Research St. Joseph's – Hamilton (RSJ-H)			**Pages** 1 of 5	**Number** 051-RSJ-H
Policy Title REDCap™ Appropriate Use			**Date** 22 April 2024	
Supersedes 31 March 2022		**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; specifically, research, educational, and operational data collection – REDCap is not permitted for clinical use. The purpose of this policy is to assist investigators, to protect patient privacy and confidentiality, to ensure that all data is collected within the bounds of the REDCap license (https://projectredcap.org/partners/termsofuse/) and institutional requirements.

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. RSJ-H is a member of this consortium and is permitted to run a copy of the software on its server (an instance). RSJ-H can allow Principal Investigators and their Project Team Members and collaborators access to the software provided that the REDCap licensing and institutional requirements are met.

The RSJ-H instance of REDCap is **NOT** currently a validated instance and should not be used for regulated clinical trials.

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 a 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** - An RSJ-H affiliated researcher responsible for the conduct of the research study or research project, including assignment of the roles and authorizations to use specific forms and functions of REDCap 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 research study or research project.

3.4 **Development Mode** - A state of the Project that allows authorized Project Team Member 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 Development Mode.

3.5 **Production Mode** - A state of the Project that allows Project Team Members to add, modify or delete data. Any data entered in Production Mode will be protected by nightly back-ups for up to 30 days. Any modification to the data collection design in Production Mode will need to be approved by a REDCap Super User. The REDCap Super User offers as a service to review proposed changes before approval to ensure data integrity.

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

3.7 **Authentication** - A confirmation from the authoritative source (REDCap table-based authentication) that the user credentials (user name and password) are valid. Additionally, persons accessing REDCap from outside of the St. Joseph's Healthcare Hamilton network will be required to provide a second level of authentication (emailed code or Google Authenticator).

3.8 **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., their own). Currently, REDCap's table-based authentication serves as the sole Authentication source. Any new use must review the online tutorials before attempting to create new Projects.

For the duration of the Project, it is the responsibility of the PI to:

1. Ensure the Project has been approved through an RSJ-H authorized research ethics board (REB),

as required.

2. Ensure that if used as part of a non-regulated multi-site research study, the RSJ-H affiliated researcher must be the lead PI of the research study and RSJ-H must be the primary, coordinating site for the study.

3. Work with RSJ-H administration to ensure that all agreements are in place with any external site that will be entering data into the RSJ-H instance of REDCap before starting data collection.

4. Provide a list of Project Team Members who will have access to REDCap to RSJ-H administration.

5. Submit amendments to REB, as necessary, to ensure continuing compliance with research protocols.

6. Build the 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. Unless there is a statistician as part of the Project team, the PI must consult with the Research Methodologies Centre prior to Project start to ensure that the data collected will meet these requirements.

7. Collect only the minimally necessary set of personal health information (PHI), in addition to those required by study design or operational requirements, to positively identify study subject during data entry in Production Mode. Mark all PHI data fields as "Identifiers =Yes".

8. Collect only the data necessary for required outcome analysis as approved by the REB. Assign and maintain the roles and authorizations for Project Team Members to use specific forms and functions (grant and restrict access via User Rights page).

9. Assign only data export rights for Projects with PHI to those individuals trained to protect PHI and who are using computers and systems that meet the requirements for containing sensitive information.

10. 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 appropriate. When a Project is in the Development Mode, no data collection can take place.

11. Once moved from Development Mode to Production Mode, data collection can commence.

12. Manage access to the Project to ensure full compliance with the Personal Health Information Protection Act (PHIPA) and all other applicable provincial and federal statutes and regulations protecting patient privacy and confidentiality (including without limitation, ensuring that each user is granted the minimum amount of access needed to perform his/her duties).

13. Once data collection is complete, move the Project to "Analysis/Cleanup" status. This will "freeze" that database so no new data can be entered.

14. Once analysis is complete, move the Project to "Complete" status or delete the Project.

15. Ensure that you have securely stored the exported data with the study documents and can keep all of them for the length of time required by applicable regulatory requirements or the retention period stated in the approved ethics application.

REDCap Super Users reserve the following rights:

1. Ability to notify and report to REB and/or St. Joe's Privacy Office on the activity and authorized users of all human research studies. The report will allow the REB to monitor protocol compliance.

2. Grant access to REB / St. Joe's Privacy Office or other authorized auditors (such as Health Canada or auditors authorized by RSJ-H) upon request to audit Projects.

3. Record and track REB approved research protocols utilizing REDCap in a database, including the name of the PI, the REB protocol number, the date of Project creation, and date the Project moved to Production Mode.

4. Suspend Projects that are deemed to be in violation of the REDCap license or institutional requirements.

5. Promptly remove or disable user access for persons and entities that no longer need access to REDCap or who are deemed to be in violation of the REDCap license or institutional requirements.

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

7. Review and assign protections to data fields with PHI by indicating "Identifiers=Yes" when moving the Project to Production Mode and assign protections to identifiers with PHI.

Appendix A

REDCap License Terms

See: https://projectredcap.org/partners/termsofuse/