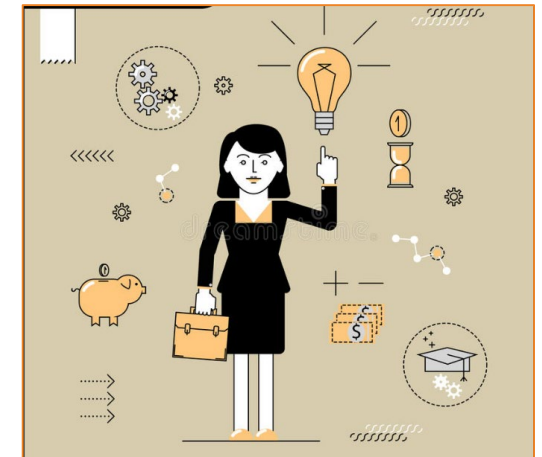USING REDCAP TO E-CONSENT RESEARCH PARTICIPANTS

REDCAP E-CONSENT

LEARNING OBJECTIVES

- Understand the e-Consent framework

- Familiarization with the REDCap e-Consent template

- Design/Customize e-Consent forms to suit your project

- Learn best practices and common pitfalls

- Q & A

WHAT IS INFORMED CONSENT?

Voluntary expression of consent by a competent subject after sufficient information disclosure about the research

- Must be written in language easily understood by the subjects

- Must minimize the possibility of coercion or undue influence

- Subject must be given sufficient time to consider participation

- Must be documented by means of a **written, signed and dated informed consent form**

REDCAP E-CONSENT

- Computer-based platform for consenting research participants

- REDCap implements consent forms through an online survey

- Participants digitally sign their consent with REDCap's '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.

TERMINOLOGY

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

WHY IS THIS CALLED A FRAMEWORK?

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

- Merely provides the general framework or mechanism to allow e-Consent

- Provides standardized tools to allow implementation of e-Consent process

THE E-CONSENT FRAMEWORK

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
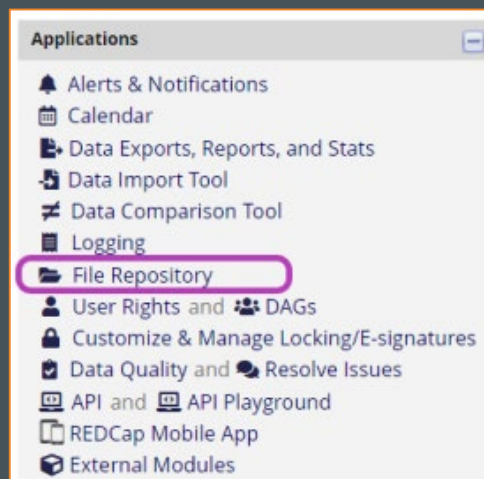
📁 **File Repository**

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.

E-CONSENT TEMPLATE

*This is a Lifespan specific process for e-Consent developed in close collaboration with the IRB, although the content should be generalizable to all REDCap instances

MODULAR COMPONENTS FOR ACCOMPLISHING AN E-CONSENT

GETTING STARTED

- Click on 'New Project'

- Choose 'Use a template'

- Select the 'e-Consent template'

- The new project is already set up with surveys enabled

CONTENTS OF THE E-CONSENT TEMPLATE

- **Informed Consent and Authorization Example** (survey)
  Standard layout and sections needed for informed consent. "Workhorse" of e-Consent template

- **Researcher Signature** (form)
  Meant for researcher use only
  Allows the researcher to digitally sign the e-Consent (following the participants completion of consent).
  A final PDF of the signed participant e-Consent and researcher signed form can be downloaded to be emailed to the participant.

CONTENTS OF THE E-CONSENT TEMPLATE (CONT)

- **HIPAA Research Authorization Example** (survey)
  Standard research authorization layout
  Study-specific. Used only when your protocol has been approved to allow for a *research authorization* instead of *informed consent.*

- **Child Assent Example** (survey)

- **Consent Sent to Participant** (form)
  Internal data entry form for researchers to use for tracking and documenting:
  - When the completed e-Consent (with participant and researcher signature) has been downloaded and emailed to the participant

REMOVE INSTRUMENTS

- After fully exploring them, you may delete instruments from the e-Consent template if not being used for your project

INSTRUCTIONAL FIELDS

- Template contains Instructional & Study Specific Fields.

- Contains guidance, tips, instructions to help the researcher.

- Meant for researcher use only. Delete the instructional fields prior to going live

INFORMED CONSENT AND AUTHORIZATION

- Survey with standard informed consent layout

- Already divided into sections needed for informed consent

INFORMED CONSENT
AND
AUTHORIZATION

Set up Stop Actions for this Survey Question ✖

🛑 **Stop Actions (for survey questions only):**
The survey participant will be prompted to end the survey when ANY choices checked below are selected for this question on the survey. Stop Actions will not be enabled on the form when viewing in REDCap as an authenticated user, but only become enabled when a participant views this data collection instrument as a survey.

> **I've read the Nature and Purpose of the Study and Explanation of Procedures sections and would like to continue with the consent process.**
> Select All | Deselect All
> ☐ Yes
> ☑ No

Save   Close

End the survey? ✖

You have selected an option that triggers this survey to end right now. To save your responses and end the survey, click the button below to do so. If you have selected the wrong option by accident and do not wish to leave the survey, you may click the other button below to continue, which will also remove the value of the option you just selected to allow you to enter it again and continue the survey.

End the survey now   Continue survey and undo last response

- Throughout the survey, there are 'Stop Fields', added at the specific direction of our IRB, which end the survey if a participant indicates that they don't want to continue when prompted

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

INFORMED CONSENT AND AUTHORIZATION

- Remember to Update Survey Settings:

  - Version & Date of Consent

  - Do NOT choose to have an email automatically sent to participant

  - e-Consent Type (Optional)

RESEARCHER SIGNATURE

- THIS INSTRUMENT MUST FOLLOW ANY E-CONSENT SURVEY REQUIRING A RESEARCHER SIGNATURE

- Allows the researcher to digitally sign the e-Consent document after completion by the participant.

- Researcher must enter REDCap username & password to complete the digital signature

E-signature: Username/password verification

Before forms can be locked using an e-signature, you must enter your REDCap username and password so that they may be validated. After three consecutive unsuccessful attempts, you will automatically be logged out of REDCap, thus ending this session.

Username: jrichardson7
Password: ••••••••

Save

RESEARCHER SIGNATURE

Online Designer View

Edit Record View

RESEARCHER SIGNATURE

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 locking

RESEARCHER SIGNATURE

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

RESEARCHER SIGNATURE

CUSTOMIZE AND MANAGE LOCKING/ E-SIGNATURES

- Click 'Customize and Manage Locking/e-Signatures to display the lock options for each instrument.
- Here, you can also choose to display e-signature option on the instrument or not
- Space is included if you want to provide custom text instead of the default record locking text

CONSENT SENT TO PARTICIPANT

- Allows you to document when informed consent has been completed and the necessary documents have been downloaded and emailed to the participant.
- It is an internal data entry form for researchers to use for tracking and documenting

Download a Completed e-Consent

Click on ID#

Click arrow

- After the signatures of participant and researcher, navigate to the record homepage for the participant

- Click 'Choose action for record' dropdown

- Select 'Download PDF of record data for all instruments'

- This document can then be emailed to the study participant

CROP THE PDF

- Drag and drop the downloaded file (from previous step) onto a new browser tab in google Chrome.
- Once the PDF is open in your browser go to the upper right-hand corner and select the print icon.
- Make sure your print destination is "Microsoft Print to PDF."
- Choose "Custom" and then the page numbers that contain only your e-Consent. This will prompt you to save the new "cropped" PDF.
- This PDF can then be emailed to the participant.
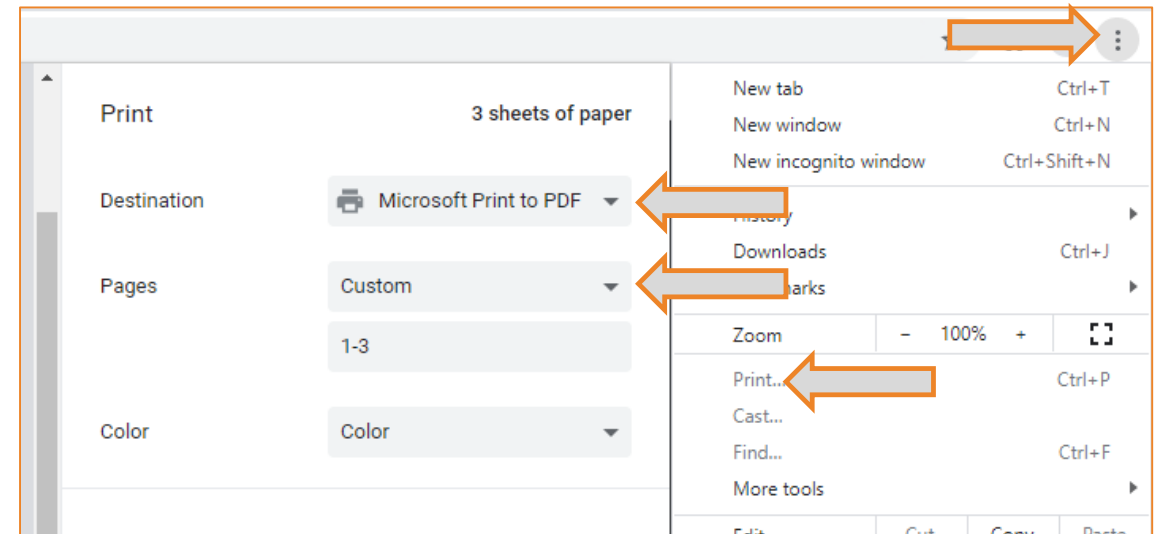
HOW TO SHARE WITH THE IRB

- For your first survey instrument, the link will always be found here in the survey distribution tools. You should be able to click this link as many times as possible and you will always be directed to your first survey.

- Links for surveys that are NOT the first survey in your project are record specific. Meaning the links will be unique each time. To obtain links for surveys that are NOT the first instrument, here is what you must do:
  - Add a new record. Enter some data for the preceding instruement and select the "Save & Go To Next Form" button.
  - In the next instrument, click Survey options -> Open survey. Copy and paste the URL from the survey that opens. In the project, be sure to select "Leave Without Saving Changes" when prompted when exiting the form. Repeat as needed for additional consents.
  - Important to note, these will be record specific links! If for some reason the surveys are submitted, the links will no longer work.
  - If you have User Rights to Rename a record, you may want to consider renaming the record to "For IRB" so it's explicitly clear the record serves this purpose. Once approved by the IRB, you can consider deleting the record. But you will need to repeat the prior steps if asked to provide survey links again.

Survey Distribution Tools

🔗 Public Survey Link   👥 Participant List   Survey Invitation Log

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: https://redcap.lifespan.org/redcap/surveys/?s=37LW3MATN8

Instrument name	Fields	View PDF	Enabled as survey
Informed Consent And Authorization Example	56	📄	✅
Researcher Signature	16	📄	Enable
HIPAA Research Authorization Example	26	📄	✅
Child Assent Example	16	📄	✅
Consent Sent To Participant	2	📄	Enable

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
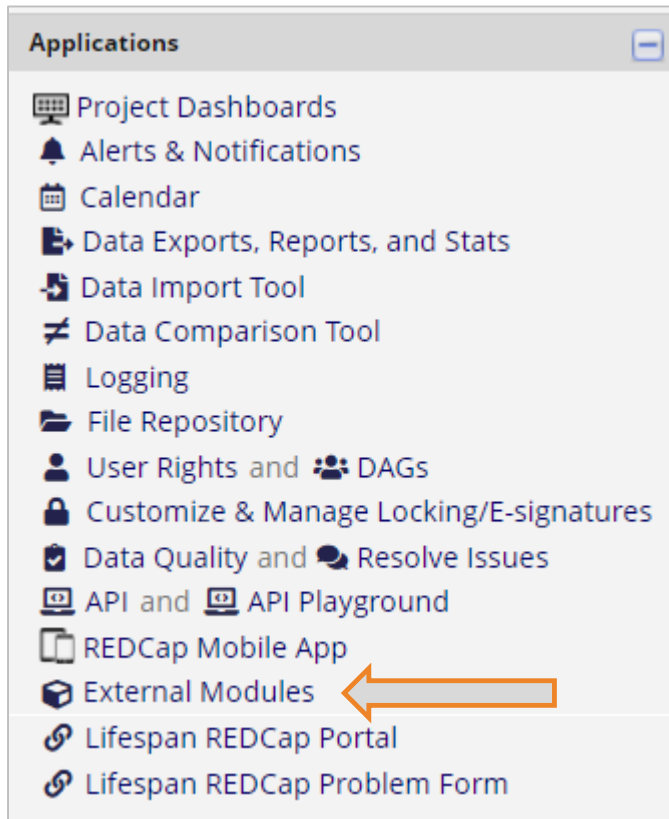
+ Enable a module

Currently Enabled Modules

None

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

View Documentation

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.

+ Enable a module

Currently Enabled Modules

Search enabled modules

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

View Documentation

Configure

Disable

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

Title of this alert: | Add Researcher Signature

STEP 1: Triggering the Alert

A) How will this alert be triggered?
- ( ) When a record is saved on a specific form/survey*
- ( ) If conditional logic is *TRUE* when a record is saved on a speci
- ( ) When conditional logic is *TRUE* during a data import, data en

B) Trigger the alert...

when | "Informed Consent And Authorization Examp ▾ | is saved with Complete status only ▾

* The alert will not be re-triggered if the form/survey is saved again, unless it is set to send Every time in Step 2 below.

STEP 2: Set the Alert Schedule

When to send the alert? ( ) Send immediately

Email From:
* must provide value

Display name (optional) | redcapsupport@lifespan.org ▾

Email To:
* must provide value

× jrichardson7@lifespan.org

+ Show more options

Or manually enter emails: | jane@example.com; john@mysite.org

Subject:
* must provide value

Add Researcher Signature

Message:
* must provide value

☑ Prevent piping of data for Identifier fields [?]

Paragraph ▾ | — | **B** *I* <u>U</u> 🔗 | ≡ ≡ ≡ ≡ | ↶ ↷

≔ ≔ ⇤ ⇥ | ⊞▾ ⊞ ⊞ | A ▾ 🖊 ▾ | Q <> 𝑇ₓ | ⤢

New consent requires a signature. [form-link:researcher_signature:Please sign here]

Add Researcher Signature

ⓘ Retention: CCPM25-Inbox-365Days (1 year) Expires: Wed 5/24/2023 5:13 AM

(R) redcapsupport@lifespan.org
To: Richardson, Jeffrey

New consent requires a signature. Please sign here

↩ Reply | → Forward

MULTI-SIGNATURE EXTERNAL MODULE

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

OTHER TIPS

- Whenever in doubt, consult with your IRB

- Work on making consent as reader friendly as possible

- Since signatures are often illegible, be sure to collect name on the consent, in addition to signature

- Try to keep the design layout similar to the paper version.

- Have a process for people who don't have email

- Have a plan in place if user enters the wrong email address and the consent survey bounces back

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

- It's possible to record a video to embed within the consent survey to offer verbal instructions
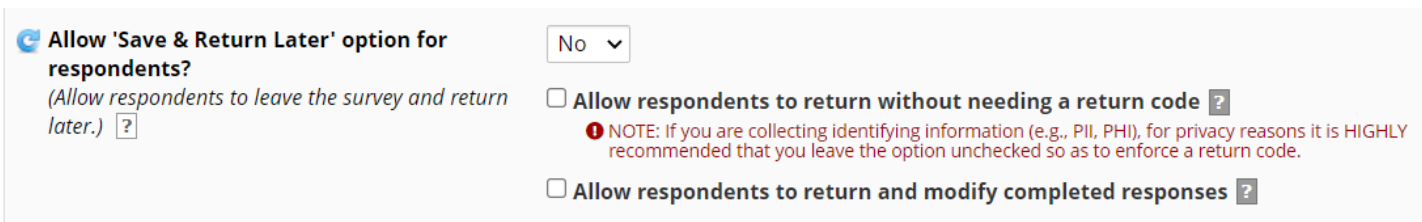
IMPORTANT!

PLAN AHEAD!

- Thoroughly test the e-Consent process prior to official use, from the perspective of both researcher and participant
- Trial many different scenarios to ensure everything functions properly
- Practice and plan how you will guide the participant through the e-Consent.
- Try to anticipate and prepare for any stumbling blocks 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?

FAQ

Do I need to inform the IRB before using consent in REDCap?

Yes! You must indicate in your IRB submission (or amendment) that you're using the e-Consent framework

Should I allow 'Save & Return Later' option for respondents?

NO! The IRB does not permit that research participants have the ability to modify their e-consent once their survey has been submitted.

The intention of the e-consent framework is to capture a true account of the consent process with documented auditing and traceability.

Therefore, we strongly discourage the enabling of "allow respondents to return and modify completed responses".

FAQ

Can I change e-Consent template fields to be un-required?

This would need to be answered by the IRB. If you are making fields unrequired and they are required on the e-consent template, likely the IRB would disapprove. However, the way you intend to administer the e-consent may also play a factor with removing these requirements.

QUESTIONS?

Please don't hesitate to contact redcapsupport@lifespan.org if you ever need assistance

Advance
RI-CTR

Advance
Rhode Island
Clinical & Translational Research

Cite: U54GM115677

THANK YOU!

LIFESPAN
BIOSTATISTICS,
EPIDEMIOLOGY &
RESEARCH
DESIGN CORE