



Everything you need to know

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#### What is REDCap?

REDCap (Research Electronic Data Capture) is a mature, secure web-based application for building and managing online data capture for research studies. REDCap is built by Vanderbilt University and licensed to Northwestern University. NUCATS is a member of the REDCap consortium.

 REDCap is a self-service tool that is offered at <u>no cost</u> to the study because Feinberg School of Medicine (FSM) subsidizes REDCap costs including support staff and IT infrastructure. Must follow FSM guidelines for usage.



How can REDCap assist my research?

REDCap assists medical research by allowing study teams to electronically collect data into research forms by creating and utilizing:

- Data entry instruments for study team members to login and record data points into forms from any location with internet access or with FSM approved devices via the Mobile App.
- Online surveys that allow study teams to send surveys/instruments directly
  to a participant via a public survey link or email address, allowing selfreporting measures to be recorded when a participant has access to an
  internet connection.



How can REDCap assist my research?

Electronic data collection benefits include:

- Allows study team members to view "real time" data collection updates
- Record status dashboard easily depicts study participant progress
- Ease of exporting data to share with statistician
- User Rights allows restricted levels of access to instruments, data, and duties for study team members including affiliates, e.g. data access groups
- Ability to easily duplicate instruments to use in other projects or to share with collaborators at other institutions (if they have a REDCap instance)
- Logging feature allows you to track easily contributor's activity within a project

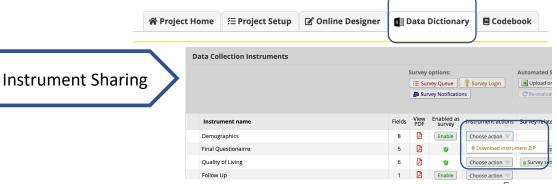


#### How can REDCap assist my research?

 $\textbf{Displaying:} \ \ \text{Instrument status only} \ \ | \ \ \underline{\text{Lock status only}} \ \ | \ \ \underline{\text{All status types}}$ 

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Participant ID	Demographics	Final Questionairre	Quality of Living		
	Version 1	6 Month	Version 1	Version 2	6 Month
<u>896</u>	(1)				
<u>897</u>		0		0	
898	+		+		<b>②</b>
899	• +	0	• +		
<u>LJH345</u>	(1)				
LV123	• +	0	+	<b>②</b>	
<u>SMM123</u>	+		+		
Tester 1	+	<u></u>	+		
ZOB123	<u>+</u>	•	<u>+</u>		







#### Who can use REDCap?

REDCap is a tool that is offered to the Feinberg School of Medicine (FSM) community in addition to research related activities at Lurie Children's and Shirley Ryan Ability Lab. Sanctioned uses of REDCap are:

#### **Human Subject Research**

- All research project status' must be determined by the IRB submission. All research types must provide the IRB number issued upon submission including IRB determined non-human subject & exempt.
- Operational projects or Quality Improvement projects <u>associated with a specific study</u> should be requested as a **research project** and should have the IRB number associated with it.

#### **Non-Human Subject Research**

- Operational projects or Quality Improvement projects for department or educational purposes must include the FSM affiliation disclosure upon project request submission. This may include descriptions that disclose FSM Faculty or usage for an FSM department.
- Lurie Children's and NMHC are <u>not approved</u> for Operational or Quality Improvement projects in which an FSM department or FSM Faculty is not the beneficiary of said usage.



When do I need to report REDCap system usage?

REDCap system details vs. REDCap usage details apply when:

- When reporting REDCap usage to IRB, details related to the study's intended use of REDCap is required but not system specific details.
- New research project requests require NU IRB study number. REDCap admin verifies
  valid IRB number and that study personnel is correctly listed on the Project Contacts list
  for the study. Lurie Children's studies must list 'REDCap User' to enable access to the
  study in Cayuse.
- Reporting usage of REDCap features, like Twillio and REDCap Mobile App, on the study's FSMIT Data Security Plan is required.



How to get started?

In order to begin, you must understand the role you will play when using REDCap. There are two defined roles and each has a set of specific requirements:

- Project User General user access to the system. Most commonly someone who will be added to an <u>existing</u> project by a Project Owner.
- Project Owner User who will be requesting a new project or transfer of an existing project and will have the unique responsibility of managing the REDCap project, i.e. design and user rights.



How do the REDCap Roles Differ?

Each role has a different set of requirements and responsibilities that must be adhered to. The requirements must be met in order to gain access.

- Project User All users, including Project Owners, are general users and are required to complete the REDCap Project User Agreement in order to gain access to the system. NU NetIDs are required for access.
- Project Owner Must complete the required New Project Owner Training Session and complete the REDCap Project Owner Agreement. Project Owners can request new projects to be created and/or transfer the ownership of an existing project. Project Owners manage the project including design and all User Rights.

How do I learn how to use REDCap?

REDCap is very user friendly! REDCap is a self-service tool, however, there are several resources to learn how to use REDCap:

- Training Videos REDCap Training Video Library offers videos that discuss the features and high-level discussion of how they work.
- o **Help & FAQ** REDCap FAQ offers detailed explanation of the features and problem-solving details.
- Shared Library Resource of templates provided by other institutions.
- Support Page Administrative details of how NUCATS REDCap instance is managed.
- o **eMail Support** Email questions to REDCap Support for trouble shooting assistance.
- o **Office Hours -** Register & attend REDCap Office Hours for one-on-one support session.

#### How do I learn how to use REDCap?

REDCap Support Page Link

**Training Videos** 

Page Link

Did you know that the NUCATS REDCap page has many answers to your most common questions? Visit NUCATS REDCap page for more information on: Access, project creation, and more!

Please log in with your user name and password. If you are having trouble logging in, please contact NU REDCap Support.

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REDCap Support Email

Username:	
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 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 ⊞ <u>brief summary video (4 min)</u>. If you would like to view other quick video tutorials of REDCap in action and an overview of its features, please see the <u>Training Resources</u> page.

Please note that any publication that results from a project utilizing REDCap should cite grant support (NUCATS is funded in part by a Clinical and Translational Science Award (CTSA) grant from the National Institutes of Health (NIH). UL1TR001422).

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.

#### **REDCap Features**

**Build online surveys and databases quickly and securely in your browser** - Create and design your project using a secure login from any device. No extra software required. Access from anywhere, at any time.

Fast and flexible - Go from project creation to starting data collection in less than one day. Customizations and changes are possible any time, even after data collection has begun.

**Advanced instrument design features** - Auto-validation, calculated fields, file uploading, branching/skip logic, and survey stop actions.

**Diverse and flexible survey distribution options** - Use a list of email addresses or phone numbers for your survey respondents and automatically contact them with personalized messages, and track who has responded. Or create a simple link for an anonymous survey for mass email mailings, to post on a website, or print on a fiver.

**Data quality** - Use field validation, branching/skip logic, and Missing Data Codes to improve and protect data quality during data entry. Open data queries to automatically identify and resolve discrepancies and other issues real-time.

Custom renorting - Create custom searches for generating renorts to

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What are common uses of REDCap?

REDCap is totally customizable but should only be used for the approved usage as reported to IRB. Common uses of REDCap are:

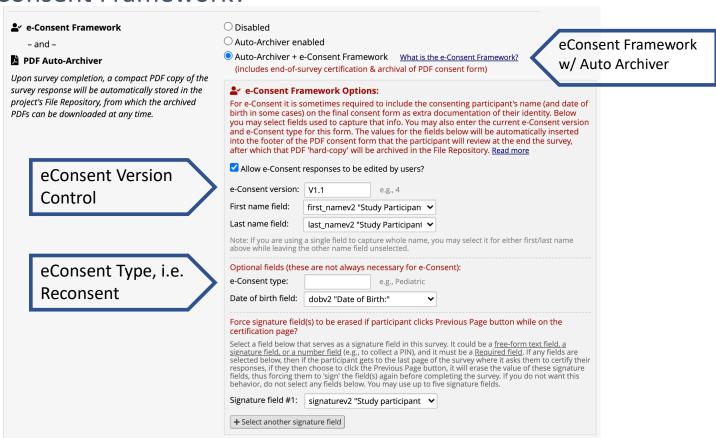
- Longitudinal Data Collection (study team member inputted)
- Recruitment Screeners (via Public Survey Link)
- Surveys sent directly to Participant's Email Address for self-reporting measures
- Electronic Consent Form Completion (eConsent)

#### What is eConsent?

eConsent is the ability to distribute and collect signatures electronically on consent forms. When utilizing the embedded eConsent Framework feature study teams can benefit from:

- o Electronic signature with time stamp and certification
- Accessible automatic central repository of signed consent forms via file repository
- Version Control of IRB approved Consent Form (settings under eConsent Framework)
- Ability to push completed pdf signed consent forms from REDCap directly to Study
   Tracker for FSM Policy Compliance

#### What is eConsent Framework?



What are the eConsent requirements?

IRB must approve usage of eConsent for all studies prior to utilizing this feature. The eConsent form should mirror exactly what is approved by IRB for your study's Consent Form.

If your study is an FDA study, additional requirements must be met:

- Completion of training specific to REDCap 21 CFR Part 11 Compliance
- eConsent: 21 CFR Part 11 Compliance Template <u>must be used</u>
- 21 CFR Part 11 Workflow must be adhered to as described in the training and compliance document. <u>Participant Validation & Record Retention are key</u> <u>components for Part 11 Compliance.</u>



What are some key tips when using eConsent?

REDCap projects are fully customizable but when working with an eConsent form be sure to consider the following when planning out your project design:

- How will you be collecting the signature? E.g. In clinic or participant self reporting on their own device
- Will there be more than one signature to collect on the consent form? E.g. Witness, Study
   Team Member, etc.
- Will the eConsent form follow a screening instrument or initiate other data collection instruments in the same project?
- Will you be utilizing the Study Tracker push/pull feature for signed consent forms?
- Will you have multiple versions of the consent form or be reconsenting a participant at any point?

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#### Thank you for your attention!

REDCap Support Team: redcap@northwestern.edu

REDCap Support Page: <a href="https://www.nucats.northwestern.edu/">https://www.nucats.northwestern.edu/</a> Search: REDCap

REDCap Office Hours: <a href="https://www.eventbrite.com/e/redcap-office-hours-">https://www.eventbrite.com/e/redcap-office-hours-</a>

registration-28947561937 (email REDCap Support for link)