HSPH REDCap Appropriate Use Policy

Purpose:

Provide guidance to HSPH Employees and Harvard Catalyst affiliates who would like to use REDCap in the conduct of Harvard School of Public Health research related matters; including clinical, academic, and operational data collection. To protect patient privacy and confidentiality while assisting researchers in conducting clinical research using REDCap database.

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. Partners HealthCare Research Computing ERIS in collaboration with the Harvard Catalyst | The Harvard Clinical and Translational Science Center offers the support and use of the service to HSPH personnel.

REDCap has an authorization matrix, allowing different members of the study team to have different levels of access (none, 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, recording all 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

PO

Project Owner. A person responsible for the conduct of non-clinical studies (ex: academic, operational) data collection, including assignment of the roles and authorizations to use specific forms and functions of the REDCap project to the members of the project team.

PI

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.

Project

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

Development mode

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 mode

A state of database that allows authorized team members to add, modify or delete data. Any data entered in this mode 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

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

REDCap Super User

HSPH 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.

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, HSPH 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:**

- Request project creation by completing the IRB Initial Application For Human Research, Exemption/Non-Human Subject Determination Request Form
- Provide a list of Project Team/Members who will have access to REDCap
- Submit Amendment to IRB to add/remove REDCap Users
- 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 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:

- Ability to notify and report to the IRB and/or HSPH Information Technology Privacy Officer on the activity and authorized users of all human research projects. The report will allow the IRB to monitor protocol compliance.
- Grant access to the IRB / Privacy Officer upon request to audit projects.
- Record and track IRB-approved research protocols utilizing REDCap in a database, including the name of the PI, the IRB protocol number, 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.
- Create "revision reports" within the project while reviewing requested changes. Reports will be deleted immediately after review.
- 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.