Research St. Joseph's – Hamilton (RSJ-H)			**Pages** 1 of 4	**Number** 051-RSJ-H
Policy Title REDCap™ Appropriate Use			**Date** 01 April 2014	
Supersedes New policy		**Cross Reference**	**Issuing Authority** RSJ-H Scientific Director	
☑ Charlton Campus	☑ West 5th Campus		☑ King Campus	

Position responsible *for developing and maintaining the policy: RSJ-H Scientific Director*

1.0. PURPOSE

Provide guidance to those associated with RSJ-H who would like to use REDCap™ in the conduct of research related matters; including clinical, academic, and operational data collection. The purpose of this policy is to assist investigators to protect patient privacy and confidentiality while assisting researchers in conducting clinical research using the REDCap database.

2.0 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. The Research St. Joseph's – Hamilton Information Services group offers the support and use of the service to those associated with RSJ-H.

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.

REDCap is third-party software. In no way does RSJ-H certify software integrity or take responsibility for the software or its operation. Unexpected behavior, data loss and failure may occur at any time and although RSJ-H will do its utmost to reduce the risk of such events it in no way certifies that they will not occur.

3.0 DEFINITION OF TERMS

3.1 **PI / Principal Investigator** - A person responsible for the conduct of the 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.

3.2 **Project Team Member** – PI, research assistants, nurses, project managers, data entry persons and other personnel granted access to REDCap projects.

3.3 **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.

3.4 **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.

3.5 **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 back-ups 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 the PI's responsibility if the changes violate data integrity or consistency.

3.6 **REDCap System Admin** - RSJ-H personnel responsible for implementation and maintenance of REDCap software and servers (example: restoring project data from back-up, system upgrades, security patches).

3.7 **REDCap Super User** - RSJ-H personnel responsible for user education and management of projects (example: moving to production, approving changes when in production).

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

3.9 **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.

4.0 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, REDCap's table-based authentication serves as the sole authentication source. Any new user is strongly encouraged to review the online tutorials before attempting to create new projects.

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

1. Ensure the project has been appropriately approved by the Hamilton Integrated Research Ethics Board (HiREB).
2. Provide a list of Project Team Members who will have access to REDCap to Research Administration.
3. Submit Amendments to HiREB, as necessary, to ensure continuing compliance with research protocols.
4. Build the REDCap project (entry forms, project design).
5. If Project consists of Personal Health Information (PHI) data, consult with REDCap Super User to ensure all identifiable/sensitive data fields are protected.
6. Collect all the data necessary for required outcome analysis as approved by HiREB. A consultation with the biostatistics unit is strongly recommended prior to project start to ensure that the data collected will meet these requirements.
7. Assign and maintain the roles and authorizations for project members to use specific forms and functions (grant and restrict access via User Rights page).
8. 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.
9. Request project be moved to production.
10. Request design changes via the user interface during production mode.
11. 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:

1. Obtain HiREB approval of the project and data collection methods.
2. Build the REDCap project (entry forms) in such a way that it corresponds to the study design and provides proper data collection tools for all the data necessary for testing study hypothesis.
3. Collect all the data necessary for testing study hypothesis.
4. Collect only minimally-necessary set of PHI data (protected health information), in addition to those required by study design or operational requirements, to positively identify study subject during data entry phase.

5. Mark all PHI data fields as "Identifiers =Yes".

6. Assign only Full Data Export rights for projects with PHI to those individuals trained to protect PHI and/or are using computers that meet the requirements for containing sensitive information.

7. Manage access to the project to ensure compliance with the *Personal Health Information Privacy and Access Act* (PHIPAA) and other provincial 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:

1. Ability to notify and report to HiREB and/or Information Technology Privacy Officer on the activity and authorized users of all human research projects. The report will allow HiREB to monitor protocol compliance.

2. Grant access to HiREB / Privacy Officer or other authorized auditors (such as Health Canada or auditors authorized by RSJ-H) upon request to audit projects.

3. Record and track HiREB approved research protocols utilizing REDCap in a database, including the name of the PI, the HiREB protocol number, the date of project creation, and date of project move to production.

4. Promptly remove or disable user access for persons and entities that no longer need access to REDCap.

5. Create "revision reports" within the project while reviewing requested changes. Reports will be deleted immediately after review.

6. Review and assign protections to data fields with Personal Health Information by indicating "Identifiers=Yes" when moving the project to production and assign protections to identifiers with PHI.