

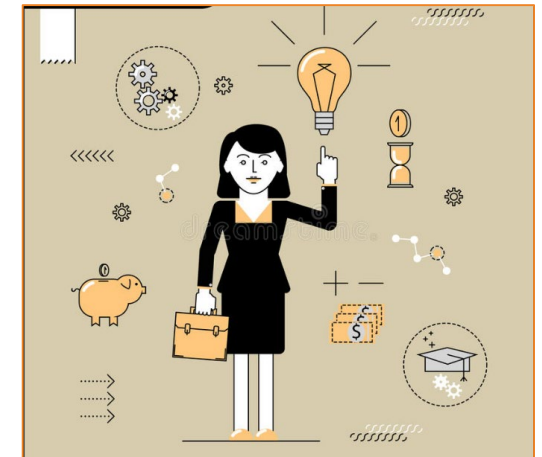


USING REDCAP
TO E-CONSENT
RESEARCH
PARTICIPANTS

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**

[Breathe \(Sheff\)](#), 2018 Jun; 14(2): 145–152.

doi: [10.1183/20734735.001918](https://doi.org/10.1183/20734735.001918)

PMCID: PMC5980471

PMID: [29875834](https://pubmed.ncbi.nlm.nih.gov/29875834/)

How to obtain informed consent for research

[Sara Manti](#)¹ and [Amelia Licari](#)²

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.

Home My Projects **+ New Project** Help & FAQ Training Videos Send-It Control Center

+ Create a new REDCap Project

You may begin the creation of a new REDCap project on your own by completing the form below and clicking the **Create** button at the bottom.

Project title:

Title to be displayed on project webpage

TERMINOLOGY

Data Collection Instruments					
<div> <div>Survey options:</div> <div> <div>Survey Queue</div> <div>Survey Login</div> <div>Survey Notifications</div> <div>Upload or download Auto Invitations</div> </div> </div> <div> <div>Add new instrument</div> <div> <div>Create</div> <div>Import</div> <div>Upload</div> </div> </div>					
Instrument name	Fields	View PDF	Enabled as survey	Instrument actions	
Informed Consent And Authorization Example	45				
Researcher Signature	6		Enable		
Consent Sent To Participant	2		Enable	Choose action	

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

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: e.g., 4

First name field: "Please type your fi" ▼

Last name field: "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: e.g., Pediatric

Date of birth 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: ▼

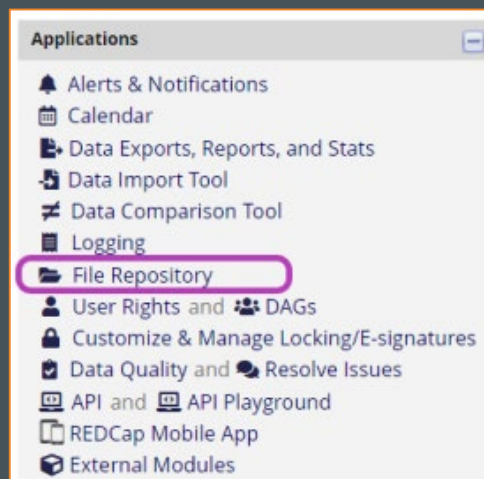
[+ Select another signature field](#)

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

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	
05/10/2021 4:34pm	2	Informed Consent and Authorization Example		10.90.8.19	Version 1 approved 01/01/2020	Adult	

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

+ New Project | Help & FAQ | Training Videos | Send-It | Control Center

+ Create a new REDCap Project

You may begin the creation of a new REDCap project on your own by completing the form below and clicking the Create Project button at the bottom.

Project title:
Title to be displayed on project webpage

Purpose of this project: How will it be used?

Assign project to a Project Folder? ☐

Project notes (optional): Comments describing the project's use or purpose that are displayed on the My Projects page.

Start project from scratch or begin with a template?

- ☐ Create an empty project (blank slate)
- ☐ Upload a REDCap project XML file (CDISC ODM format) ?
- ☒ Use a template (choose one below)

★ Choose a project template (comes pre-filled with fields, forms/surveys, and other settings) [+ Add templates \(Administrators only\)](#)

select template	Template title (sorted by title)	Template description
<input type="radio"/>	Basic Demography	Contains a single data collection instrument to capture basic demographic information.
<input checked="" type="radio"/>	e-Consent template	This is a modular template for building an E-consent process for your study. The template contains built-in instructions fields to understand how to use the template and how to digitally sign a document as a researcher.

✓ Your new REDCap project has been created and is ready to be accessed.
You may now begin exploring your project and the many features available to you. Below are some instructions to help you get started.

Project status: Development Completed steps 0 of 7

Main project settings

Not started

? [VIDEO: How to create and manage a survey](#)

?

CONTENTS OF THE E-CONSENT TEMPLATE

Data Collection Instruments		Survey options:		Add new instrument:		
		Survey Queue	Survey Login	Create	a new instrument from scratch	
		Survey Notifications		Import	a new instrument from the official REDCap Shared Library ?	
		Upload or download Auto Invitations ^		Upload	instrument ZIP file from another project/user or external libraries ?	
	Instrument name	Fields	View PDF	Enabled as survey	Instrument actions	Survey-related options
	Informed Consent And Authorization Example	56			Choose action ^	Survey settings + Automated Invitations
	Researcher Signature	16		Enable	Choose action ^	
	HIPAA Research Authorization Example	26			Choose action ^	Survey settings + Automated Invitations
	Child Assent Example	16			Choose action ^	Survey settings + Automated Invitations
	Consent Sent To Participant	2		Enable	Choose action ^	

- **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

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

RESEARCH STAFF





This section is for research staff only. Please enter your name, and signature.
Then mark the form as completed, lock the form and check the esignature box.

[Add Field](#) [Add Matrix of Fields](#)

    Variable: no_consent_warning Branching logic: [consent_option] = '0' [How to embed a field elsewhere](#)





THIS PARTICIPANT DID NOT CONSENT. YOU CAN NOT SIGN THEIR E-CONSENT DOCUMENT.

[Add Field](#) [Add Matrix of Fields](#)

    Variable: check [How to embed a field elsewhere](#)





I have checked the participant e-Consent for completeness before signing. ☐ Yes ☐ No [reset](#)

[Add Field](#) [Add Matrix of Fields](#)

    Variable: researcher_first_name Branching logic: [consent_option] = '1' [How to embed a field elsewhere](#)





Researcher: Please record your first name

[Add Field](#) [Add Matrix of Fields](#)

    Variable: researcher_last_name Branching logic: [consent_option] = '1' [How to embed a field elsewhere](#)

Researcher: Please record your last name





[Add Field](#) [Add Matrix of Fields](#)


    Variable: researcher_sign Branching logic: [consent_option] = '1' [How to embed a field elsewhere](#)

Researcher: Signature of Researcher [Add signature](#)

Click the "Add Signature" and sign your name

[Add Field](#) [Add Matrix of Fields](#)

    Variable: researcher_date_time_sign Branching logic: [consent_option] = '1' [How to embed a field elsewhere](#)

Researcher: Date and time when signed  Now M-D-Y H:M
Click the "Now" button

Record ID 2


RESEARCH STAFF

This section is for research staff only. Please enter your name, and signature.
Then mark the form as completed, lock the form and check the esignature box.

I have checked the participant e-Consent for completeness before signing. ☒ Yes ☐ No

Researcher: Please record your first name


Researcher: Please record your last name

Researcher: Signature of Researcher 
[signature_2021-05-11_0333.png\(0.01 MB\)](#)
Click the "Add Signature" and sign your name


Researcher: Date and time when signed
Click the "Now" button

Form Status

Complete? ☐ Complete ☒ Complete

☒  **Lock** [Unlock form](#)

Lock this instrument?
If locked, no user will be able to modify this instrument for this record until someone with Instrument Level Lock/Unlock privileges unlocks it.

☒  **E-signature** ([What is this?](#))

E-signed by jrichardson7 (Jeffrey Richardson) on 05/11/2021 4:12am



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

Data Collection Instrument	Status
Informed Consent And Authorization Example (survey)	
Researcher Signature	 

 **Researcher Signature**

 E-signed by jrichardson7 (Jeffrey Richardson) on 05/22/2021 2:37pm


 **Instrument locked by jrichardson7** (Jeffrey Richardson) on 05/22/2021 2:37pm
The instrument "Researcher Signature" has been locked for record "5". If you have ins
you may unlock this instrument at the bottom of the page.

RESEARCHER SIGNATURE


CUSTOMIZE AND MANAGE LOCKING/ E-SIGNATURES

Form Status

Complete? H Complete ▼

Lock this instrument? ☒  **Lock**

If locked, no user will be able to modify this instrument for this record until someone with Instrument Level Lock/Unlock privileges unlocks it.

☒  **E-signature** [\(What is this?\)](#)

- 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

Applications	Display the Lock option for this instrument?	Data Collection Instrument	Also display E-signature option on instrument?	Lock Record Custom Text	Edit / Remove Custom Text
Alerts & Notifications	<input checked="" type="checkbox"/>	Informed Consent And Authorization Example	<input type="checkbox"/>	<input type="text"/> Save	
Calendar	<input checked="" type="checkbox"/>	Researcher Signature	<input checked="" type="checkbox"/>	<input type="text"/> Save	
Data Exports, Reports, and Stats	<input checked="" type="checkbox"/>	HIPAA Research Authorization Example	<input type="checkbox"/>	<input type="text"/> Save	
Data Import Tool	<input checked="" type="checkbox"/>	Child Assent Example	<input type="checkbox"/>	<input type="text"/> Save	
Data Comparison Tool	<input checked="" type="checkbox"/>	Consent Sent To Participant	<input type="checkbox"/>	<input type="text"/> Save	
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					
Configure Email Alerts					
Help & Information					
Help & FAQ					
Video Tutorials					
Suggest a New Feature					

CONSENT SENT TO PARTICIPANT

The screenshot shows the configuration interface for an instrument titled "Consent Sent To Participant". At the top, there is a "Return to list of instruments" button and a "Preview instrument" button. The main area contains two sections, each with "Add Field" and "Add Matrix of Fields" buttons. The first section has a variable named "this_section_allows_you_to" and a text field containing the instruction: "This section allows you to document that informed consent has been completed and the necessary documents have been downloaded and emailed to the participant." The second section has a variable named "dt_copy" with a branching logic rule "[consent_option] = '1'", and a radio button question: "A copy of this complete (note total number of pages in footer) signed consent form has been given to the participant." with options "Yes" and "No". A "reset" link is located at the bottom right of the second section.

[Return to list of instruments](#)

Current instrument: **Consent Sent To Participant** [Preview instrument](#)

[Add Field](#) [Add Matrix of Fields](#)

Variable: this_section_allows_you_to [How to embed a field elsewhere](#)

This section allows you to document that informed consent has been completed and the necessary documents have been downloaded and emailed to the participant.

[Add Field](#) [Add Matrix of Fields](#)

Variable: dt_copy Branching logic: [consent_option] = '1' [How to embed a field elsewhere](#)

A copy of this complete (note total number of pages in footer) signed consent form has been given to the participant. ☐ Yes ☐ No [reset](#)

[Add Field](#) [Add Matrix of Fields](#)

- 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

- 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

Click on ID#

Record ID	Informed Consent And Authorization Example	Researcher Signature	Consent Sent To Participant
1			

Record Home Page

The grid below displays the form-by-form progress of data entered for the currently selected record. You may click on the colored status icons to access that form/event.

Choose action for record ▾

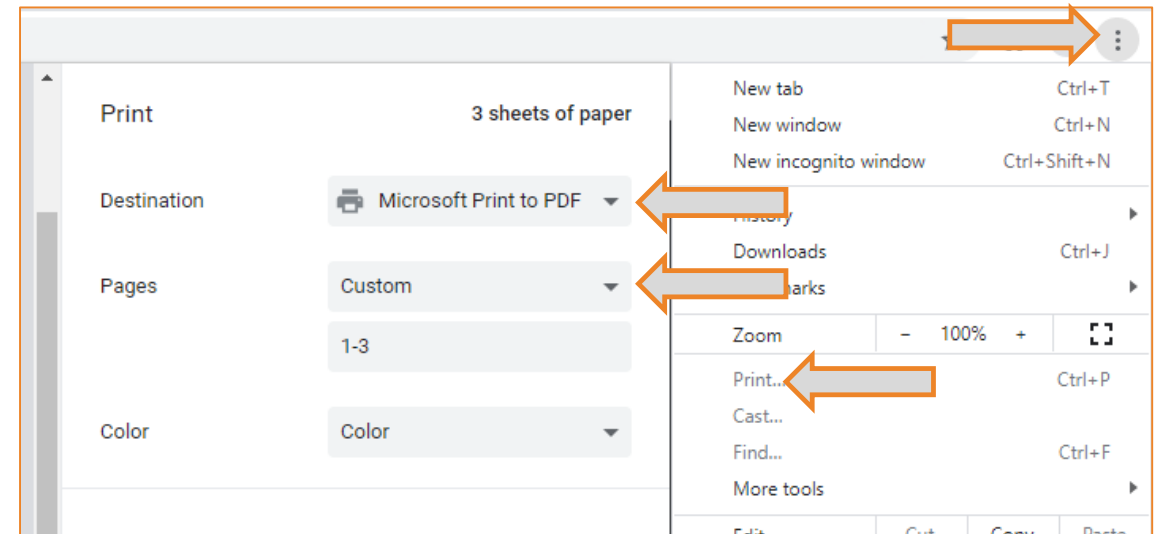
Click arrow

Choose action for record ▾

- Download ZIP file of all uploaded documents
- Download PDF of record data for all instruments
- Download PDF of record data for all instruments (compact)
- Lock entire record
- Rename record
- Delete record (all forms)

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 instrument 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](#)

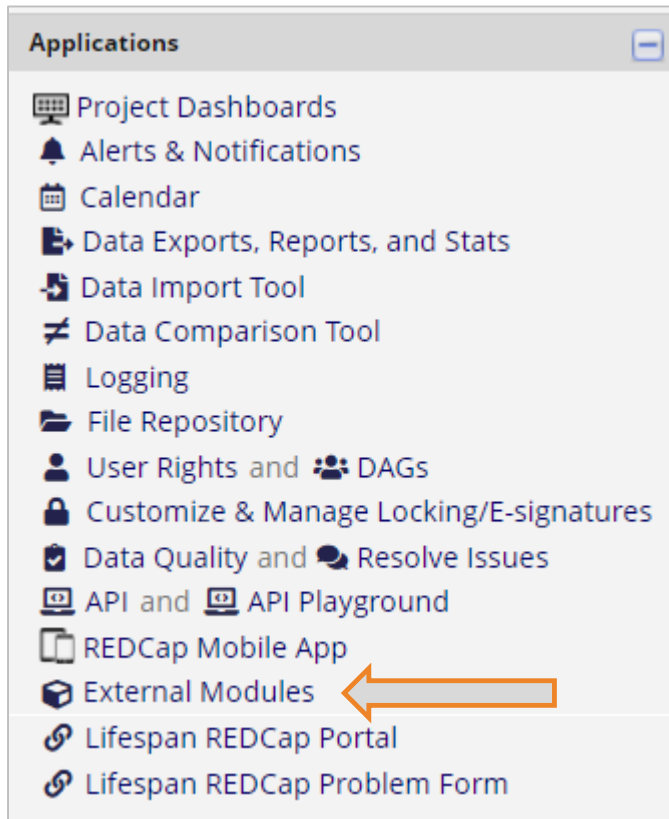
Using a public survey link is the simplest and fastest way to collect responses for your survey. You may obtain the survey link below to email it to your participants. Responses will be collected anonymously (unless the survey contains questions asking for identifying data from the participant). **NOTE:** 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



[+ 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](#)

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

Configure Module: Multi Signature Consent

Project: E-Consent Template Copy

Settings

Values

1. Instruments to Merge:

+

-

1. Form:

* must provide value

informed_consent_and_authorization

2. Instruments to Merge:

+

-

2. Form:

* must provide value

researcher_signature

File Field

This is where the PDF will be saved in the record and it must be a file-upload field:

* must provide value

pdf_up - PDF

Update Logic

When this logic is true and one of the above forms is saved, then create the PDF. This logic should not be true until all forms are complete:

* must provide value

[researcher_signature_complete] = '2'

MULTI-SIGNATURE EXTERNAL MODULE

- **SETUP ALERTS & NOTIFICATIONS**
 - Notify researcher when consent has been completed
 - Send signed consent with researcher signature

Alert #1: Add Researcher Signature [Edit](#) [Options](#) Unique Alert ID: A-508

🔔 When the instrument "Informed Consent And Authorization Example" is saved and has a Complete status.

➡ Send immediately

1x Send one time (only once per record - i.e., never re-trigger)

📧 Activity: 9 records were alerted ([view list](#)) ✓ Last sent: 05/24/2022 5:13am

Email [Preview](#)

From: redcapsupport@lifespan.org

To: jrichardson7@lifespan.org

Subject: Add Researcher Signature

New consent requires a signature. [form-link:research...]

Alert #2: Send Signed Consent [Edit](#) [Options](#) Unique Alert ID: A-507

🔔 When the instrument "Researcher Signature" is saved and has a Complete status.

➡ Send immediately

1x Send one time (only once per record - i.e., never re-trigger)

📧 Activity: 7 records were alerted ([view list](#)) ✓ Last sent: 05/24/2022 5:16am

Email [Preview](#)

From: redcapsupport@lifespan.org

To: [participant_email]

Subject: Copy of Informed Consent

Thank you for participating. Attached is your copy of t...

Attachments (1):

📎 [pdf_up]

SETUP ALERTS: Notify researcher when consent has been completed

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

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

Add Researcher Signature

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

 redcapsupport@lifespan.org
To: Richardson, Jeffrey

New consent requires a signature. [Please sign here](#)

MULTI-SIGNATURE EXTERNAL MODULE

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

Title of this alert:

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 specific form/survey
☐ When conditional logic is *TRUE* during a data import, data entry


B) Trigger the alert...


when is saved with

* 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

 redcapsupport@lifespan.org
To: Richardson, Jeffrey

 pid12328_formInformed_Conse...
613 KB

Thank you for participating. Attached is your copy of the signed informed consent.

Email To:
* must provide value
[+ Show more options](#)

Or manually enter emails:

Subject:
* must provide value

Message:
* must provide value

☒ Prevent piping of data for Identifier fields ?

Thank you for participating. Attached is your copy of the signed informed consent.

In the subject or message, you may use [Piping](#) and [Smart Variables](#)
Example: Hi [first_name]! Please complete this survey: [survey-link:followup_survey]

Message Attachments (Max file size: 10MB)

File Upload fields:

You may utilize files attached to records that have been uploaded into File Upload or Signature fields.

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!

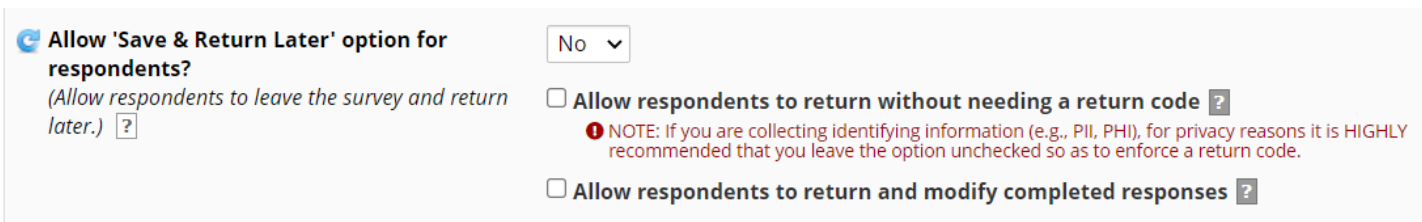
- Thoroughly test the e-Consent process prior to official use, from the perspective of both researcher and participant
- Trial many different scenarios to ensure everything functions properly
- Practice and plan how you will guide the participant through the e-Consent.
- Try to anticipate and prepare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


A screenshot of the REDCap e-consent settings interface. It features a light gray background with a blue circular icon containing a white 'e' on the left. The main text reads 'Allow 'Save & Return Later' option for respondents?' followed by a dropdown menu currently set to 'No'. Below this, a smaller line of text says '(Allow respondents to leave the survey and return later.)' with a question mark icon. To the right, there are two unchecked checkboxes. The first is 'Allow respondents to return without needing a return code' with a question mark icon. Below it is a red warning icon followed by a note: 'NOTE: If you are collecting identifying information (e.g., PII, PHI), for privacy reasons it is HIGHLY recommended that you leave the option unchecked so as to enforce a return code.' The second checkbox is 'Allow respondents to return and modify completed responses' with a question mark icon.

 **Allow 'Save & Return Later' option for respondents?**

(Allow respondents to leave the survey and return later.) 

☐ **Allow respondents to return without needing a return code** 

 **NOTE:** If you are collecting identifying information (e.g., PII, PHI), for privacy reasons it is **HIGHLY** recommended that you leave the option unchecked so as to enforce a return code.

☐ **Allow respondents to return and modify completed responses** 

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
Rhode Island**
Clinical & Translational Research

Cite: U54GM115677

THANK YOU!



**LIFESPAN
BIostatISTICS,
Epidemiology &
RESEARCH
DESIGN CORE**

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