



REDCap Research Projects: Part 11 Compliance and e-Consenting

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What is REDCap?

- REDCap stands for **R**esearch **E**lectronic **D**ata **C**apture and was initially created at Vanderbilt University to aid researchers across the world in sharing their projects. It has resulted in over **1.3 million** projects from over **2 million** users and **16K** journal articles which cite REDCap. Research is one of the main ways we use REDCap at Children's.
- 655 active research projects supported in CHOA REDCap for both CHOA and Emory

CHOA REDCap Homepage Overview

- Office hours take place every first Wednesday of the month.
- New project submissions are also completed on the REDCap home page.
- Webinars are monthly to discuss features in REDCap that can enhance any project.
- REDCap Basic Training takes place every month

<https://redcap.choa.org/redcap/>

Submit a New Project Request

Submit ticket to resolve REDCap ISSUES

Sign Up for a REDCap Training Class

REDCap Webinar Series

The REDCap team is offering monthly Webinars discussing features in the tool that can enhance any project. While you are anxiously awaiting the next in our series you can catch up on ones you missed by clicking [HERE](#)

Basic REDCap Training Dates and Times

Training classes cover basic REDCap skills needed to create a project and use basic features of the REDCap system. Classes are held each month and all trainings are from **9:00am to 1:00pm** and held in the **Support Building 1, (1575 NE Expressway)**.

November 19th: Conference A156, 1st Floor
December 10th: Conference A148, 1st Floor



REDCap Fees for Research

- All **externally funded** research must pay for the use of REDCap.
- All study teams at both CHOA and Emory should include REDCap service in their budget if externally funded.

Researchers will add REDCap as the data collection tool and storage for the study during the grant proposal stage. The following fees will be part of the budget process before the Notice of Award (NOA) is announced. The fees per study include:

REDCap Maintenance (one-time)	\$500
Consulting & Meetings and Development (five hours at \$60/per hour)	<u>\$300</u>
Total Fees per Study	\$800

Services	SLA	Pricing
Consulting & Meetings	Services will be provided between the hours of 8:00 a.m. and 5:00 p.m., Monday through Friday, except holidays.	\$60 per hour
Project Development	Services will be provided between the hours of 8:00 a.m. and 5:00 p.m., Monday through Friday, except holidays.	\$60 per hour
Maintenance and Support (includes storage, software upgrades, new module installation, environment testing)	Maintenance- will occur within established timeframes Support – Will follow established IS&T Major Incident Management Procedures	Included in initial fee
Training	Monthly training sessions are provided	Free Service



FDA 21 CFR Part 11+ REDCap

Validation complete: 4/9/21

JAF Consulting (Vanderbilt)

Expiration: 4/9/31



FDA 21 CFR Part 11

- FDA studies that capture and store data electronically **must** meet the regulations outlined under Part 11. All clinical trials must meet FDA standards.
- It is the **responsibility of the Sponsor and PI** to determine if their REDCap needs to meet 21 CFR Part 11 regulations and ensure compliance, not the REDCap team.

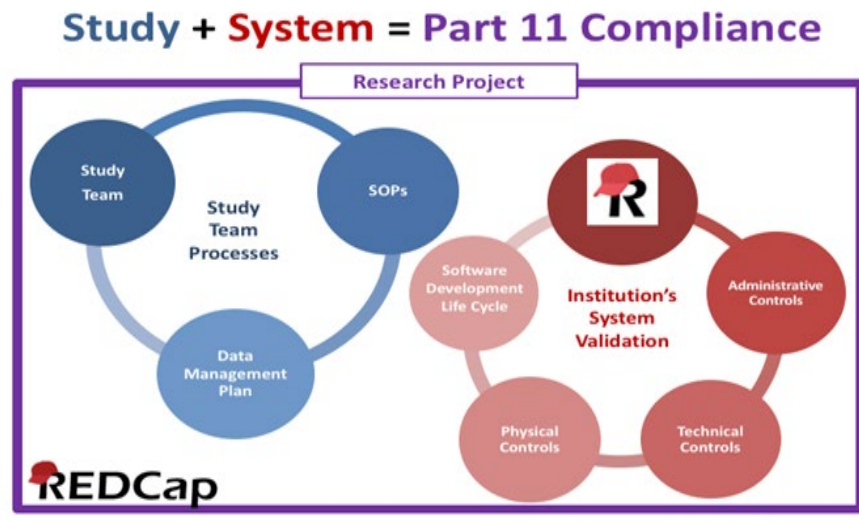
Sponsor and Investigator Responsibility for Part 11 Compliance

 <p>Sponsor</p> <ul style="list-style-type: none">• Responsibility for ensuring part 11 compliance in general lies with the sponsor• Sponsors should ensure part 11 compliance for the systems that they own and control and for Information Technology (IT) services that they outsource	 <p>Investigator</p> <ul style="list-style-type: none">• Responsible for the systems that they (or clinical site) own and control (e.g., an electronic investigator site file under the clinical investigator or site's direct control for archiving essential documents)	 <p>Sponsor-Investigator</p> <ul style="list-style-type: none">• Assumes the responsibilities of and must comply with FDA regulations applicable to both a sponsor and an investigator; these responsibilities include the submission and maintenance of an IND
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FDA Studies in REDCap

- CHOA REDCap has been validated for Part 11 Compliance
- To ensure your database will meet part 11 compliance, thoroughly complete the new project intake form to ensure the FDA project template is used. There is a training that must be completed by each study team for Part 11.
- The project template provided by the REDCap team has all the necessary functions turned on to ensure 21 CFR Part 11 for the system.



Requesting a Research Project

Request a new project

The screenshot shows the REDCap website navigation bar with links for Home, My Projects, New Project, Help & FAQ, Training Videos, Send-It, Messenger, and Control Center. A red-bordered box contains a warning: "Operational and Quality Control Projects must have a Director and above approval before moving projects into production. Project assistance services are no longer provided for *Operational* REDCap projects, effective January 2021." A red arrow points from this box to a blue button labeled "Submit a New Project Request". Below this button are two other buttons: a red one for "Submit ticket to resolve REDCap ISSUES" and a green one for "Sign Up for a REDCap Training Class". A light blue-bordered box at the bottom provides "Basic REDCap Training Dates and Times": "Training classes cover basic REDCap skills needed to create a project and use basic features of the REDCap system. Classes are held each month and all trainings are from 9:00am to 1:00pm and held in the Support Building 1, (1575 NE Expressway). June 25th: Conference A156, 1st Floor; July 30th: Conference A132, 1st Floor; August 27th: Conference A148, 1st Floor."

When completing the intake form, select “Research” and complete necessary fields including:

1. Funding information
2. IRB information
3. Whether the study needs to meet FDA Part 11 Compliance

Part 11 Compliance in REDCap

Key Features

- User rights and access
- Logging/Audit Trail
- Record-locking
- e-Consent framework
 - IRB approvals
 - Elements of Consent
 - Survey Distribution
 - e-Document storage
 - File repository
- Additional customizations

Key feature: e-Consent

- Electronic informed consent (eIC) may be used to either supplement or replace paper-based informed consent processes in order to best address the subject's needs throughout the course of the study.
- The information will be in language understandable to the potential subject or the subject's Legally Authorized Representative (LAR) and conveyed in a manner that minimizes the possibility of coercion or undue influence regarding the subject's decision to participate in a study (45 CFR 46.116 and 21 CFR 50.20).
- To ensure that the eIC is presented appropriately and that subjects will have enough time to dedicate to the eIC process, the subjects should be informed of approximately how long the process will take and what information will be presented to them.

e-Consent: 21 CFR Part 11 and IRB

- Electronic consent (e-Consent) must be approved by the IRB.
- The e-Consent should be identical to the paper form, not just the signature section. Paper copies can also be uploaded to REDCap.
- Once the e-Consent (consent/assent) has been drafted in REDCap, a PDF copy must be sent back to the IRB for final approval. e-Consent **cannot** be used until the IRB has approved it.
- For compliance purposes, the version date must always be listed on the consent.
- It is the PI's responsibility, not REDCap Admin, to ensure consent is compliant with the IRB and has been approved prior to its use.

***NOTE:** Any approved e-Consent record in the system must not be edited post approval or deleted for compliance.*

e-Consent: 21 CFR Part 11 and IRB

- The investigator must obtain IRB approval for any subsequent modifications to the study-related information, whether electronic or in hard copy (see 45 CFR 46.109 and 21 CFR 56.109).
- There shall be an operation and use procedure
- The subject can be re-consented
- HHS and FDA regulations require that the person signing the informed consent (i.e., the subject or the subject's LAR or the parents or guardians of subjects who are children) be given a copy of the written informed consent form (45 CFR 46.117(a) and 21 CFR 50.27(a)), unless the requirement for documentation of informed consent has been waived under 45 CFR 46.117(c) and 21 CFR 56.109(c)).

NOTE: Consent notes should still be entered into the EHR, not REDCap.

e-Consent Framework in REDCap

- The REDCap e-Consent Framework provides standardized tools to ***obtain consent and store consent documentation*** with a certification screen and a storage function which automatically generates a ‘hard-copy’ PDF of the signed form. *
- The ‘Auto-Archiver + e-Consent Framework’ survey option ensures a static copy of their responses in the form of a consent-specific PDF will be stored in the project’s File Repository.



FDA Project Template and Setup

Data Collection Instruments

Add new instrument:

- [Create](#) a new instrument from scratch
- [Import](#) a new instrument from the official [REDCap Instrument Library](#)
- [Upload](#) instrument ZIP file from another project/user or [external libraries](#)

Survey options:

- [Survey Queue](#)
- [Survey Login](#)
- [Survey Notifications](#)

Automated Survey Invitation options:

- [Upload or download Auto Invitations](#)
- [Re-evaluate Auto Invitations](#)

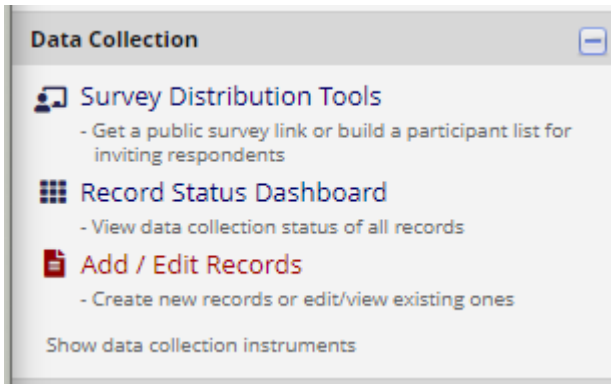
Instrument name	Fields	View PDF	Enabled as survey	Instrument actions	Survey-related options
Demographic Form	16			Choose action	Survey settings + Automated Invitations
Study Informed Consent (Subject 18+)	19			Choose action	Survey settings + Automated Invitations
Study Informed Consent Form (Parent)	23			Choose action	Survey settings + Automated Invitations
Study Assent Form For Minors	11			Choose action	Survey settings + Automated Invitations
Consent Signature Form Staff Only	17			Choose action	Survey settings + Automated Invitations
Assent Signature Form Staff Only	18			Choose action	Survey settings + Automated Invitations
Consent Signature Form: Translator	12			Choose action	Survey settings + Automated Invitations
Witness Information	3			Choose action	Survey settings + Automated Invitations
Consent Signature Form: Witness	12			Choose action	Survey settings + Automated Invitations
Protocol Deviation	10		Enable	Choose action	
Adverse Event	23		Enable	Choose action	

NOTE: Any changes to this template's project setup/settings and e-consent framework may render the project **no longer compliant** with 21 CFR Part 11.

The sponsor/PI will be responsible for any findings during an audit.

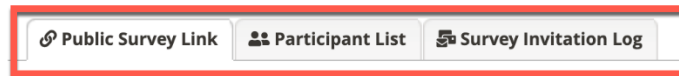
e-Consent Survey Distribution

- Under the Data Collection tab and verify the following links are available:
 - Survey Distribution Tools, Record Status Dashboard and Add / Edit Records.
 - Select “Survey Distribution Tools” and verify the following links are available:
 1. Public Survey Link
 2. Participation List
 3. Survey Invitation Log/Auto Survey Invitations (ASI)



The screenshot shows the 'Data Collection' menu with three main options: 'Survey Distribution Tools' (with a sub-description: '- Get a public survey link or build a participant list for inviting respondents'), 'Record Status Dashboard' (with a sub-description: '- View data collection status of all records'), and 'Add / Edit Records' (with a sub-description: '- Create new records or edit/view existing ones'). A 'Show data collection instruments' link is also visible at the bottom.

Survey Distribution Tools



Using a public survey link is the simplest and fastest way to collect responses for your survey. You may obtain the survey link below to email it to your participants. Responses will be collected anonymously (unless the survey contains questions asking for identifying data from the participant). **NOTE:** Since this method uses a single survey link for all participants, it allows for the possibility of participants taking the survey multiple times, which may be necessary in some cases.

To obtain the survey link, copy the URL below and paste it into the body of an email message in your own email client. Your email recipient(s) can then click the link to begin taking your survey.

Public Survey URL: 

Need Help?

- Once a project is in production, any questions or changes need to be made should be submitted through our ticketing system. To put in a ticket, use the big red button on the REDCap homepage.

Submit ticket to resolve REDCap ISSUES

Type of Problem
* must provide value

Access
Data/Reporting
Redcap is slow
Request changes to a project
Request a REDCap Consultant
Request API Token
REDCap Admins (do not use)
Other

in it

* must provide value

The image shows a screenshot of a web form. At the top, there is a green header with the text 'Type of Problem' and a red asterisk followed by 'must provide value'. Below this is a dropdown menu with a white background and a grey border. The menu is open, showing a list of options: 'Access', 'Data/Reporting', 'Redcap is slow', 'Request changes to a project', 'Request a REDCap Consultant', 'Request API Token', 'REDCap Admins (do not use)', and 'Other'. To the right of the dropdown menu, there is a small grey box with the text 'in it'. Below the dropdown menu, there is a red asterisk followed by 'must provide value'.

Questions???



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<https://redcap.choa.org/redcap>