



REDCapAdmin@URMC.Rochester.edu

Agenda

- ▶ Introductions
- ▶ What is e-Consent?
 - ▶ REDCap Framework
 - ▶ Auditing & Storage
- ▶ Getting Started
 - ▶ IRB Approval
 - ▶ AIT Implementation
- ▶ Sample e-Consent Demo

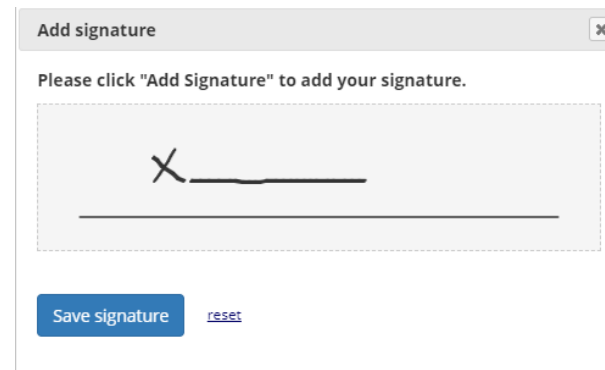
- ▶ Important Links
 - ▶ [OHSP Policy Document](#)
 - ▶ [AIT Implementation Request](#)

Introductions

- ▶ Yvonne Watson
 - ▶ Academic IT Department
 - ▶ Project Manager
- ▶ Kim Kaukeinen
 - ▶ Department of Biostatistics and Computational Biology
 - ▶ Sr. Analyst/Programmer
 - ▶ Academic IT Department
 - ▶ REDCAP Admin
- ▶ Amanda Davin
 - ▶ Academic IT Department
 - ▶ Sr. Analyst Programmer
 - ▶ REDCAP Admin
- ▶ Sampson Abiola
 - ▶ Academic IT Department
 - ▶ Sr. Analyst Programmer
 - ▶ REDCAP Admin

What is e-Consent?


- ▶ Digital process to capture a subjects (individual or LAR) consent to participate.
- ▶ Composed of multiple steps to ensure informed consenting.
 - ▶ Identity verification of the subject.
 - ▶ Presentation of the consent documentation.
 - ▶ Electronic signature capture.
 - ▶ Certification of submitted responses.
- ▶ Relies on an electronic signature method.
 - ▶ Signature fields within REDCap do not constitute an informed consent on their own.



The screenshot shows a web interface for adding a signature. At the top, there is a title bar that says "Add signature" with a close button (an 'x' in a square). Below the title bar, there is a text instruction: "Please click 'Add Signature' to add your signature." Underneath this instruction is a large, dashed rectangular box containing a handwritten signature that looks like 'X' followed by a horizontal line. Below the signature box is a solid horizontal line. At the bottom of the interface, there are two buttons: a blue button labeled "Save signature" and a smaller, light blue link labeled "reset".

REDCap Framework

- ▶ Within REDCap, e-Consent is facilitated through an integrated framework within the REDCap application which provides a platform for securely processing informed consent electronically.
- ▶ The e-Consent framework, once enabled, does not automatically imply that a project is ready to process informed consents.
- ▶ The framework is customizable depending on what is required for consent, not all options must be used.

 **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: ▼

Last name field: ▼

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: ▼

Auditing & Storage

▶ Archived Documents


- ▶ REDCap creates an (unmodifiable) PDF of the completed responses from the participant and stores it in the File Repository of the project.
- ▶ PDFs can be accessed by any user with File privileges within the project to be downloaded and viewed.
- ▶ Even if you change the participant responses within REDCap, the PDFs are not changed nor will they be re-created.

▶ Logging

- ▶ All actions including submission of responses are logged.
- ▶ Along with timestamps the IP address of the computer that submitted the consent is recorded.


Getting Started

- ▶ IRB Approval!
 - ▶ Must have approval before contacting AIT for implementation.
- ▶ AIT Implementation
 - ▶ Fill out the e-Consent implementation request survey located on the login page for REDCap.
 - ▶ IRB has required that AIT implement e-Consent in your project, we will provide a walkthrough of the workflow once the implementation is complete.



In-Person Appointment

- [Schedule Now](#)



Upcoming Training Sessions

- [Survey Basics](#)
- [Data Quality](#)

Class size is limited. Additional offerings will be coming soon!

Usage of e-Consent within REDCap requires IRB approval and implementation by Research & Academic IT. If you have IRB approval and are ready to have Research & Academic IT implement e-Consent within your project, please fill out this [e-Consent request survey](#).