REDCap Appropriate Use Guidelines

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Overview

The Clinical and Translational Science Institute (CTSI) has made Research Electronic Data Capture (REDCap) available to the Wake Forest Baptist Medical Center (WFBMC) community. REDCap provides a secure web application for building and managing online surveys and databases. REDCap enables rapid project development and provides users with advanced functionality, complete autonomy and control of projects, and direct exports to common statistical packages.

Purpose

The purpose of this policy is to provide guidance to WFBMC employees who utilize REDCap in the conduct of research related matters; including clinical, academic, and operational data collection.

WFBMC Model

REDCap is an open source software program created by Vanderbilt University and supported by the REDCap Consortium. WFBMC is a member of the REDCap Consortium; the software is available at no charge to Consortium Partners.

At WFBMC, there are three separate instances of REDCap. Wake Forest CTSI hosts two of these instances through the CTSI REDCap Portal located at https://redcap.wakehealth.edu. The CTSI also hosts a separate instance for the Wake Forest Comprehensive Cancer Center (WFUCCC) that can be accessed at https://redcap.wakehealth.edu/redcapccc.

CTSI REDCap Instances

The CTSI REDCap instances can be used for all institutional projects. The project team has complete control of their projects (from designing the project, assigning user roles, and completing tasks such as data entry, reporting, and data exports). The two instances are:

- **Internal:** REDCap Internal is completely contained within the WFBMC network and is available for all researchers' projects; most projects should be created within REDCap Internal, but there are instances where building on REDCap External is necessary.
- **External:** REDCap External is available for research projects that have been approved by the IRB and either have a public-facing survey or external collaborators. Also, non-research projects, such as event registrations that need a public-facing survey, will be hosted through REDCap External.

WFUCCC Instance

The WFUCCC REDCap instance is for Cancer Related Research Projects. Researchers are invited to use the WFUCCC REDCap when their projects are reviewed by the Cancer Center's Protocol Review Committee. The Cancer Center also offers assistance in setting up projects in the CCCWFU REDCap instance, utilizing staff in Clinical Research Management, Cancer Center administrative staff as well as Cancer Center Biostatisticians.

Servers

REDCap servers are behind the institution's firewall and are maintained by WFBMC Information Security (IS). The servers are backed up once daily, and back-up data are saved for thirty (30) days.

CTSI REDCap Account Access

If you are a medical center faculty, staff or student (anyone with a @wakehealth.edu email) you can automatically login to the CTSI REDCap system using your medical center ID and password at https://redcap.wakehealth.edu. While you can automatically login to the system, we highly recommend attending a training session or contacting the CTSI REDCap Team at ctsiredcap@wakehealth.edu before you get started with a project.

External User Access

External users (users that do not have a @wakehealth.edu email) can receive a login to our CTSI External REDCap system if they are working on a collaborative or multi-center project with WFBMC. External users must be working directly with a WFBMC employee in order to gain access to the CTSI REDCap system.

Only WFBMC users that have access to 'User Rights' on a project can request to add an external user account. The following is the responsibility of the WFBMC user that requests the account and not the responsibility of the CTSI REDCap Team:

- Ensure that the added external user adheres to all Wake Forest policies and procedures;
- Provide REDCap support (questions, trainings, etc.) for the added external user; and
- Grant the external user access to only the specific REDCap project they requested the account for.

CCCWFU REDCap Account Access

In order to gain access to the CCCWFU REDCap, contact Amy Landon (alandon@wakehealth.edu).

Pricing

REDCap is available for use to all WFBMC employees at no cost.

An individual may request the CTSI REDCap Team to provide project development (inclusive of data entry forms, surveys, etc.) for a fee. Please contact the CTSI REDCap Team at ctsiredcap@wakehealth.edu for a cost estimate based on the specific project needs.

Compliance

It is the user's responsibility to comply with all WFBMC policies and guidelines. If you are collecting data for the purpose of human subjects research, IRB approval is required.

IRB Responsibilities

The CTSI REDCap Team is not responsible for granting, approving, or waiving IRB project approvals. Any questions regarding IRB compliance with regard to project data should be directed toward the appropriate review board. Project Principal Investigators are responsible for ensuring that their project protocols allow for data capture, storage, and retrieval on our institution's REDCap instances and their REDCap project only collects data approved in their IRB application.

Training/Getting Started

REDCap is designed to be a self-service tool with minimal external instruction required to develop and deploy a project. Tutorial videos, a built-in Frequently Asked Questions knowledge bank, and embedded documentation are available and are used collectively to guide the user in utilizing the software.

Each REDCap consortium institution hosts its own separate and independent REDCap server(s) instance. REDCap software options, features and policies will vary at each institution. Please direct all inquiries you might have to the REDCap Administrators (ctsiredcap@wakehealth.edu) responsible for the WFBMC instances. The CTSI REDCap Team has access to many resources only available to REDCap Administrators; if a question is asked and the answer is unknown, we have contact sources to help answer unique or challenging questions that may arise.

CTSI REDCap Projects: Classroom Training

The CTSI offers two REDCap courses to teach users the functionality of REDCap. The first course is a prerequisite for the subsequent course. If a user feels strongly that the first course is not needed and

wishes to advance directly to the next course, contact the CTSI REDCap Team for consideration. All classes will be offered in Classroom A or B in the Coy C. Carpenter Library. Use the following link to register for an upcoming class: https://redcap.wakehealth.edu/redcap/surveys/?s=JPCXR8PCPK.

Beginner REDCap: Getting Started with REDCap
The Beginner REDCap course is designed to help users understand the benefits of using the REDCap software and its features. Course attendees will learn to create a database, enter data, and move a database into production. Within the creation of a database, attendees will also learn about creating a survey, field types, field validation, and basic forms of branching logic. (Prerequisite: None)

Advanced REDCap: Special Topics
This course is designed to provide exposure to applications and special features that are not covered in the Beginner class. This course will discuss the difference between classic and longitudinal projects, review how to create custom reports, and review advanced survey functionality, including the participant list, survey queue and automated survey invitations. (Prerequisite: Beginner REDCap)

CTSI REDCap Projects: One-on-One Consultations
After a REDCap user has attended classroom training sessions, if additional support is needed, a one-on-one consultation can be set up with a member of the CTSI REDCap Team. This will provide additional support for specific project needs.

CTSI REDCap Projects: Team Trainings
If an entire project team wants to receive training on a specific project, group trainings, separate from classroom training, can be scheduled. We request that this include several people at once, and requests will be reviewed as they are received.

Feature Presentations
The CTSI REDCap Team will present on general features and functionality of REDCap to a department, division, study team, etc. This presentation is not meant to train individuals, but to provide an introduction to the tool and allow individuals to ask questions to see if the tool could benefit an individual's project.

CCC REDCap Project Training
Any user that has a project in the CCC REDCap and would like REDCap training should contact the CTSI REDCap Team at ctsiredcap@wakehealth.edu.

Definition of Terms

Principal Investigator (PI)
The Principal Investigator is the person responsible for the conduct of the clinical research study and is typically the faculty leader conducting the research. This role includes responsibility for assignment of the project roles and authorizations to use specific forms and functions of the REDCap database to the members of the research team. The PI is the responsible party for making sure data collected in REDCap for research purposes aligns with the approved IRB protocol.

Project Owner
The project owner is the individual that creates the REDCap project. The Project Owner, in the absence of the PI, is responsible for assignment of roles and authorizations to use specific forms and functions of the REDCap project to the members of the project team.

Project Team/Member
Project Team/Members include the PI, Project Owner, research assistants/nurses, project managers, data entry persons and other personnel who have access to a REDCap project.

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Project

A project is a database or survey implemented in REDCap. It is a set of data entry forms, schedules and other REDCap instruments pertaining to a specific study or research project.

REDCap Administrator

REDCap Administrators are personnel responsible for implementation and maintenance of REDCap software, user education, and management of projects (e.g. approving project changes when in production). Those on the CTSI REDCap Team are the Administrators over all three institutional instances; additional REDCap administrators support the creation of projects specifically for the CCC instance.

Development Mode

Development mode is a state of the project that allows authorized team members to add, modify or delete data entry forms and other elements of the study design. Development mode allows for rapid project development as all changes to a project are immediately applied. This includes deletion of a project. Only test data should be entered into the database; no live data is allowed in REDCap until a project is thoroughly tested, moved into Production mode (described below), and IRB approval (if required) is granted.

Production Mode

Production mode is a state of the project that allows authorized team members to add, modify, or delete data. Any modification to the data collection design in this mode will need to be approved by a REDCap Administrator. The approval process allows changes to be reviewed and checked for errors to ensure data integrity.

Audits

The CTSI REDCap Team will complete one audit every quarter on the two CTSI REDCap Instances. This is to help properly maintain the system. The four audits are described below.

Inactive Projects

If a project has had no activity within the past year, it will be subject to the archival or deletion process. Projects will be reviewed with recommendations sent to the Project Owner with a deadline to acknowledge and approve the recommendation or provide an alternate solution.

Project Types/Purpose

REDCap projects are noted with one of many project types/purposes when being created: Practice/Just for fun, Operational Support, Research, Quality Improvement, and Other. Projects will be reviewed to fix any incorrect project purposes, with a specific focus on Research projects. All projects identified as Research will also be verified for correct PI, IRB, and study information.

Project Status

A project can exist in "development" or "production" status. Projects that are collecting live data are required to be in production status; this audit will review project statuses and update appropriately.

External REDCap Users

REDCap allows for external users through table-based authentication. This audit will review those created users, verify the project activity, and determine if that user is still a study team member on the specified project. All identified external users that are no longer involved in a project with WFBMC will be deleted from the system.

Ongoing

Terminated WFBMC employee lists are sent to the CTSI REDCap Team on a monthly basis. These lists are compared to the active accounts in our CTSI REDCap system and accounts are suspended as identified. This is an ongoing effort, with accounts checked when employee lists are provided to the Team.

Additional Maintenance

The CTSI REDCap Team will perform periodic system upgrades as needs are identified. Upgrades will include bug and security fixes, as well as new features and functionality. The CTSI REDCap Team will send an email to all accounts in the CTSI REDCap systems four business days in advance (if possible) to notify of system down time. During this time, users and survey responders will not be able to access REDCap. Most system upgrades require minimal amounts of down time (typically 30 minutes to 1 hour); if a longer down time is expected, this will be communicated further in advance to REDCap users.