConsent.