USING REDCAP TO E-CONSENT RESEARCH PARTICIPANTS
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

doi: 10.1183/20734735.001918

PMCID: PMC5950471
PMID: 29075834

How to obtain informed consent for research
Sara Mansi¹ and Anuilla Licari²
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.
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 '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
Before a participant completes the survey, an extra certification page is added to the 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
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.
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.
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.
• **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
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
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
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
### 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.

**RESEARCHER SIGNATURE**

**Online Designer View**

**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.

<table>
<thead>
<tr>
<th>Field</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>I have checked the participant e-Consent for completeness before signing.</td>
<td>Yes</td>
</tr>
</tbody>
</table>

**Researcher:** Please record your first name

Nibbles

**Researcher:** Please record your last name

Woodaway

**Researcher:** Signature of Researcher

![Signature Image]

Click the "Add Signature" and sign your name.

**Researcher:** Date and time when signed

05-11-2021 03:33

**Form Status**

Complete?

Yes

**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.

Locked by jrichardson7 (Jeffrey Richardson) on 05/11/2021 4:12am

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

**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
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.
• 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

- 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 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.
**MULTI-SIGNATURE EXTERNAL MODULE**

**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.
Configure Module: Multi Signature Consent

**Project:** E-Consent Template Copy

**Settings**

1. **Instruments to Merge:**
   - **Form:**
     - *must provide value
     - `informed_consent_and_authorization`

2. **Instruments to Merge:**
   - **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
  o Notify researcher when consent has been completed
  o 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
   - When 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, or data cleaning

B) Trigger the alert...

   when [Informed Consent And Authorization Exams] 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]

Email To:
   - [must provide value]
   - show more options
   - [must provide value]

Subject: [must provide value]

Message: [must provide value]

Prevent piping of data for identifier fields

Add Researcher Signature

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

Add Researcher Signature


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:** Send Signed Consent

**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 or data entry

B) Trigger the alert...
- [ ] "Researcher Signature" 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 To:**
- [ ] must provide value

**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.

**Copy of Informed Consent**

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

**Message Attachments**

- [ ] Max file size: 10 MB
- [ ] PDF

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?

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”.
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.
THANK YOU!

Advance
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Cite: U54GM115677

LIFESPAN BIOSTATISTICS, EPIDEMIOLOGY & RESEARCH DESIGN CORE

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