ADMINISTRATIVE POLICY AND PROCEDURE

SUBJECT: APPROPRIATE USE OF REDCap and REDCap Survey		
OWNER: RESEARCH INFORMATICS CORE of ICTR		
EFFECTIVE DATE: 7/18/2011	REVISED DATE: N/A	SUPERSEDES: N/A

Scope:

All researchers wishing to use REDCap for managing clinical research data or REDCap Survey for collecting study participants' responses on-line.

Purpose:

To protect patient privacy and confidentiality while assisting clinical researchers in conducting clinical research.

Preamble:

REDCap (Research Electronic Data Capture) and REDCap Survey are powerful software programs created by Vanderbilt University and supported by the REDCap Consortium to facilitate Institutional Review Board (IRB)-approved clinical research and basic research. Data collected in the course of the research are managed by the program, and can be analyzed by commonly used statistical packages, including SAS, Stata, SPSS, and R.

REDCap has a flexible and fine-grained 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 database 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.

REDCap enforces data integrity protection by design; all "databases" created by users are logical data sets on top of relational database with built-in integrity protection controls. 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:

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.

Research Team

PI, Research assistants, nurses, data entry persons and other personnel granted access to the REDCap clinical research database.

Database

Clinical Research Database 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 database that allows authorized research 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 research team members to add, modify or delete clinical research data. Any data entered in this mode will be protected by regular mirroring to the stand-by server and periodic backups. Any modification to the data collection design in this mode will need to be approved by the RIC (by REDCap design). RIC offers as a service to review proposed changes before approval to ensure data integrity; should PI opt out by requesting that RIC automatically approve any changes, it will be PI's responsibility if the changes violate data integrity or consistency.

RIC

Research Informatics Core of the ICTR. A group responsible for implementation and maintenance of the REDCap, for user education, and for management of databases (moving to production, approving changes when in production, restoring from backup etc.).

ICTR

Montefiore-Einstein Institute for Clinical and Translational Research.

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 databases (e.g., demo databases) and create a new database or modify a database to which a corresponding authorization is granted (e.g., his/her own). Currently, Yeshiva University Active Directory, Einstein College of Medicine LDAP and Montefiore Intranet serve as authentication sources. Montefiore users who do not have Yeshiva University Exchange account or Einstein College of Medicine LDAP account or Montefiore Intranet account need to contact RIC (call (718) 430-2440 or email richelp@einstein.yu.edu) to get access to the REDCap. There are two REDCap installations available: http://informatics22.aecom.yu.edu/redcap (development only) and http://informatics23.aecom.yu.edu/redcap (development and production).

Any new user is strongly encouraged to make an appointment with RIC for an introduction to REDCap (about 1 hour) before attempting to create a new database in REDCap. Please send a proposed study design (protocol or grant submission) to RIC at least 1 working day before the appointment.

Any new database will be created in development mode. When in development mode the user cannot enter any identified patient information. For testing purposes use made-up identifiers. RIC will periodically review contents of all databases in development mode to ensure compliance and report violations to the Privacy Officer of the institution whose data is being used. In the case of data regarding patients or subjects of Montefiore or Einstein, all users must comply with Montefiore's "Policy for the Use of Patient Medical Records in Research" Policy # PNP29 and "Electronic protected health information security" Policy # JH69.1.

It is the responsibility of the PI to:

- Build the REDCap database (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 (hypotheses)
- Collect all the data necessary for testing study hypothesis (hypotheses)
- Collect only minimally-necessary set of PHI, in addition to those required by study design or operational requirements, to positively identify study subject during data entry phase

Alternatively, the PI may request that RIC assist with development of the REDCap database for the study.

To move a database into production, the study PI or authorized PI representative needs to request a review by RIC, providing the following information:

- IRB-approved research protocol (for clinical studies) or final version of the research protocol (for studies not requiring IRB approval)
- IRB approval letter (for clinical studies)
- A signed copy of this policy.

After review and approval, RIC will move the database into production and the study team will be able to collect research information.

REDCap and REDCap Survey are being supported by RIC. RIC bears responsibility for maintenance of the software, database deployment (moving to production) and data security and integrity.

The PI is responsible for managing access to the PI's database(s) to ensure compliance with HIPAA and other state and federal regulations protecting patient privacy and confidentiality.

Review of audit trails of any user over any period of time will be undertaken at the request of the Decision Support Group, Director of MIS, Director of HIPAA Security or Chair of the Institutional Review Board.

IRB-approved research protocols, utilizing REDCap or REDCap survey, will be recorded by the RIC in a database, which will keep the name of the PI, the title of the protocol, the IRB protocol number, the date of access provision, and date of access deactivation.

IRB Auditing

- The IRB will be regularly sent an auditing report on the activity and authorized users of all human research projects. The report will allow IRB to monitor protocol compliance.
- Upon request, the IRB will have access through RIC to an audit report of IRB approved use.