Tulane SPHTM REDCap Appropriate Use Policy **January 6, 2016**

Purpose:

Give guidance to Tulane SPHTM faculty, staff, students and affiliates who are interested in using REDCap for research and operational data collection. To better protect the privacy and confidentiality of research participants while assisting researchers in best practices for research using REDCap.

Scope:

REDCap (Research Electronic Data Capture) is a web-based software program created by Vanderbilt

University and supported by the REDCap Consortium to facilitate research and data collection. Tulane University SPHTM CAEPH offers the support and use of the service to Tulane SPHTM 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 and operational studies, including assignment of the roles and the assigning of authorizations to use specific forms and functions of the REDCap project to the members of the project team.

Principal Investigator

A person responsible for the conduct of the clinical research study, including assignment of the roles and authorizations to use specific forms and functions of the REDCap clinical research database to the members of the research team.

Project Team / Member

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

Development instance

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. In the development mode, the database is temporary and is not backed up. No data is guaranteed to be preserved in the database in this mode.

Production instance

A state of database that allows authorized team members to add, modify or delete data. Any data entered in this instance will be protected by nightly backups for up to 30 days. Any modification to the data collection design in this mode will need to be approved by a REDCap Super User (by REDCap design). The REDCap Super User offers as a service to review proposed changes before approval to ensure data integrity; should PI opt out by requesting that the REDCap Administrator automatically approve any changes, it will be PI/PO's responsibility if the changes violate data integrity or consistency.

REDCap System Admin

Tulane CAEPH personnel responsible for implementation and maintenance of REDCap software and servers (ex: restoring project data from backup, system upgrades, security patches).

REDCap Super User

Tulane SPHTM personnel responsible for user education and management of projects (ex: moving to production, approving changes when in production).

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.

Policies

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, Tulane'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.

For the duration of the REDCap project, it is the responsibility of the PI/PO to:

- Provide a list of Project Team/Members who will have access to REDCap
- Build the REDCap project (entry forms, project design)
- If Project consist of Level 3 data, consult with REDCap Super User to ensure all identifiable/sensitive data fields are protected
- Collect all the data necessary for required outcome analysis
- Assign and maintain the roles and authorizations for project members to use specific forms and functions (grant and restrict access via User Rights page)
- 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, it is the responsibility of the PI/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 (containing sensitive information).

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 Super Users 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 instance (aka Training Instance) at any time.