





## Standard Operating Procedure: REDCap Project Lifecycle

SOP Number:	101
Version Number:	1.0
Approved Date:	December 14, 2020
Department/System:	Digital Solutions – Data Management /REDCap

### DOCUMENT HISTORY

Version Number:	Summary of Changes Made:	Effective Date
1	New Document	December 16, 2020

### APPROVALS

Approver Name	Approver Signature	Date
Gurm Dhugga Associate Director, Research & Digital Technologies UBC Faculty of Medicine		December 16, 2020
Ashley McKerrow Team Lead, Data Management UBC Faculty of Medicine		December 16, 2020

#### 1. PURPOSE

- 1.1. To define the standard project management approach for projects that are conducted in the UBC Faculty of Medicine (FoM) 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 FoM DM Team members involved in project management, and Principal Investigators (PI) and Project Administrators (PA) involved in managing and developing a REDCap project.

### 3. RESPONSIBILITIES

- 3.1. The PI is responsible for ensuring that the study meets all of the applicable regulatory, International Conference on Harmonisation (ICH) Good Clinical Practice (GCP), Sponsor, and local requirements.
- 3.2. FoM DM Team is responsible for overseeing all stages of FoM REDCap projects, conveying issues to the Research/Project Team and communicating with FoM Digital Solutions Team as necessary.
- 3.3. PI or PA is responsible for providing the necessary study-specific content that is required for setting up the REDCap project, and following any applicable standard operating procedures and policies at each step in the process.
- 3.4. FoM Research DM Team members are responsible for following the Project Lifecycle Tool and any standard operating procedures, policies, working practices and guidelines related to the lifecycle.

### 4. RELATED SOPS/DOCUMENTS

- 4.1. FoM Research DM SOP 102 REDCap Project Request
- 4.2. FoM Research DM SOP 103 REDCap Service Agreement
- 4.3. FoM Research DM SOP 104 REDCap Project Creation and Initiation
- 4.4. FoM Research DM SOP 105 REDCap User Access
- 4.5. FoM Research DM SOP 106 REDCap Project Training
- 4.6. FoM Research DM SOP 107 REDCap Instrument Design and Development
- 4.7. FoM Research DM SOP 108 REDCap Project Data Collection Closure
- 4.8. FoM Research DM SOP 109 REDCap Project Archiving
- 4.9. FoM REDCap Project Request Form

### 5. DEFINITIONS

- 5.1. **Principal Investigator (PI)/Project Lead:** Primary individual in charge of and responsible for the proper conduct of a research project and/or sponsor for non-research projects.
- 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/Project Team:** Research/project assistants, nurses, data entry and other personnel involved with and granted access to the REDCap project. The Team members report to the PI/Project Lead but are generally directly supervised by the PA.
- 5.4. **FoM Research Data Management (DM) Team:** Team Lead, Scientific Analyst and other FoM DM individuals responsible for managing projects in REDCap and assisting Research/Project Teams in conducting research studies or projects.
- 5.5. **REDCap Project:** A set of data entry forms, surveys, schedules and other data management tools pertaining to a specific research study or project.
- 5.6. **Service Agreement:** The joint contract agreed to by both the FoM Research DM Team and the PI or PA for commencement of work and services related to REDCap project data management as outlined. For clinical trials sponsors this document constitutes transfer of responsibility of duties for services under section 5.2 of ICH E6 GCP as adopted by Health Canada under the Food and Drug Regulations Amendment 1024.
- 5.7. **Project Lifecycle Tool:** An active, internal project used by the FoM Research DM Team to track the lifecycle of projects and to assist in REDCap data management.
- 5.8. **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.
- 5.9. **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 as per UBC IT EduCloud Backup Service. 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 the review of proposed changes before approval to ensure data integrity. Should the PI opt out by requesting that the REDCap Administrator automatically approve any changes, it will be the PI/PA's responsibility if the changes violate data integrity or consistency.
- 5.10. **REDCap Project Archiving:** Procedure in which a completed REDCap project is removed from access by study personnel. Projects are moved to the 'Archive' status when data collection is complete, they have completed all analysis and are no longer in use. Once archived, the project can be moved back to production status by the FoM Research DM Team upon request.

## 6. PROCEDURE

- 6.1. Projects within FoM REDCap are divided into five phases:



- Project Creation
- Development
- Production
- Analysis
- Archiving

6.2. The steps within each phase are completed sequentially. There may be some variation from project to project. Omission of a phase or step must be discussed and approved with the FoM Research DM Team. Planned or unplanned deviations from a FoM Research Standard Operating Procedure must be discussed and reviewed with the FoM Research DM Team. All deviations from a Standard Operating Procedure are documented by the FoM Research DM Team in the Project Lifecycle Tool.

### 6.3. Project Creation phase

The Project Creation phase starts when a PI or PA requests a new project in FoM REDCap by completing the FoM REDCap Project Request Form (See FoM Research DM SOP 102 REDCap Project Request). The FoM Research DM Team are alerted to the project via email. The REDCap Project Request Form summarizes initial information about the study/project. Projects are defined, a FoM REDCap Service Agreement is completed (See FoM Research DM SOP 103 REDCap Service Agreement), and the project is created in REDCap (See FoM Research DM SOP 104 REDCap Project Creation and Initiation). User accounts are enabled for the PI and PA and added to the appropriate User Roles in the project (See FoM Research DM SOP 105 REDCap User Access).

### 6.4. Development phase

The Development phase includes creating and designing Instruments (See FoM Research DM SOP 107 REDCap Instrument Design and Development), initial REDCap training (See FoM Research DM SOP 106 REDCap Project Training), testing and the set-up of Users Accounts with User Rights and project specific User Roles (See FoM Research DM SOP 105 REDCap User Access). In most instances, the Research Team

6.4.1. When the FoM Research DM Team is in charge of the project implementation, the required project deliverables will be configured, tested and documented by FoM Research 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.



6.4.2. If the FoM Research DM Team has not been involved in the design and implementation aspects of the project, its 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.

#### 6.5. Production phase

6.5.1. Once the REDCap project has been designed and tested, the project will be moved to Production Mode. Authorized personnel in the research/project team involved in different aspects of the data entry process will start to operate.

6.5.2. Any changes to the project while in production can be made in “draft mode” and approved by the FoM Research DM Team.

6.5.3. The PA can monitor data at this phase to ensure all procedures are being followed.

6.5.4. At this phase, User Rights in the project should be adjusted for each user according to their role, on a need-to-know basis. FoM Research DM Team will review user rights and make recommendations when moving projects to production.

6.5.5. The FoM Research DM Team will provide ongoing support as per the requirements specification and as per the REDCap Service Agreement. Upon request, FoM Research DM Team will assist Research/Project Team members in resolving project-specific problems. This one-on-one assistance will be provided via by contacting the FoM Research DM Team directly.

#### 6.6. Analysis phase

After data has been collected and all data management tasks are completed, the project is ready for Analysis. Prior to starting Analysis, the PA should perform Data Collection Closure (see FoM Research DM SOP 108 REDCap Project Data Collection Closure), including disabling Surveys, adjusting User Rights and locking data collection forms. Data can then be exported and analyzed in a statistical package.

#### 6.7. Archiving phase

After Analysis is completed, the project should be Archived for long-term retention. The PI/PA initializes the Archiving process (see FoM Research DM SOP 109 REDCap Project Archiving). Archiving involves removal of access to project from the research team. Project archival is done in a format that will allow access to project data and audit logs at a later date as per institutional, REB and regulatory requirements, as applicable.



## 7. REFERENCE(S)

- 7.1. Clinical Research Ethics - <http://www.phsa.ca/researcher/ethicsapprovals/institutional-approvals>
- 7.2. Post Approval Notes- <https://ethics.research.ubc.ca/clinical-research-ethics/crebguidance-notes/post-approval-guidance-notes>
- 7.3. Network of Networks (N2) resources - Network of Networks (N2) Standard Operating Procedures, Version 8. Effective May 2019.
- 7.4. UBC IT EduCloud Backup Service: <https://it.ubc.ca/services/web-serversstorage/educloud-server-service/educloud-server-faq#backup>