LSU Health New Orleans SPH Epi Data Center REDCap Appropriate Use Policy

Purpose:
To provide guidance to LSU Health New Orleans faculty, staff, students, and affiliates who plan to use REDCap (Research Electronic Data Capture) for research or administrative data collection and management. To better protect research participants' privacy and confidentiality while assisting researchers in best practices for research using REDCap.

Scope:
REDCap is a web-based software program created by Vanderbilt University and supported by the REDCap Consortium to facilitate research and data collection. LSU Health New Orleans offers the support and use of the service to LSU Health New Orleans faculty, staff, students and affiliates.

REDCap has an authorization matrix, allowing different members of the study team to have different levels of access (no access, read-only or edit) to data entry forms, and access to project management and data export tools. There are provisions to restrict access to data export to allow export of de-identified data only.

REDCap enforces authorization granted to each user by providing and/or enabling certain functions, tabs, links and buttons according to granted privileges.

REDCap includes full audit trail, logging all changes and operations on the data, including viewing and exporting. The audit log records operation, date and time, and the user performing the operation, permitting review of the audit trail as necessary. Additionally, REDCap can help to ensure data quality through use of Double Data Entry mode, forms and records locking and electronic signatures.

Definition of Terms:
Project
Database or survey implemented in REDCap. This can include a set of data entry forms, study schedules and other REDCap instruments pertaining to a specific study, research project or for operational use.

Project Owner
A person responsible for the data collection for academic, clinical research and operational studies designed using REDCap. A PO is defined as the single person who will liaise with the EDC to request: a project to be set-up and assistance while designing a project. A PO's role includes adding users to the project and to delineating the users and their roles and authorizations to use specific forms and functions within the project.

Principal Investigator
A person responsible for the conduct of the clinical research study.

Project Team / Member / User

PI/PO, research assistants/nurses, project managers, data entry persons and other personnel granted access to REDCap projects.

REDCap System Administrators
LSU Health New Orleans EDC personnel responsible for maintenance of REDCap software and servers, user education and management of projects (ex: system upgrades, security patches, adding users to the Whitelist, moving to production, approving changes when in production, restoring project data from backup,).

External Users
A person who is not an LSU Health New Orleans faculty, staff member or student. This person can only obtain access to a project after the EDC has received a request to be added to the LSU Health New Orleans REDCap system by an internal LSU Health New Orleans user which will act as the external user's sponsor. This account needs to be renewed on a yearly basis.

Development Server
The development server is available to develop and refine new features and versions. It is not intended to capture real data. Production status has been disabled and is not allowed on development server. Both the Production and development servers are secure REDCap installations, so that any real data stored on the either server will be protected. Projects that are discovered to be collection real data on the Demo server will have to be moved by the Project Administrator to the Production server.

Production Server
The Production server is intended for IRB-approved projects (or projects with IRB exemption or waivers) that contain real data. Production status is only permitted on this server, as it requires a greater level of administrative oversight. Projects may be developed directly on the Production server but should be thoroughly tested before being moved to production status in order to avoid delays.

Project Status
A project can exist in "development" or "production" status. Development status allows for rapid project development as all changes to a project are immediately applied.
Once a project is moved to "production status" certain design changes must be approved by a REDCap administrator. The approval process allows changes to be reviewed and checked for logical errors that could lead to data corruption.

Development status
A status of the project that allows authorized team members to add, modify or delete data entry forms and other elements of the project design. No data is guaranteed to be preserved in the database in this status. All projects begin in development status. They are fully designed and tested with appropriate fictitious test data to ensure the design is complete and accurate. Projects must be moved to production status when they are ready for real data entry.

Production status
A status of the project that allows authorized team members to add, modify or delete data, but not edit a data entry form. Any data entered in this status will be protected by nightly backups for up to 30 days offsite.

Draft Mode

A project in Production Status needs to be in Draft Mode in order to make any changes to the form(s). If the changes are non-critical, they will be automatically approved while returned the project to production status. Critical changes must be approved by a REDCap Administrator before returning to production status.

Authentication
A confirmation from the authoritative source (Active Directory, LDAP etc.) that the user credentials (user name and password) are valid.

Authorization
A set of rights to access specific objects (forms, tabs, controls) in specific mode (read-only, read-write or edit, full data set, de-identified data set) granted to a user.

Policy
Any authenticated user has a right to access REDCap, review public projects (e.g., demo databases) and request a new database or modify a database to which corresponding authorization is granted (e.g., his/her own). Currently, LSU Health New Orleans EDC's LDAP and REDCap's table-based authentication serve as authentication sources. Any new user is strongly encouraged review the online tutorials before attempting to create new projects.

User Passwords
Access to the secure REDCap servers is provided in compliance with LSUHSC-NO guidelines. Each user is responsible for the security of their password.

User Right/Access
POs are granted full user rights to their project. POs are responsible for assigning appropriate privileges to all other users within the project.

For the duration of the REDCap project, if the PO elects to design the project his/herself, it is the responsibility of the PO to:

- Build the REDCap project (entry forms, project design)
- If Project consists of Level 3 data, consult with REDCap System Administrator to ensure all identifiable/sensitive data fields are protected
- Collect all the data necessary for required outcome analysis
- Test the project (User Acceptance Testing) prior to requesting the project be moved to production mode, including data entry, review of project unique identifier, data export formats, etc., to ensure the project design is suitable and appropriate
- Request project be moved to production
- Request design changes via the user interface during production mode
- Move the project to "Inactive" or "Archive" status once the project is complete

In addition to the above and specific to clinical research studies collecting data for the purposes of human subject research, if the PO elects to design the project his/herself, it is the responsibility of the PI or PO to:

- Obtain IRB approval of the project and data collection methods.
- Build the REDCap project (entry forms) in such a way that it corresponds to the study design and provides proper data collection tool for all the data necessary for testing study hypothesis.
- Collect all the data necessary for testing study hypothesis.

- Collect only minimally-necessary set of PHI/Level 3 data (protected health information), in addition to those required by study design or operational requirements, to positively identify study subject during data entry phase.
- Mark all PHI/Level 3 data fields as "Identifiers = Yes".
- Assign only Full Data Export rights for projects with PHI to those individuals trained to protect PHI and/or are using computers with encrypted disks.
- Manage access to the project to ensure compliance with HIPAA and other state and federal regulations protecting patient privacy and confidentiality (ensure that each user is granted the minimum amount of access needed to perform his/her duties).

REDCap System Administrators reserve the following rights:

- Record and track REDCap project databases, including the name of the PI, the date of project creation, and date of project move to production.
- Promptly remove or disable user access for persons and entities that no longer need access to REDCap.
- Review and assign protections to data fields with Level 3 information by indicating "Identifiers=Yes" when moving the project to production and assign protections to identifiers with Level 3 information.
- Delete data from the development server at any time.

Moving project from Development Status to Production Status Checklist:

- ✓ Review Identifier Fields
- ✓ Review PI/IRB/Project Use fields – make sure they are complete
- ✓ Review User Rights (Roles / Users)
  - Are Data Access Groups configured? If so, are users in them?
- ✓ Test records completed
- ✓ Review Forms/Events for completeness and proper settings
- ✓ Review Surveys and Survey Settings
  - Are Automatic Survey Invitations rules defined?
    - Have they been tested?
  - Is the Survey Queue, Email Designation or Auto-Continue set up for multiple surveys?
    - Has it been tested?
  - Is Survey Login being used?
    - Has it been tested?
- ✓ Review Missing Data Codes
- ✓ Check Branching logic for errors
- ✓ Review Data Management
  - Multiple choice fields intended for single-answer but defined as Checkbox – convert to dropdown or radio.
  - Multiple choice fields with choice ranges that overlap or have gaps – correct ranges.
  - Radio or dropdown fields intended for multi-answer – convert to checkbox field type.
  - Different coding for yes/no fields – should be coded consistently.
  - Different date formats (i.e, mix of mdy and ymd) – validate consistently across all dates.
  - Text fields that appear to be numeric or date-types without validation – validate appropriately.
  - Field appear to be identifiers and not tagged – need to tag HIPAA identifier fields as identifiers.

- Three or more fields that contain the same set of radio/checkbox options and no matrix questions – consider matrix questions.
- Variable names that contain the gibberish from a copying a field– create better variable names.

✓ Download a dataset to be sure statistician approves the results.
✓ Review all settings in the Project Setup module, including additional customizations.