USING REDCAP TO E-CONSENT RESEARCH PARTICIPANTS

REDCAP E-CONSENT

What is Informed Consent?

The informed consent process is the critical communication link between the prospective human subject and researcher. It involves three key features: (1) disclosing to potential research subjects information needed to make an informed decision; (2) facilitating the understanding of what has been disclosed; and (3) promoting the voluntariness of the decision about whether or not to participate in the research.

The procedures used in seeking and obtaining informed consent should be designed to communicate with the subject population in terms that they can understand. Information about a research project must be presented in such a way that enables each person to voluntarily decide whether or not to participate as a research subject. Thus, the information must be conveyed in language understandable to those being asked to participate as subjects in the research.

The consent is a continuous process and its documentation may need to revised throughout the course of a study. Such revisions must be reviewed and approved by an IRB prior to the revised consent being utilized.

The Use of REDCap to Obtain Consent

- REDCap provides a computer-based platform for consenting research participants

- REDCap implements consent forms through an online survey in which the participants digitally sign their consent 'Signature' field type

- The informed consent process should be similar to when completed in person. We do NOT want to just send off the consent surveys and wait for the participants to return them. Should be in contact (telephone, zoom, etc) and collaboratively complete the consent.

This guide will provide more information on eConsenting and detailed review of how you can implement it for your project

CLARIFYING KEY TERMS

- Project

  - Instrument

    - Survey

      - Accessed through a web link

      - No REDCap account required

    - Form

      - Access from within REDCap

      - Data is entered by REDCap personnel

TERMINOLOGY

How do participants use eConsent?

The potential participant will first read through the consent on a tablet, computer or mobile device. If they choose to participate in the study, they will sign their name using the "signature" field and complete any other required information.

They will then select "Next Page" and view a read-only copy of the consent. This extra certification step allows the participant to confirm that all their information in the document is correct and review the consent prior to submitting. To submit, they will check the statement which reads "I certify that all my information in the document above is correct, and I understand that signing this form electronically is the equivalent of signing a physical document." Once this is selected, they will submit the eConsent.

The eConsent will not be considered complete until the certification step is complete.

Review eConsent — 1

Sign eConsent — 2

Review Signed PDF & Confirm — 3
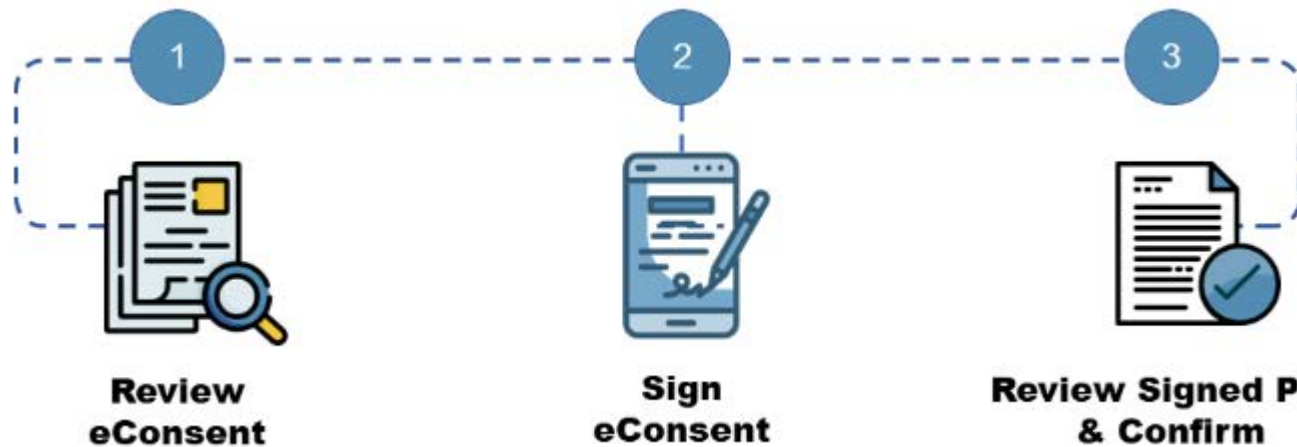
How does the eConsent framework work?

The REDCap eConsent Framework provides standardized tools to obtain consent and store consent documentation with a certification screen and a storage function which automatically generates a 'hard-copy' PDF of the signed form.

Enabling this option alone does not provide an e-Consent process .

Click here for the eConsent Framework Video Tutorial

THE E-CONSENT FRAMEWORK

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 also enter the current e-Consent version and e-Consent type for this form. The values for the fields below will be automatically inserted into the footer of the PDF consent form that the participant will review at the end 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: [Version 1 appro]   e.g., 4
First name field: [first_name "Please type your fi ⌄]
Last name field: [last_name "Please type your la ⌄]
Note: If you are using a single field to capture whole name, you may select it for either first/last name above while leaving the other name field unselected.

Optional fields (these are not always necessary for e-Consent):
e-Consent type: [Adult]   e.g., Pediatric
Date of birth field: [-- select a field -- ⌄]

Force signature field(s) to be erased if participant clicks Previous Page button while on the certification page?
Select a field below that serves as a signature field in this survey. It could be a free-form text field, a signature field, or a number field (e.g., to collect a PIN), and it must be a Required field. If any fields are selected below, then if the participant gets to the last page of the survey where it asks them to certify their responses, if they then choose to click the Previous Page button, it will erase the value of these signature fields, thus forcing them to 'sign' the field(s) again before completing the survey. If you do not want this behavior, do not select any fields below. You may use up to five signature fields.

Signature field #1: [-- select a field -- ⌄]

[+ Select another signature field]

The 'Auto-Archiver + e-Consent Framework' survey option adds two things to the typical survey-taking process:

- **End of Survey Certification**

- **PDF Auto-Archiver**
  - PDF files of responses are automatically captured and stored in REDCap upon completion of the consent survey – serves as the traditional "hard-copy" consent form previously stored inside file cabinets

END OF SURVEY CERTIFICATION

Before a participant completes the survey, an extra certification page is added to end of the survey that displays an in-line PDF copy of their survey responses in which they will be asked to confirm that all information in the document is correct. Once they confirm all is correct, the survey will then be marked as complete. The survey will not be considered complete until they fulfill the certification step.

- Extra certification page added at the end

  - Displays an in-line PDF copy of the document

  - Participant asked to confirm everything is correct

  - The survey will not be considered complete until they confirm

PDF AUTO-ARCHIVER
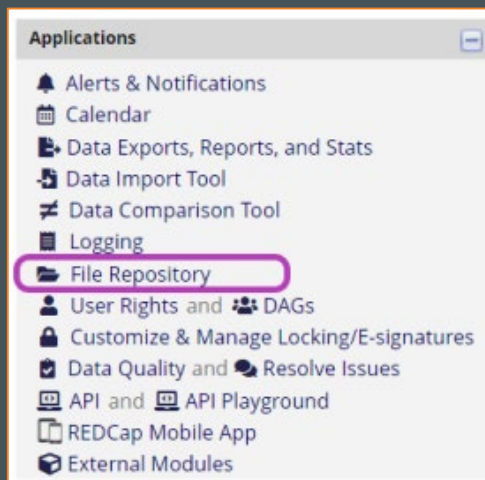
📁 **File Repository**

This page may be used for storing and retrieving files and documents used for this project. You may upload files here to save for retrieval later, or you may download previously uploaded files in the file list below. Whenever a data export is performed, the resulting data and syntax files are stored here also.

| 👥 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 were 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   Search

Survey Completion Time	Record	Survey	Identifier (Name, DOB)	IP Address	Version	Type	Download
05/10/2021 4:37pm	1	Informed Consent and Authorization Example	A A	10.90.8.19	Version 1 approved 01/01/2020	Adult	PDF
05/10/2021 4:34pm	2	Informed Consent and Authorization Example		10.90.8.19	Version 1 approved 01/01/2020	Adult	PDF

Applications

- 🔔 Alerts & Notifications
- 📅 Calendar
- 📊 Data Exports, Reports, and Stats
- 📥 Data Import Tool
- ≠ Data Comparison Tool
- 📋 Logging
- 📁 File Repository
- 👤 User Rights and 👥 DAGs
- 🔒 Customize & Manage Locking/E-signatures
- 📝 Data Quality and 💬 Resolve Issues
- 🖥 API and 🖥 API Playground
- 📱 REDCap Mobile App
- 📦 External Modules

Upon completion of the survey, a static copy of their responses in the form of a consent-specific PDF will be automatically stored in the project's File Repository, and serves as hard copies for all signed e-Consents by the participants.

The PDF is consent-specific. It will have the values of the e-Consent Framework Options inserted at the bottom of each page in the PDF as extra documentation of the identity of the person who is consenting.

What is required to set up an eConsent in REDCap?

- The usage of REDCap eConsent for the collection and storage of consent documents must be consistent with the confidentiality plans described to the IRB in your application, protocol, consent, etc.

- The consent language in the forms must also match your IRB-approved documents.

READY to GET STARTED

Create a new instrument – this will be used as your eConsent.

**If your consent has multiple parts, or if you are including your HIPAA as well, you will need to create additional instruments.

STEP 2

Copy your consent language into the new instrument.

You may copy /paste text from the PDF or word document version of the consent. Consider using the rich text editor to help with formatting. Break long pieces of text into multiple fields.

STEP 3

Add the signature under the consent statement and a date validated field.

Choose "signature" from the field type and ensure field is required.

STEP 4

Enable surveys on the "Project Setup" page

AND

Enable the consent instrument as a survey

STEP 5

Within survey settings, scroll down to "eConsent framework". Enable the "auto-archiver + eConsent Framework".

**You may include several items which will be included at the bottom of the exported PDF, including first/last name, eConsent type (e.g., pediatric). "Type" is typically used when a project contains multiple eConsent forms.

**You may also include the version number of the consent. This, along with consent tpe and participant name will appear at the bottom of the final PDF consent.

**The version of a consent form is determined by the number of revisions to the document. The first version of a consent might simply be "1" with any subsequent revisions of the consent (and thereby a new version) being "2" (and so on).

**The final section of the eConsent framework involves clearing signature fields should a participant return to the eConsent after viewing the confirmation page. After submitting an eConsent, the participant is asked to review a PDF copy of the consent and confirm that their information is correct. If the participant sees an error and returns to the document to correct or update information, they will need to re-sign. This ensures they sign the most up to date version of the document. This section is only required for studies needing Part 11 compliance, however, it may be useful for any study.

STEP 6

SAVE

TEST, TEST, TEST

Test the entire eConsent workflow to ensure everything is working as expected.

Once you are ready to begin using your eConsent, move your project into production.

Where are the completed PDFs stored?

Upon completing an eConsent survey, a read-only copy is stored both in the file repository and in a secure vault. The PDF consent will include the information from the eConsent Framework options at the bottom of each page in the PDF.

To view/download completed PDFs:
- On the left hand side menu, click "File Repository". This sits under the Applications header.
- Click the PDF Survey Archive tab
- You may then search for specific consents and download PDF copies.

Basic Rights

☒ Expiration Date *(if applicable)* _____ (M/D/Y)

Highest level privileges:

≡ Project Design and Setup ☑

👤 User Rights ☑

👥 Data Access Groups ☑

Privileges for data exports (including PDFs and API exports), reports, and stats:

▣ Data Exports
  * De-identified means that all free-form text fields will be removed, as well as any date/time fields and Identifier fields.
  ○ No Access
  ○ De-Identified*
  ○ Remove all tagged Identifier fields
  ◉ Full Data Set ⬅

🔍 Add/Edit/Organize Reports ☑
  Also allows user to view ALL reports (but not necessarily all data in the reports)

📊 Stats & Charts ☑

You may find this under "user rights"

**Note: only those with access to the 'full data set' under user rights will be able to download documents from the file repository.

ADDITIONAL CONSIDERATIONS

eConsents must be opened as a survey before the participant signs and submits. It may be helpful to place a reminder at the top of the instruments to prompt study staff. This reminder is not visible to participants if using the action tag "@HIDDEN-SURVEY"
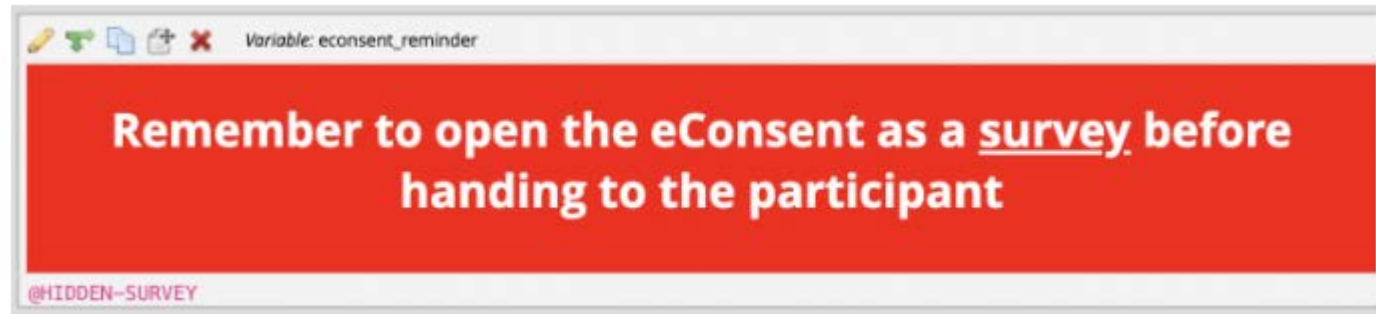
For a warning like the image above, copy the code below into the "descriptive text" REDCap Field:

<div style="background-color:red; padding:20px;"><h1 style="text-align:center; font-size:200%; line-height: 35px; color:white;">Remember to open the eConsent as a <u>survey</u> before handing to the participant</h1></div>

CONTACTLESS CONSENTING

What is contactless consneting?

Many research studies require fully contactless consent, where the individual obtaining consent and the potential participant are never in the same physical location. It is possible to use REDCap-based eConsent fully remotely by sending a link to access the web-based eConsent to the potential participant.

There are two options to send the eConsent document to a prospective participant's electronic device:

– You may create a public survey link which can be broadly distributed OR
– Use individualized survey links to send the consent to specific individuals

Including Multiple Signatures on an eConsent Document

Consenting processes may involve collecting multiple signatures, for example, that of the potential participant and of the individual who obtained consent or witness.

For in-person consenting, the study staff or witness may sign the same consent document as the participant (either electronically via eConsent or on the physical consent paper document). However, multiple signatures must be handled differently in the case of fully remote consenting.

Including Multiple Signatures on an eConsent Document

To do this electronically and remotely:

1. Add additional instrument(s) for consent attestation after setting up your eConsent document in REDCap and enabling the eConsent framework.

2. Add attestation language and a signature field. For example: "Statement by Individual Obtaining Consent: I have explained the research study to the participant. I have answered all questions about this research study to the best of my ability."

3. Enable the attestation as a survey and enable the eConsent framework.

4. Enable the attestation as a survey and enable the eConsent framework.

5. Enable survey notifications to alert the study coordinator when a consent document is completed.

Click her for the video tutorial
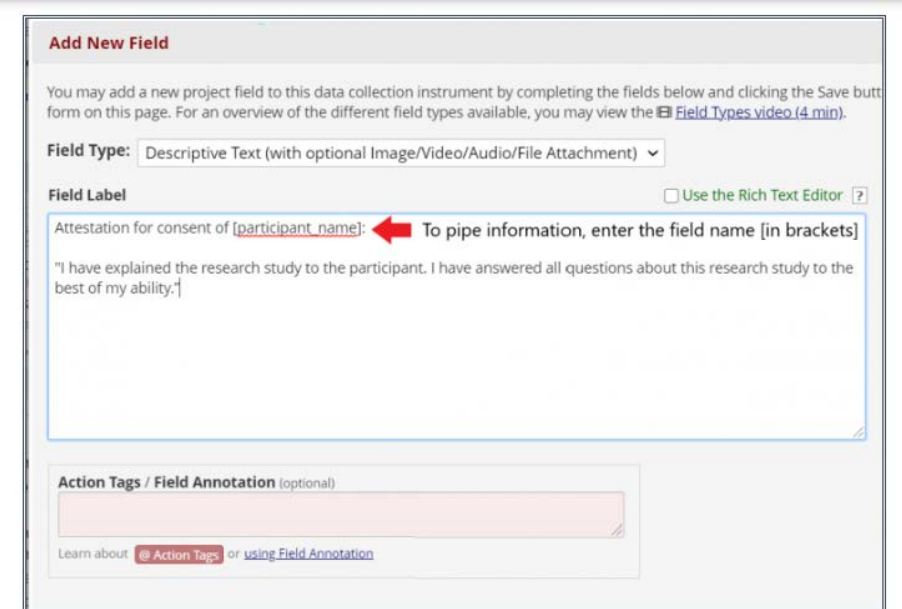
For studies involving both in-person and remote consenting

These studies may consider using an 'eConsent intro form', which can serve as an intake mechanism to capture key details about the consent encounter.

1. Create an instrument which will serve as the eConsent intro form. Include key fields such as participant name/ID and how the consent will be completed (e.g., in-person or remote).

2. If the eConsent instrument includes multiple signatures (for example, participant and individual obtaining consent), utilize branching logic to only show additional signatures when consenting is occurring in-person.

3. Follow the instructions above to add a consent attestation. This form will be completed for remote consents.

For studies involving both in-person and remote consenting

It is possible to "pipe", or carry-over, information into the attestation form, such as the date and time of consent and the participant's name or participant ID number. To do this, include the field name you wish to include in brackets. Then, the form will automatically pull this information from the previous instrument.

Need Multiple Signatures

For consent workflows with multiple forms which will need to be completed remotely, follow the same steps listed above for the attestation. These forms will be linked within the same REDCap record and can be sent via email to the responsible party.

For example, if a study doctor must review the signed consent and attest, create a separate study doctor attestation instrument. A link to this instrument may be sent to the study doctor after the consent is completed by the participant.

* for more detailed information, see section on Multi Signature Module

Need Multiple Signatures

Both consent and attestation are linked within a single REDCap record, which represents an individual participant. Both the participant eConsent and the Coordinator Attestation can be viewed and printed from the File Repository in the eConsent Framework.

Additional Information

The attestation instrument should be enabled as a survey, with the eConsent framework and signature clearing functionality enabled.

Before completing this instrument, the coordinator should open the form as a survey, as such a warning notification should be added:

For a warning like the image above, copy the code below into the "descriptive text" REDCap Field:

```
<div style="background-color:red; padding:20px;"><h1 style="text-align:center; font-size:200%; line-height: 35px; color:white;"><b>Remember to open the eConsent as a <u>survey</u> before handing to the participant</b></h1></div>
```

MORE INFO ON RESEARCHER SIGNATURE & RECORD LOCKING

THE RESEARCH SIGNATURE INSTRUMENT MUST FOLLOW ANY E-CONSENT SURVEY IN WHICH IT IS REQUIRED

This allows the researcher to digitally sign the e-Consent document after completion by the participant signature

Researcher Signature

Online Designer View

Edit Record View

eSignatures

E-SIGNATURES

- To sign the consent as a researcher, the form must be marked as completed, and the locked and e-signature boxes checked. This will be indicated with icons (a lock and a green shield) in the participant record

- **E-signatures are an extension of the record locking/unlocking functionality.** Once a data collection instrument has been locked for a given record in the project, a person with e-signature privileges may then apply an e-signature to that form, if they wish.

- The form will display the time it was locked and the user who locked it, and all fields on the form will be disabled/read-only until someone with Lock/Unlock privileges unlocks the form.

- Although locking a record prevents its data from being modified, the e-signature goes a step farther, and serves as the equivalent of a handwritten signature. If a record has been e-signed, then it denotes that its data has been both **locked** (to prevent further changes) **and authorized** (i.e. by a user with e-signature privileges).
- Similar to the record locking functionality, the e-signature history is also stored in REDCap's data audit trail on the Logging page

Customize and Manage Locking / eSignatures

- Click 'Customize and Manage Locking/e-Signatures to display the lock options for each instrument.

- Here, you can also choose to display eSignature option on the instrument or not

- Space is included if you want to provide custom text instead of the default record locking text

RECORD LOCKING

- Record locking is a feature which freezes data, ensuring that users don't accidentally modify it without authorization.
- Data cannot be EASILY modified on a locked instrument
- The project creator and PI are responsible for ensuring that staff who have been trained and are IRB approved to perform consent have user rights enabled for "Locking/ Unlocking with E-signature authority.
- Ensure that 'Record Locking and Customization' is enabled for the appropriate staff
- There is a helpful video within REDCap which explains more about record lockin

eConsent Versioning

E-CONSENT VERSION & TYPE

- **Versioning**
  - Alpha-numeric designation to represent most current consent version
  - Apply a new version whenever consent is modified
  - Download & save data dictionary BEFORE making changes for referencing archived version if needed

- **Type**
  - Optional. Adds label in PDF footer
  - Helps distinguish between multiple consents within same project

eConsent Versioning

Although REDCap keeps track of all edits made to an eConsent document, it is critical to ensure that you maintain all versions of your eConsent in your project.

Even though REDCap stores PDF versions of all signed consents, you need to still maintain versions in digital forms for when you make changes to an instrument in REDCap, records automatically update to reflect the changes made to the instruments. Although the PDF copy will accurately reflect the version of the eConsent signed at the time, the non-PDF record (i.e., the case report form) will be updated to make it appear that the individual signed the new version of the eConsent. This could make it appear that the individual consented to any new elements when, in fact, they did not.

eConsent Versioning

Option 1: Branching Logic

In general, this option is recommended as having many different consent instruments may increase the risk of user error.

1. After setting up your eConsent, add a "version" drop down field at the top of your instrument. Indicate the current eConsent version

2. To automatically set a version and hide this field from participants, add the following to the "action tag" section of this field: @HIDDEN-SURVEY @DEFAULT = "1"

**Note: as you update the eConsent version, be sure to change the default value to reflect the most up to date version of the eConsent.

eConsent Versioning

eConsent Versioning

Option 1 Branching Logic continued:

3. For new versions, add the new relevant fields to the eConsent instrument or, if changes are needed to existing sections, copy the field and make changes.

4. Add branching logic to new or changed sections so that these sections appear when the correct version of the eConsent is selected.

5. If you have not already done so, add branching logic to out of date sections, so they appear when the previous version of the consent is selected and do not appear for new versions.

6. Update the "version" within the eConsent framework (under survey settings).

eConsent Versioning

eConsent Versioning

Option 2:

Instrument for New Versions

1. Name the eConsent instrument with the version number or date. Adding the version number or date is important to distinguish this consent instrument from others in the future.

2. For each new iteration of the eConsent (i.e., Version 2, Version 3), create a new instrument. You can accomplish this by copying the previous instrument and renaming with the new version number/date. Be sure to enable the eConsent framework on new instruments.

MULTI-SIGNATURE EXTERNAL MODULE

MULTI-SIGNATURE EXTERNAL MODULE

Applications

- 🖥️ Project Dashboards
- 🔔 Alerts & Notifications
- 📅 Calendar
- 📤 Data Exports, Reports, and Stats
- 🔁 Data Import Tool
- ≠ Data Comparison Tool
- 📋 Logging
- 📁 File Repository
- 👤 User Rights and 👥 DAGs
- 🔒 Customize & Manage Locking/E-signatures
- 📋 Data Quality and 💬 Resolve Issues
- 🖥️ API and 🖥️ API Playground
- 📱 REDCap Mobile App
- 📦 External Modules
- 🔗 Lifespan REDCap Portal
- 🔗 Lifespan REDCap Problem Form

You may to request the REDCap Admin to enable this external module in your project.

➕ Enable a module

Currently Enabled Modules

None

Multi Signature Consent - v1.1.2
A template for a REDCap External Module

📄 View Documentation

➕ Enable a module

Currently Enabled Modules

Multi Signature Consent - v1.1.2
A template for a REDCap External Module

📄 View Documentation

Configure

Disable

Search enabled modules

Multi Signature Consent
A REDCap External Module that allows you to define one or more instruments. When they are complete, a combined PDF with signatures (and other fields) from those instruments is generated, saved to a field in the project, and also to the file repository for the project (like a normal e-consent PDF).

You can couple this with an Alert and Notification to then send a copy of the combined PDF to a participant.

MULTI-SIGNATURE EXTERNAL MODULE

MULTI-SIGNATURE EXTERNAL MODULE

- ## SETUP ALERTS & NOTIFICATIONS

  - Notify researcher when consent has been completed

  - Send signed consent with researcher signature

MULTI-SIGNATURE EXTERNAL MODULE

SETUP ALERTS: Notify researcher when consent has been completed

MULTI-SIGNATURE EXTERNAL MODULE

- ## SETUP ALERTS: Send signed consent with researcher signature

MORE INFORMATION

- Thoroughly test the e-Consent process prior to official use, from the perspective of both researcher and participant. Try many different scenarios to ensure everything functions properly.

- Practice and plan how you will guide the participant through the e-Consent and anticipate any issues the participant may encounter:
    - What if they're hard of hearing?
    - What if their Internet is down?
    - What if they're late and make you wait?

- People may make mistakes on their consent, like entering the wrong date. Since records are locked, the participant must re-consent

- Whenever in doubt, consult with your IRB

Sharing with the IRB

- IRBs will have varying requirements for submitting your eConsent. Please consult with them on what specifically needed. In general, we recommend:
  - o Reach out to the IRB early in the process to see what is required to submit/approve an eConsent
  - o Submitting both a PDF copy of your eConsent and the public survey link, to allow the IRB to view the consent as a participant.
  - o For any external modules, include any additional text in a separate document. Submit any embedded videos along with a transcript.
  - As a reminder, the usage of REDCap eConsent for the collection and storage of consent documents must be consistent with the confidentiality plans described to the IRB in your application, protocol, consent, etc.