Standard Operating Procedure:
REDCap Project Lifecycle

SOP Number:	111
Version Number:	3
Department/System:	Health Research BC/BC SUPPORT Unit
Supersedes:	N/A
Number of pages including cover:	5

Document History

Version Number:	Summary of Changes Made:	Effective Date:
1	New document	April 2, 2020
2	Update/refresh	March 11, 2020
3	Change of legal name and logo from BC AHSN to Health Research BC	March 18, 2022

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1. PURPOSE

1.1. To define the standard project management approach for projects that are conducted in Health Research BC REDCap. All REDCap projects should broadly fit within this approach; however, some details may be specific to a particular project.

2. SCOPE

2.1. This procedure applies to all Health Research BC DM team members, designated Project Administrators (PA) and Principal Investigators (PI) involved in managing and developing a REDCap project.

3. RESPONSIBILITIES

3.1. The PA/PI is responsible for ensuring that the study meets all of the applicable regulatory, International Conference on Harmonisation (ICH) Good Clinical Practice (GCP), and local requirements.

3.2. The PA/PI is responsible for providing the necessary study-specific content required and following any standard operating procedures and policies at each step in the process.

3.3. The Health Research BC DM team is responsible for overseeing all stages of Health Research BC REDCap projects, conveying issues to the project teams and communicating with Health Research BC DM team members as necessary.

3.4. The Health Research BC DM team members are responsible for following the lifecycle tool and any standard operating procedures, policies, working practices and guidelines related to the lifecycle.

4. RELATED SOPS/DOCUMENTS

4.1. Health Research BC REDCap Project Request form
4.2. Health Research BC REDCap Approval and Payment form
4.3. SOP 100 – Health Research BC REDCap New Project Request
4.4. SOP 101 – Health Research BC REDCap Adding New Users
4.5. SOP 102 – Health Research BC REDCap User Training
4.6. SOP 103 – Health Research BC REDCap Service Agreement & Project Creation
4.7. SOP 104 - Health Research BC REDCap Invoicing & Payment
4.8. SOP 107 – Health Research BC REDCap Project Archiving

5. DEFINITIONS

5.1. **Principal Investigator (PI):** Primary individual in charge of and responsible for the proper conduct of a research project.

5.2. **Project Administrator (PA)**: Person responsible for the development of REDCap data instruments and the overall management of the project data.

5.3. **Research team**: Research assistants/nurses, data entry personnel and other personnel involved in the clinical research study and granted access to REDCap projects. The Research team members report to the PI but are generally supervised by the PA.

5.4. **Health Research BC Data Management (DM) team**: team that is responsible for managing projects in REDCap and assisting research teams in conducting research studies.

5.5. **REDCap Project**: A set of data entry forms, surveys, schedules and other data management tools pertaining to a specific study or research project.

5.6. **Project Lifecycle Tool:** An active, internal project used by the Health Research BC DM team to track the lifecycle of projects and to assist in REDCap data management.

5.7. **Service Agreement:** The joint contract agreed to by both the Health Research BC DM team and the PI or PA for commencement of work and services related to REDCap project data management as outlined.

6. PROCEDURE

6.1. Service Agreement Preparation & Approval

- *See SOP 103: Health Research BC REDCap Service Agreement & Project Creation.*

6.2. Project Creation

This applies to projects with a Service Agreement that has been approved by the Health Research BC DM team and signed by the PI/PA.

- *See SOP 103: Health Research BC REDCap Service Agreement & Project Creation.*

6.3. Development Phase

The development phase includes creating and designing instruments (*see SOP 103*), training (*see SOP 102*), testing and the set-up of user accounts and user rights/roles (*see SOP 101*). In most instances, the research team will design their own study. In this phase, the REDCap project is in Development Mode.

a) If the Health Research BC DM team is in charge of the project implementation, the required project deliverables will be configured, tested and documented by Health Research BC DM team. The DM team may also be responsible for approved changes and control of the changes if new requirements are requested or discovered during the course of the project, or the research team will be trained to modify their project directly.

b) If the Health Research BC DM team has not been involved in the design and implementation aspects of the project, the team's role will be restricted to train the research team members to perform implementation procedures correctly in REDCap. It is the sole responsibility of the research team to ensure that the implementation of the project follows their own procedures and any applicable regulations.

6.4. Production Phase

a) Once the project has been designed and tested by the PA/PI and has been requested to go to production, the Go To Production tool should be run to ensure sufficient testing and no design deficiencies. If any deficiencies are observed, they will be sent back to the research team for further review and modification, prior to being authorized to move to production.

b) Any changes to the project while in production can be made in "Draft Mode" and approved by the Health Research BC DM team.
- Changes beyond what is considered safe to be authorized automatically, will be reviewed and approved by the DM team. The DM team will contact the research team if necessary, to alert of the possibility of data loss and suggest an appropriate solution.
- The PA should monitor data before and after Draft Mode, to ensure data integrity and all procedures are being followed.

c) At this phase, user rights in the project should be adjusted for each user according to their role, on a need-to-know basis. The Health Research BC DM team will review user rights and make recommendations when moving projects to production.

d) The Health Research BC DM team will provide ongoing support as per the requirements specification and as per the REDCap Service Agreement. Upon request, the DM team will assist the research team in resolving project-specific problems. This one-on-one assistance will be provided either in person, over the phone, email or via ticket system correspondences (see SOP 102).

6.5. Analysis Phase

a) After the data collection is complete, all data management tasks are completed and final data delivery accomplished, the project is ready for analysis.

b) Prior to starting analysis, the PA/PI should perform the following data collection closure steps. (Note: closing data collection is fundamental to preventing inadvertent or unauthorized changes once the final analysis, reporting of the data have begun).

6.5.1 Disabling surveys
6.5.2 Adjusting user rights and remove data entry privileges
6.5.3 Locking data collection forms so no additional changes can be made
6.5.4 Verify data quality and integrity using the Data Quality module

c) PA/PI can then export the data from REDCap (with appropriate security for storage and data transfer), and analyze in a statistical package.

6.6. Archiving Phase

- *See SOP 107: Health Research BC REDCap Project Archiving.*

6.7. Additional Project Development Support

a) If additional services are requested, the DM team refers the research team to various training materials and/or sets up training (see SOP 102).

7. REFERENCES

- N/A