IRB Monthly IRB-Investigator Meeting (MIM)

Electronic consent and REDCap

Rascal IRB 2.1

September 24, 2020
Agenda

- Overview of electronic consent (e-Consent) guidance
- REDCap and e-Consent (Richard Buchsbaum)
- Rascal IRB 2.1: Q&A
Zoom Webinar Logistics

• To submit a question during the live webinar, use Zoom’s Q & A function. (Chat feature is disabled)

• Questions may be posted anonymously. However, if we don’t get to your question during the session, we will not be able to respond to you directly afterwards.

• Participants’ video and audio are by default turned off.

• Slides will be posted on the HRPO website.
Electronic Consent

Definition: the use of electronic systems and processes, whether in person or remotely, that employ multiple electronic media (e.g., text, graphics, audio, video, podcasts, websites, etc.) to convey information relating to a research study and to document informed consent of subjects who wish to participate in such study.

Types of e-consent:

- In person e-Consent: person obtaining consent (POC) and potential participant are physically in the same location, consent discussion occurs in-person, consent document is presented electronically (e.g. via an iPad, tablet, etc), and consent may be documented electronically (if documentation of consent is required)

- Remote e-Consent: potential participant reviews the consent document electronically in the physical absence of a member of the research team consent may be documented electronically (if documentation of consent is required)
Basic Principles of E-Consent

1. **All elements of informed consent must be included** (as required by HHS and FDA [if applicable] regulations), unless specifically waived.

2. The e-Consenting system should be easy to navigate, allowing the user to proceed forwards and backward, and to stop and continue at a later time.

3. For REMOTE consent, there should be information for the potential participant regarding how questions may be asked and answered from a remote location.

4. Individuals obtaining e-Consent or answering questions for remote consent must be appropriately delegated and trained.

5. Each e-Consenting mechanism should provide for the generation of a copy of the informed consent form signed by the participant.
6. The e-Consenting process should incorporate procedures to ensure that electronic documents can be archived appropriately and that all versions of the IRB-approved e-Consent form and all signed e-Consent Forms can be accessed and retrieved easily.

7. HIPAA authorization may be obtained electronically, either separately or as part of the e-Consent form. If separate, a copy of the HIPAA Authorization Form must be provided to the Subject.
Electronic Signature

**Definition:** an electronic sound, symbol or process, attached to or logically associated with an electronic record and used by a person with the intent to sign such record.

- The electronic signature must be linked to the individual completing the signature.
- If an individual cannot be linked to the action of agreeing to participate, a waiver of written documentation of informed consent by the IRB may need to be considered.
- FDA-regulated clinical investigations are subject to requirements set forth by 21 CFR 11
  - verification of the identity of the signing individual is required prior to the e-signature.
University Specific Guidance

• Any multi-user system storing Sensitive Data (e.g., PHI, RHI, PII) must be certified in RSAM for that data type.

• A HIPAA Business Associate Agreement (BAA) may be required if an external system/entity will receive PHI from Columbia. Some examples include, but are not limited to:
  - When a researcher contributes PHI based on a waiver of HIPAA authorization
  - When disclosing quality improvement and research data

• FDA-regulated clinical investigations that utilize e-consent must include a process for verifying and documenting the identity of the signatory

• REDCap (Irving Institute installation) is certified to house sensitive information, including RHI and can be used to obtain electronic signatures.

• DocuSign is an approved platform at the University to obtain electronic signatures for consent forms containing health information that, with the signature, would be linked to the participant.
  • There is a cost per signature for use of DocuSign.
Acceptable use of e-Consent

- Generally, remote e-Consenting is NOT recommended for research studies that involve greater than minimal risk. However, the IRB can approve such situations on a case-by-case basis.

- A request to use e-Consenting in a study must be submitted and approved by the IRB prior to its implementation.
  - Include a description of the e-Consenting process, the applicable e-Consenting system or software and all ancillary information that will be provided to a participant through links or branching options.
  - When a research study will involve a vulnerable population, the manner in which the e-Consenting process will address the specific characteristics of such population should be described.
E-Consent Resources

• Columbia University (May 2017)
  • https://research.columbia.edu/sites/default/files/content/HRPO/369_e-Consenting_Guidance.050117.pdf

• Joint FDA and OHRP Guidance for IRB, Investigators, and Sponsor (December 2016)

• FDA Draft Guidance for Industry (June 2017)

• https://research.columbia.edu/COVID-19_Research/Communicating-With-Research-Subjects
Informed Consent Procedure

Paper/Traditional
- Ascertainment/evaluation
- Paper ICF
- Discussion, questions, assessment
- Signature
- Distribution of copy
- File signed form
Informed Consent Procedure

Paper/Traditional
- Ascertainment/evaluation
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- Discussion, questions, assessment
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Online Survey
- Ascertainment/evaluation
- Web-based survey
- Discussion, questions, assessment
- Electronic signature
- Distribution of documentation
- Database
Requirements for E-Signature

• Affirmative action
  • Button click, checking box, entering name, etc.
  • Additional steps based on culture, comfort, etc.

• Traceable to an individual
  • Individual link
  • Personal email
  • Direct communication
  • DocuSign, etc./Confirmation code, etc.

• Documented date/time
  • File modification date
  • Database record
  • Date entered
  • DocuSign, etc.
Electronic Consent Via Web-Based Survey

- Survey Monkey
  - Available to anyone, difficult to limit access
  - Separate step to confirm identity
  - Limited logic/dependencies
  - No way to distribute copy

- Qualtrics
  - Easy logic/dependencies
  - Must pre-generate personal links
  - No easy way to distribute copy

- REDCap
  - Easy logic/dependencies
  - Built-in personal links and email messaging
  - All surveys associated with a participant
  - Completed surveys locked
  - Easy to download and/or mail copy
  - Optional built-in e-consent framework
Enforcement of E-Signature Requirements

• Involves entire procedure, not just platform
• Study SOP
• Staff training
• Management/oversight/enforcement
REDCap Basics

• Free software developed by Vanderbilt University
• Requires web and database servers, PHP and MySQL expertise
• Multiple installations on CUIMC campus

• Irving Institute installation
  • Available to anyone with a UNI
  • Requires payment
  • Tech support is available
  • No programming assistance available
Welcome to the Irving Institute REDCap Administration application.
You do not have a REDCap account associated with your UNI.

Create a REDCap account and new REDCap project (Note: these activities will incur charges)

If you feel you are receiving this message in error, contact Chris Wilcosky (cw2615@cumc.columbia.edu).

https://www.sac-cu.org/REDCap
Irving Institute REDCap: Create Project

Please enter information for your new project.

<table>
<thead>
<tr>
<th>Project Information</th>
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<tbody>
<tr>
<td><strong>Project Name</strong></td>
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<td><strong>Project Type</strong></td>
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<td><strong>Funding Source</strong></td>
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<td><strong>Project Notes</strong></td>
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</tbody>
</table>

[Buttons: PREVIOUS, NEXT]
Irving Institute REDCap: Payment

Please enter your payment information.

Payment Information
- I will enter the payment information (Columbia University chart string) myself.
- I will delegate the payment entry to someone else.

Unit: COLUM
Account: 64250
Department: 784870
PC Business Unit: GENRL
Project: GG010400
Activity: 01
Initiative: 70003
Segment: h2023
Fiscal Year: 2020

Current REDCap fees:
- $40.00/quarter per project
- $10.00/quarter per project user
REDCap: Access Project

Log In
GO TO THE REDCAP ADMINISTRATION WEBSITE HERE TO CREATE PROJECTS, ENTER CHART STRINGS, PAYMENT INFORMATION, MANAGE USER RIGHTS, CREATE DATA ACCESS GROUPS (DAGs), AND SET UP USER ROLES.

For details on how to use the REDCap Administration site, download the policy and procedures document here.

Please log in with your username and password. If you are having trouble logging in, please contact Christopher Wiltzke cwiltzke@penn.medsch.edu.

Username: In2023
Password: ********

Log in
Forgot your password?

Welcome to REDCap!
REDCap is a secure web platform for building and managing online databases and surveys. REDCap's streamlined process for rapidly creating and designing projects offers a vast array of tools that can be tailored to virtually any data collection strategy.

REDCap provides automated export procedures for common statistical packages (SPSS, SAS, Stata), as well as a built-in project calendar, a scheduling module, ad-hoc reporting tools, and advanced features, such as branching logic, file uploading, and calculated fields. Learn more about REDCap by watching a Brief summary video (3 min). If you would like to view other quick video tutorials of REDCap in action and an overview of its features, please see the Training Resources page.

NOTICE: If you are collecting data for the purposes of human subjects research, review and approval of the project are required by your Institutional Review Board. If you require assistance or have any questions about REDCap, please contact Christopher Wiltzke cwiltzke@penn.medsch.edu.

REDCap Features
Build online surveys and database quickly and securely - Create and design your project rapidly using secure web authentication from your browser. No extra software is required.
Fast and Flexible - Conversion to production-level survey/database in less than one day.
Export data to common data analysis packages - Export your data to Microsoft Excel, PDF, SAS, Stata, R, or SPSS for analysis.
Ad Hoc Reporting - Create custom queries for generating reports to view or download.
Easily manage a contact list of survey respondents or create a single survey link - Build a list of email contacts, create custom email invitations, and track who responds, or you may also create a single survey link to pass out or post on a website.

https://redcap.sac-cu.org
REDCap: Access Project

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Listed below are the REDCap projects to which you currently have access. Click the project title to open the project. Read more. To review which users still have access to your projects, visit the User Access Dashboard.

<table>
<thead>
<tr>
<th>Project Title</th>
<th>Records</th>
<th>Fields</th>
<th>Instrument</th>
<th>Type</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Enter Project Title Here</td>
<td>0</td>
<td>2</td>
<td>1 form</td>
<td></td>
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</tbody>
</table>
Add Survey

Enable surveys in project
Add Survey

Click “Designer” to view list of surveys
Distribution Options

• Give user option to download pdf at conclusion of survey

• Retain pdf of survey to fulfill user requests

• Enable “E-consent Framework”
Option of downloading

Survey Settings -> Survey Customizations

- Question Numbering
  - Auto numbered

- Question Display Format
  - All on one page
  - Display page numbers at top of survey page
  - Hide the 'Previous Page' button (i.e., Back button) on the survey page

- Allow participants to download a PDF of their responses at end of survey?
  - No

- Survey-specific email invitation field
  - Select a field

- For 'Required' fields, display the red 'must provide value' text on the survey page?
  - Yes

- Allow survey respondents to view aggregate survey results after completing the survey?
  - Disabled

Additional settings:
- Minimum number of responses required before participants are allowed to view aggregate data (recommended = 10)
- Do not show plots for questions lacking diversity in response values? (what does this mean?)
Archive PDF

Survey Settings -> Survey Termination Options -> Auto Archiver
E-Consent Framework

Survey Settings ->
Survey Termination Options ->
Auto Archiver
E-Consent Framework

- Creates template for e-consent survey
- Presents participant with confirmation page
- Autoarchives copy with Framework options at bottom of pdf
- Automatically displays personal data, survey data and metadata on pdf
- “Framework”: Still requires survey design and configuration
REDCap E-Signature Types

- Submit button
- Check box
- Type name (or other value)
- Signature field
- Other
Summary

• Evaluate traditional, in-person process, and adapt as necessary
• Online surveys (esp. REDCap) have many valuable tools, but must be used with consideration
• Platform is not a self-contained solution – process must incorporate entire procedure
• Training, SOP and oversight are essential elements