e-Consent Refresher Session

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Agenda

- Introductions

- What is e-Consent?

  - REDCap Framework

  - Auditing & Storage

  - 21 CFR Part 11 Compliance

- Getting Started

  - IRB Approval

  - AIT Implementation

- Sample e-Consent Demo

- Important Links

  - [OHSP Policy Document](#)

  - [AIT Implementation Request](#)

Introductions

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    - Project Manager

- Kim Kaukeinen
  - Department of Biostatistics and Computational Biology
    - Sr. Analyst/Programmer
  - Academic IT Department
    - REDCAP Admin

- Amanda Davin
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    - Sr. Analyst Programmer
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- Sampson Abiola
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    - Sr. Analyst Programmer
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What is e-Consent?

▶ Provides mechanism to share written or interactive information, evaluate subject comprehension and document consent electronically.

▶ Composed of multiple steps to ensure informed consenting.

  ▶ Identity verification of the subject.

  ▶ Presentation of the consent documentation.

  ▶ Capture of digital signature.

  ▶ Certification of submitted responses.

▶ Relies on a digital signature method.

  ▶ Signature fields within REDCap do not constitute an informed consent on their own.

▶ e-Consent does not replace required consent signature meant to be stored in regulatory binders.
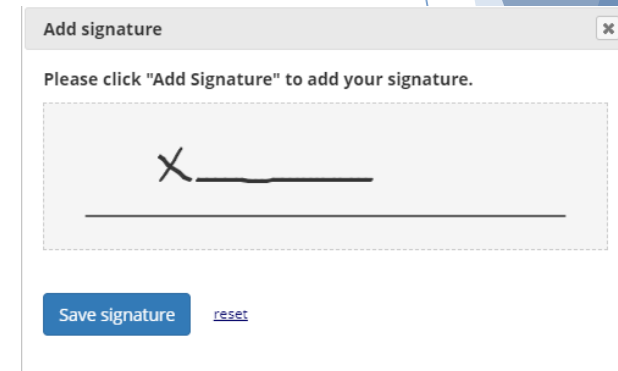
REDCap Framework

▶ Within REDCap, e-Consent is facilitated through an integrated framework within the REDCap application which provides a platform for securely processing informed consent electronically.

▶ Adds 2 things to a typical survey-taking process:

   ▶ Certification page added to end of survey that displays an in-line PDF copy – subject will be asked to verify everything is correct.

   ▶ Upon completion a static copy of their responses in the format of a consent specific PDF is stored in the File Repository.

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: [1]   e.g., 4

First name field: [econsent_par_fname "First Nar ▼]

Last name field: [econsent_par_lname "Last Nar ▼]

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: [Sample]   e.g., Pediatric

Date of birth field: [econsent_par_dob "Date of Bir ▼]

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: [econsent_par_signature "Pleas ▼]

[+ Select another signature field]

Where are completed PDFs stored?

- Archived Documents
  - REDCap creates an (unmodifiable) PDF of the completed responses and stores it in the **File Repository** under "PDF Survey Archive".
  - PDFs can be accessed by any user with "Full Data Set" privileges.
  - Completed e-Consent PDFs should be downloaded & printed from the File Repository and maintained in paper format with your regulatory files.
- Logging
  - All actions including submission of responses are logged.
  - Along with timestamps the IP address of the computer that submitted the consent is recorded.

File Repository

- ▶ Multiple versions of same consent to accommodate for updates/amendments.

- ▶ Multiple consent types within same project.

📁 **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
04/19/2021 11:31am	2	University of Rochester Sample e-Consent	Allison Jones, 2021-04-19	10.151.144.174	v02	Pediatric	PDF ⬇
04/19/2021 11:29am	1	University of Rochester Sample e-Consent	Carolyn Jones, 1989-04-01	10.151.144.174	v01	Parent	PDF ⬇
04/19/2021 11:26am	1	University of Rochester Sample e-Consent	Allison Jones, 2021-04-19	10.151.144.174	v01	Pediatric	PDF ⬇

21 CFR Part 11 Compliance

▶ The University's instance of REDCap is **NOT** 21 CFR Part 11 compliant.

▶ REDCap should not be used to document consent where an electronic signature (e-signature) is required, more specifically in FDA-regulated research.

  ▶ REDCap captures a digital signature, not an approved e-signature.

▶ There is no e-signature solution at the University at this time.

▶ More to come in future SCORE meeting.

Getting Started

▶ According to the [OHSP guidance](#), Research & Academic IT is <u>required</u> to set up the e-Consent in REDCap, including any future consent amendments.

▶ IRB Approval is required before contacting Research & Academic IT for implementation.

▶ Research & Academic IT Implementation

    ▶ Fill out the e-Consent implementation request survey located on the login page for REDCap.

    ▶ Our team will provide a walkthrough of the workflow once the implementation is complete.