ATRIUM HEALTH
OFFICE OF CLINICAL AND TRANSLATIONAL RESEARCH
STANDARD OPERATING PROCEDURE

Procedure No.: A-111   Title: REDCap Use
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Description: REDCap Use & Policy Statement   Version: 001

SUBJECT: Use of the REDCap application within the Atrium Health system, from either an internal or external (e.g., Citrix) connection, is held to the same SOPs, user guidelines, regulations, conditions, and principles of GCP that other applications across the system are subject to. Creating REDCap projects within the REDCap application allows for the collection of data and is the primary purpose of the application. When collecting data with REDCap, users are held to the same standards mentioned above, are the primary owners of that data, and are directly responsible for its collection, use, and management. Users of REDCap are responsible for providing accurate, up-to-date, and sufficient information regarding the project's purpose, use, design, and status as needed and/or requested by administrators.

POLICY: Data stored in any Atrium Health REDCap project is owned by Atrium Health. It is the responsibility of both the REDCap administrators and REDCap users to maintain, secure, capture, analyze and report on all data appropriately. REDCap administrators are responsible for maintaining good data management practices from the application and system level, while REDCap users are responsible for maintaining good data management practices at the project and system level. Default data responsibilities within a given project are maintained by the REDCap users who have created, requested, and operate daily within that project.

APPLICABLE REGULATIONS, GUIDELINES, POLICIES AND SOPs:
DAT 50.00 Data Governance Policy Statement
DAT 50.01 External Access to Data

A. User Access, Rights, and Management:
User access to and within REDCap is maintained by both REDCap administrators and project owners, respectively.

The process for a new user to gain access to REDCap and to be assigned and/or given privileges to/in a REDCap project proceeds as follows:
1. New potential user requests a new account in REDCap by completing the New User Access form
2. REDCap administrators create account for new user
3. New user receives confirmation email and follows link in email to log into REDCap

for the first time, creating a password
4. New user accesses new project for the first time via the My Projects page (when logged in) and creates a security password
5. Existing user(s) add new user to their projects via the projects' User Rights page

At this point, user access is complete. A user can be added to a REDCap project at any time by having the owner/creator/manager of that project add them via the User Rights page

B. Defining a "Project Owner"
1. By default, the owner of a REDCap project is the user who requested the creation of the project. REDCap administrators have access to all REDCap projects but do not own them nor are they directly responsible for their use and data contained.

The responsibilities of the Project Owner are as follows:
   a. if the current Project Owner is no longer involved in the project or no longer has reason to be the owner of a project, then it is their responsibility to assign ownership of that project to the appropriate team member.
   b. It is considered best practice to create a role in a project's User Rights section giving and labeling it "Owner", adding any user(s) to it who may need to accept the responsibilities of the Project Owner.
   c. Project Owners are designated by the users and their team, not by REDCap Administrators.

2. User rights within a project are the responsibility of the project's Owner
Project Owners are responsible for the rights of all users added to their respective projects. If a new user is added to a project, the Project Owner must set the rights allowed and restricted for that newly added user, and update user rights for all users in the project as appropriate. A project owner should be certain to not remove their rights to modify the rights of other users, as this will lock them out of the ability to manage user rights for the project.

3. Project-level access is granted to a project by the Project Owner
REDCap administrators do not assign users to projects without explicit written and documented requests from Project Owners that specify each individual right needed for the user. Due to this burden, Project Owners are responsible for adding new users to their projects, effectively giving the user access to their project, at whichever level of user rights they deem necessary for the newly-added users role.

4. Request for access must be submitted personally for each user
Each new user who requests access to REDCap must submit the request form located at https://rces.atriumhealth.org/redcap/surveys/?s=4A7T8PNAJE. Prospective users may NOT request accounts/complete this form on the behalf of anyone else. Each user must complete this request form for themselves and themselves only. If a user is in violation of this item, their account may become suspended for a specific period or be banned (deleted) altogether.

5. New user accounts require an institutional email address
   Any new user account request must include an email address that belongs to the company, institution, organization, or professional group with which the user belongs. Providing personal email addresses will not be permitted and will result the account request being rejected.

C. Restrictions

Restrictions on sharing credentials or using another user's credentials
1. REDCap users are not permitted to share their account credentials with any other individuals or groups to be used by anyone other than themselves.

2. This includes their username and password. This is in accordance with the IAS Account Management Policy regarding the misuse of system user account credentials. If a user is in violation of this item, their account may become suspended for a specific period or be banned (deleted) altogether.

Restrictions on sharing API credentials

3. REDCap users are not permitted to share their API credentials with any other individuals or groups to be used by anyone other than themselves.

4. This includes any API keys that they have assigned to them. API keys are created for users by Administrators and are intended to be unique to individual users in individual projects.

5. This is in accordance with the IAS Account Management Policy regarding the misuse of system user account credentials. If a user is in violation of this item, their account may become suspended for a specific period or be banned (deleted) altogether.

D. External Users

External user sponsorship
1. If a user accounts belongs to an individual that is not an employee of Atrium Health, then that individual and their account are "external".

2. All external user accounts are required to have an associated sponsor user who is an internal user and employee of Atrium Health.

3. User account requests for external users who do not stipulate an internal sponsor shall not be granted.

4. Once assigned to a sponsor, the activity and validity of the external user and their account becomes the secondary responsibility of their sponsor user.

5. REDCap Administrators will contact a sponsor if needed in place of contacting the external user or if the external user is unavailable.

6. Sponsors are given the ability to re-send account creation emails, reset passwords, set/update account expiration dates, and suspend/unsuspend external user accounts.

E. Management

Automated user management
1. Users/user accounts will be automatically suspended by the system if their account is inactive for greater than 185 consecutive days.

2. Inactivity is defined as a state where a user has not taken an action within a project within a given period. Accessing and/or browsing a project does not constitute as taking an action.

3. Users/user accounts will be automatically deleted (including any connection to project's they previously had, but not affecting any project metadata or collected data) if their account is suspended for greater than 365 days.

E. Project Types

Project Types, Purposes, and Use
1. When requesting a new project in REDCap, it is required that you provide/select the appropriate type of project you are creating, designating it accordingly.

2. The project types are Research, Quality Improvement, Operational Support, Practice, and Other.

3. These are not REDCap-specific, nor personally-defined options chosen by the user, but rather institutional- and industry-defined designations for clinical data collection repositories and datasets.

4. The project type which a user chooses is highly significant. They are each defined, designated, and are to be used as follows:

   a. Research
   b. Quality Improvement
   c. Operational Support
   d. Practice
   e. Other

5. Each of these types serves a specific purpose and is required to be correctly identified by the user who requests the creation of the project, at the time of the

project's creation.

6. All projects require the completion of at least two metadata fields (information fields provided to collect explanatory information pertaining to the scope and use of the project), Title and Project Notes.

7. If a user is in violation of improperly using a project that is not designated appropriately, their account may become suspended for a specific period or be banned (deleted) altogether.

Research project type

1. When using the Research project type, users must provide a variety of information pertaining to marked required fields.

2. All required fields must be completed before the project can be used in a live setting (Production Mode).

3. All information fields presented when selecting the Research project type are required unless otherwise noted.

4. IRB numbers are required for Research project types. If an IRB number is not available at the time of project creation, "TBD" may be used as a place holder until an IRB number is obtained.

5. The IRB Number will be required before moving to Productionmode.

Quality Improvement project type

1. When using the Quality Improvement project type, users must complete the standard Title and Project Notes fields.

2. As well, a copy of a completed and signed IRB QI vs Research form is required to be uploaded to the project's File Repository once the project is approved by Administrators.

3. The Quality Improvement project type is to be used when a project is deemed Quality Improvement by the IRB.

4. This project type is not up to the discretion of the REDCap user or REDCap Administrators to determine.

Operational Support project type

1. When using the Operational Support project type, users must complete the standard Title and Project Notes fields.

2. The Operational Support project type is to be used when a project is not collecting patient data in any way, is being used to support a departmental need for data

collection and analysis and does not pertain to any clinical investigatory objective.

3. This project type may not be used when conducting any form of research or quality improvement practices, studies, or operations.

Practice project type
1. When using the Practice project type, users must complete the standard Title and Project Notes fields. The project's title will automatically be tagged with a suffix of "(TEST)" by Administrators.

2. The Practice project type is to be used when a user simply needs a project to test a design, try out a function of REDCap, or practice using REDCap to become more adept with the application.

3. At no point may a Practice project be converted into a project type of any other category.

4. At no point may a Practice project go into production mode.

5. At no point may a Practice project contain patient data.

6. Practice projects are not secured data projects and therefore may not be used in any live data collection setting or study.

7. Practice projects may be cleared of data or deleted by Administrators as needed or required by the REDCap Administration team.

Other project type
1. When using the Other project type, users must complete the standard Title and Project Notes fields.

2. They must also provide a response in the "Please specify:" field explaining in detail why their project should be considered eligible of the Other project type.

3. Nearly all projects created in REDCap should fall into project types other than Other.

4. Other is reserved for special cases where non-research related data collection is required, and the project does not fit either Operational Support or Practice definition.

Project Statuses
1. Projects in REDCap will always exist in one of the four status stages:
   a. Development
   b. Production
   c. Archived

        d. Inactive

2. All new projects are automatically started in Development mode and then moved to Production mode when a user requests the move via the Project Setup page within their project.

3. Each status has a particular purpose and requirement before and during use.

F. Types of Uses

Use of Development mode
1. Projects immediately begin in Development mode once the project is approved to begin design and building by REDCap Administrators.

2. This mode is the stage in a project's lifecycle where the user will create the fields and instruments that will make up the project's data collection battery and tool set.

3. This is also the period when users will set all project settings, customize the design, test the project, and in all ways prepare the project to be used live for real data collection in Production mode.

4. In Development mode, live/real/actual patient data may not be entered, captured, collected, or otherwise stored in any area of module of the project. Any "data" (mock/trial/fake /test) that is entered into a project in Development Mode must be deleted in whole when moving to Production mode.

5. Data security features are not fully enabled in Development mode and any data stored in a Development project is not properly secured by Data Governance standards.

6. Therefore, all data in Development projects must be and is uniformly considered to be test data and is required to be removed before going into Production mode.

Use of Production mode
1. When a project's design is completed and tested, and the user is ready to begin live data collection , a project needs to be moved to Productionmode.

2. This action is initiated by the user at the bottom of the Project Setup page within the project itself. REDCap Administrators will review the "Move to Production" request and will either approve the project or ask the user to make edits to the project in order for it to pass successfully into Production mode.

3. When a project is moved to Production mode, all record data will be deleted so that the project begins without an obscuring data points or incorrect data set additions. Live data collection may not begin until a project is in Production mode.

4. Unless under special circumstance, once in Production mode a project must remain in this state until data collection is complete.

Use of Archived mode

1. A project should enter into an Archived state once all use of the project and its data have been completed.

2. Archived status does not delete data, nor does it modify it.

3. Archived status locks a project from further access and securely stores the data it contains until it is either ready for deletion or is required to be opened again at a later time if access to the data is required.

4. Users are required to manage their project statuses and will need to move their projects to Archived mode when ready and appropriate per their guidelines or research requirements.

5. Projects 1) in Production mode and 2) containing data, will automatically be eligible for Administrators to move them to Archived status if either of the following are true:

   a. The project is orphaned (contains no users)
   b. The project has had no user activity for greater than 365 days or 1 year

6. Users may move their projects to Archived mode at appropriate times (determined by their research requirements, grant rules, and Atrium Health data governance policies) by visiting the Other Functionality tab via the Project Setup page within their project.

7. Once a project is placed in Archived status, it will not appear on a user's My Projects page as access to the project would then be in a restrictive state.

8. To regain access to an Archived project, users must request as much from an Administrator.

Use of Inactive mode

1. A project should enter into an Inactive state when data collection is paused or restricted for specific circumstances or an extended period of time or if data collection is complete, but access to the data is still required.

2. Inactive status does not delete data, nor does it modify it. Inactive status restricts specific features in a project so that further data collection my not be allowed.

3. Users are required to manage their project statuses and will need to move their projects to Inactive mode when ready and appropriate per their guidelines or research requirements.

4. Projects 1) in Production mode and 2) containing data, will automatically be eligible for Administrators to move them to Inactive status the project has had no user activity for greater than 183 days or 6 months.

5. Users may move their projects to Inactive mode as needed by visiting the Other Functionality tab via the Project Setup page within their project.

Bringing a project Offline (Administrators only)
1. At any time, for specific reason, an Administrator may bring a project into an Offline state. Specific reasons for doing so must fit one or more of the following criteria:
   a. Part of the project's design is found to be in violation of REDCap SOPs, Data Governance requirements, data use agreements, and/or Atrium Health guidelines
   b. The project's integrity has been compromised by users of the project due to poor project management, improper access, or violating data collection practices.

G. Deletions

Project deletion
1. Projects in REDCap can be deleted by users or Administrators alike.

2. Users can "request" a project be deleted on the Other Functionality tab via the Project Setup page.

3. Administrators can then review and approve deletion of the project as appropriate.

4. Administrators are also able to delete projects if any of the following are true:

   a. The project is orphaned (contains no users) and contains no data
   b. The project has had no user activity for greater than 365 days or 1 year and contains no data
   c. If the project is a Practice project

5. Deleting a project deletes both the projects design, and all of the data collected in that project.

Deleting Practice projects
1. Practice projects should be deleted by the owner of the project (the user who started the project or the current user with highest privileges) or may be deleted by Administrators at any time due to need and database cleaning.

2. Practice projects are not intended to be kept long term. Because they are transient projects and do not have a data collection purpose, they are able to be removed

without concern over data loss.

3. It is the responsibility of the project owner to manage their Practice projects and delete them when they are no longer being used.

4. If a Practice project is left without any activity for greater than 365 days or 1 year, it will be eligible for deletion by REDCap Administrators.

Deleting projects that have exceeded archive requirement time windows
1. All projects in REDCap are held to Atrium Data Governance standards (IS.PHI 600.05, IS.PHI 600.06) regarding archiving andsaving research data.

2. Users are required to adhere to those standards and policies. Non-research data (Quality Improvement , Operational Support) is not held to these standards and should be deleted once it is no longer being used or required by any teammate or for any project or initiative.

H. Data Management and Collection

Data Management
1. Primarily, data contained within REDCap projects is the responsibility of the project owner and other users assigned to the project.

2. Once a project moves to Production mode, the users within that project take ownership of the data that is collected and captured.

3. Managing data within a project includes all responsibilities involved with collection, organization, reporting, exporting, importing, monitoring , and archiving a project's data set.

4. Data management within REDCap follows policy guidelines held in IS600.02.

Data collection only in Production mode
1. Data may not be collected or captured in any way while a project is in Development mode. It must be moved to Production before live/real/actual data can be collected and captured.

2. It is the responsibility of the user to limit test data entered into a Development mode project and never enter nor allow the entry of real patient or study data into a project in Development mode.

3. When a project is moved from Development to Production mode, all data within that project will be deleted.

   a. If live data is found to be entered into a project before it is moved to Production mode, the data must be deleted promptly, and the user will be

temporarily suspended from accessing REDCap.
      b. Repeated offenses of this nature will result in a user's account being suspended for 6 weeks.

Record ID field may not contain PHI

1. Projects will not be allowed to be moved into Production or therefore be used to collect any data if the project's design is such that the Record ID field has been edited or is being used to capture and PHI or HIPAA protected data elements.

2. The Record ID field, mandatory and automatically included in every REDCap project, is a unique value field used to identifyrecords.

3. This field may be used **in** a project-specific way to individually label new records added to a project, but it is set by default to automatically number new records in serial order (1, 2, 3….437, 438, 439...).

4. This setting can be changed the field can be customized, but it cannot be used to collect PHI or **HIP**AA protected data elements.

Standardization of data elements

1. When designing a new project, Atrium Health REDCap data collection standards should be followed.

2. These include field name labeling, variable name design, multiple-choice field choice coding and labeling, marking of identifiable fields, and data validation settings.

3. Specific common fields have been identified and have bee pre-built into all REDCap project templates.

4. Standardization will be reviewed as a project is moved from Development to Production.

5. Standardization rules must be met before a project can be moved to Production, unless appropriate justification can be made otherwise, namely if another coding system or variable naming system is being used on other standardized data collection instruments that are being built in REDCap for the purposes of the study or project.

6. If those standards are required to be used in the project for study-specific reasons, they will be allowed.

De-identifying exported data from a REDCap project

1. When exporting data from a REDCap project, de-identifying the data set is required if the data set contains identifying data elements. A user may only export full or complete data sets, including identifying data elements, if all of the following are

true:
    a. The data set will be accessed only by project teammates who have privileges and rights to be able to view the identifying data
    b. The data will not be released, posted, or transferred to any party in any manner outside of the Atrium Health system
    c. Exporting of the full data set is not restricted by other regulations pertaining to the study or project (e.g., grant restrictions)
    d. There is a project-specific need to export the full data set

2. Users of a project are fully responsible for all data within and exported from a project.

Avoiding the orphaning of projects
1. A project becomes orphaned when there are no longer any active REDCap users connected to that project.

2. If a project contains no users, it is immediately considered orphaned and REDCap Administrators will take appropriate action on closing and/or removing the project and its data.

3. To avoid this, project owners must make sure that appropriate access to their project is always maintained for other involved users.

4. If a project owner leaves their position and is no longer the owner of the project, their supervisor or another designated user must take over responsibilities of the project, else it is in danger of becoming orphaned and being closed or removed.

Archiving projects
1. Project owners or UHP (users with highest privileges) are responsible for archiving a project once it is no longer being used.

2. This is required to meet data governance standards and to maintain appropriate data security.

3. The determination of a project needing to be archived is left to the owners of the project and its data, however if the project should be neglected and/or meet any of the criteria mentioned in the "Types of Users" section, then it will become eligible for REDCap Administrators to take ownership of the project and archive it accordingly.

Using the REDCap Mobile App
1. When using the REDCap Mobile App to collect data for a project, data is stored on the mobile device itself, saved, to later be uploaded to the REDCap project once a secured internal internet connection can be achieved.

2. Therefore, REDCap Mobile App devices and data collected on them must be

Atrium Health approved devices (approved by IAS), and must follow guidelines outlined in IS 600.07.

3. Use of the REDCap mobile app must be installed on an Atrium approved and vetted device. Use of the device and data stored on it must be secured in accordance with Atrium device standards (IS 600.07, IS.PHI 600.01).

Administrative control and maintenance over REDCap

1. REDCap Administrators bear the responsibilities of monitoring, auditing for, and enforcing these standard operating procedures.

2. At periods chosen by REDCap Administrators, projects in REDCap may be audited for any and all conditions specified in this document for the purposes of data protection, patient protection, study design compliance, regulatory compliance, and in cooperation with appropriate efforts of other administrative bodies (e.g., IRB).

APPROVALS

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