



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.



Basic Principles of E-Consent (cont'd)

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)
 - <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/use-electronic-informed-consent-questions-and-answers/index.html>
- FDA Draft Guidance for Industry (June 2017)
 - <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/use-electronic-records-and-electronic-signatures-clinical-investigations-under-21-cfr-part-11>
- 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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- File signed form

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

Irving Institute REDCap: Admin Application

Data Management Unit

Statistical Analysis Center

Irving Institute REDCap Administration

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)*

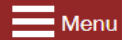
If you feel you are receiving this message in error, contact **Chris Wilcosky** (cw2615@cumc.columbia.edu).

<https://www.sac-cu.org/REDCap>

Irving Institute REDCap: Create User Accounts

Data Management Unit

Statistical Analysis Center



Menu

Irving Institute REDCap Administration

Please enter information for your new account.

User Information

Username	<input type="text" value="lh2023"/>	* <i>project owner</i>
First Name	<input type="text"/>	
Last Name	<input type="text"/>	
Suffix	<input type="text"/>	
Email	<input type="text"/>	
Password	<input type="password"/>	
Confirm Password	<input type="password"/>	
Security Question	<input type="text" value="---Select---"/>	▼
Answer	<input type="text"/>	
Affiliation	<input type="text" value="---Select---"/>	▼
School		* <i>not applicable</i>

NEXT

Irving Institute REDCap: Create Project

Data Management Unit

Statistical Analysis Center



Menu

Irving Institute REDCap Administration

Please enter information for your new project.

Project Information

Project Name	<input type="text" value="Enter Project Title Here"/>
Project Type	<input type="text" value="Research"/> <input type="text" value="Basic research/lab"/>
IRB	<input checked="" type="checkbox"/> This project required an approval from CUIMC IRB <input checked="" type="checkbox"/> I have the protocol number <input type="text" value="AARP1234"/> Enter protocol number
Funding Source	<input type="text" value="CUIMC grant (CTSA, school award, departmental award, etc.)"/>
Project Notes (optional)	<input type="text"/>

PREVIOUS

NEXT

Irving Institute REDCap: Payment

Data Management Unit

Statistical Analysis Center

Menu

Irving Institute REDCap Administration

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	<input type="text" value="COLUM"/>
Account	<input type="text" value="64250"/>
Department	<input type="text" value="784870"/>
PC Business Unit	<input checked="" type="radio"/> GENRL <input type="radio"/> SPONS
Project	<input type="text" value="GG010400"/>
Activity	<input type="text" value="01"/>
Initiative	<input type="text" value="70003"/>
Segment	<input type="text" value="lh2023"/>
Fiscal Year	<input type="text" value="2020"/>

Current REDCap fees:

\$40.00/quarter per project
\$10.00/quarter per project user

PREVIOUS

NEXT

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 (DAG's), 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 user name and password. If you are having trouble logging in, please contact [Christopher Wilcosky](mailto:cw2615@cumc.columbia.edu), cw2615@cumc.columbia.edu.

Username:	<input type="text" value="lh2023"/>
Password:	<input type="password" value="*****"/>
<input type="button" value="Log In"/>	Forget 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 seamless data downloads to Excel and common statistical packages (SPSS, SAS, Stata, R), 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 \(4 min\)](#). 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 is required by your Institutional Review Board.

If you require assistance or have any questions about REDCap, please contact [Christopher Wilcosky](mailto:Christopher.Wilcosky.cw2615@cumc.columbia.edu), cw2615@cumc.columbia.edu.

REDCap Features

Build online surveys and databases quickly and securely - Create and design your project rapidly using secure web authentication from your browser. No extra software is required.

Fast and flexible - Conception 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 simple 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 email out or post on a website.

<https://redcap.sac-cu.org>

REDCap: Access Project



Home

My Projects

Help & FAQ

Training Videos

Send-It

Messenger

Logged in as
lh2023

My Profile

Log out

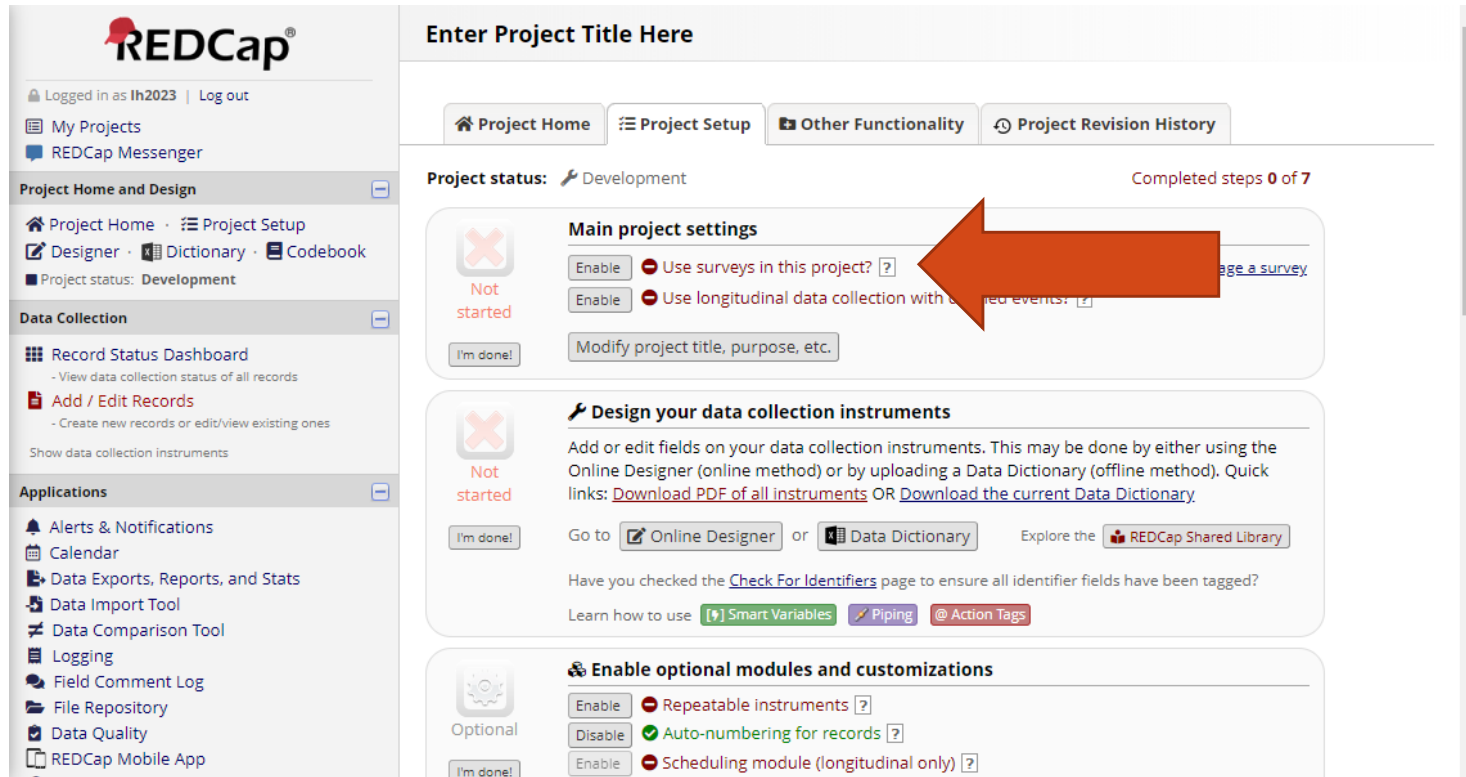
GO TO THE REDCAP ADMINISTRATION WEBSITE [HERE](#) TO CREATE PROJECTS, ENTER CHART STRINGS, PAYMENT INFORMATION, MANAGE USER RIGHTS, CREATE DATA ACCESS GROUPS (DAG's), AND SET UP USER ROLES.

For details on how to use the **REDCap Administration site**, download the [policy and procedures document here](#).

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](#).

Project Title	Records	Fields	Instrument	Type	Status
Enter Project Title Here	0	2	1 form	■	🔧

Add Survey



The screenshot shows the REDCap project setup interface. The left sidebar contains navigation menus for 'Project Home and Design', 'Data Collection', and 'Applications'. The main content area is titled 'Enter Project Title Here' and includes a breadcrumb trail: 'Project Home > Project Setup > Other Functionality > Project Revision History'. The 'Project status' is 'Development' with 'Completed steps 0 of 7'. The 'Main project settings' section is highlighted with a red arrow pointing to the 'Use surveys in this project?' checkbox, which is currently disabled. Other settings include 'Use longitudinal data collection with scheduled events?' (disabled) and 'Modify project title, purpose, etc.' (I'm done!). The 'Design your data collection instruments' section is also highlighted with a red 'X' and 'Not started' status, with options for 'Online Designer' or 'Data Dictionary'. The 'Enable optional modules and customizations' section includes 'Repeatable instruments?' (disabled), 'Auto-numbering for records?' (enabled), and 'Scheduling module (longitudinal only)?' (disabled).

Enable surveys in project

Add Survey

The screenshot shows the REDCap web interface. The top navigation bar includes 'Project Home', 'Project Setup', 'Online Designer', 'Data Dictionary', and 'Codebook'. A red arrow points to the 'Designer' link in the left sidebar under the 'Project Home and Design' section. The main content area displays 'Enter Project Title Here' and a table of 'Data Collection Instruments'.

Instrument name	Fields	View PDF	Enabled as survey	Instrument actions	Survey-related options
My First Instrument	1		Enable	Choose action	

Click “Designer” to view list of surveys

Distribution Options

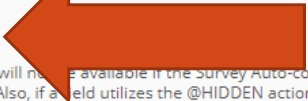
- Give user option to download pdf at conclusion of survey
- Retain pdf of survey to fulfill user requests
- Enable “E-consent Framework”

Option of downloading

Survey Customizations:

Question Numbering
For custom numbering, each question's number will be blank by default until manually added via the Online Designer or Data Dictionary.
Auto numbered

Question Display Format
One page or multiple pages? Section headers, which begin new sections on the instrument, will serve as the page break in a multi-page survey, in which each page will begin with a section header.
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 (prevents respondents from going back to previous pages)

Allow participants to download a PDF of their responses at end of survey?
Display a button for the participant to download a PDF file of their responses for the survey they just completed.
No 
This option will not be available if the Survey Auto-continue or Survey Queue auto-start option is enabled. Also, if a field utilizes the @HIDDEN action tag, it will not be displayed in the PDF.

Survey-specific email invitation field
Designate an email field for sending survey invitations for this survey only.
-- select a field --
Note: This option will override the project-level email invitation field (if enabled on the Project Setup page) and will also override any email address originally entered into the Participant List. Also, if this field has no value and the project-level email field is enabled, then the project-level email field's value will be used instead.

For 'Required' fields, display the red 'must provide value' text on the survey page?
Yes
If 'No', then it will NOT display the following text beneath all 'Required' fields: * must provide value

Allow survey respondents to view aggregate survey results after completing the survey?
After completing the survey, participants can view ALL responses in aggregate graphical format and/or as descriptive statistics. Also, the individual respondent's answers will be highlighted in the results.
Disabled

Additional settings:
10 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?)

Survey Settings ->
Survey Customizations

Archive PDF

Survey Termination Options:

(Optional) Auto-continue to next survey: Automatically start the next survey instrument after finishing this survey [?]

— OTHERWISE —

Redirect to a URL
(Redirect to a webpage when survey is completed)

Provide a full URL, e.g. `http://www.example.com/mypage.html, [survey-url:other_survey]`
[How to use Piping here](#)

— OR —

Survey Completion Text
(Displayed after survey is completed as 'thank you' text or as acknowledgement text)

Paragraph **B** *I*

Thank you for taking the survey.

Have a nice day!

[How to use Piping here](#)

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

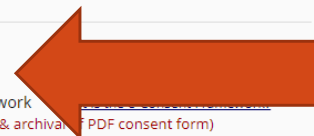
Auto-Archiver + e-Consent Framework
(includes end-of-survey certification & archival PDF consent form)

Send confirmation email (optional)?

(Email the respondent when they complete the survey)

Save Changes

Survey Settings ->
Survey Termination Options ->
Auto Archiver



E-Consent Framework

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:

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:

Send confirmation email (optional)?
(Email the respondent when they complete the survey)



Survey Settings ->
Survey Termination
Options ->
Auto Archiver

E-Consent Framework

- Creates template for e-consent survey
- Presents participant with confirmation page
- Auto-archives 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