THE UNIVERSITY OF BRITISH COLUMBIA
Digital Solutions
Faculty of Medicine

Standard Operating Procedure:
REDCap Project Data Collection Closure

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Department/System:	Digital Solutions – Data Management /REDCap

DOCUMENT HISTORY

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1	New Document	December 16, 2020

APPROVALS

Approver Name	Approver Signature	Date
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1. PURPOSE

1.1. To define the practices necessary for data collection closure and transition to the analysis phase of REDCap projects supported by UBC Faculty of Medicine (FoM) Research Data Management (DM) Team.

2. SCOPE

2.1. This procedure applies to all REDCap projects that are managed and hosted by the FoM Research Data Management (DM) Team.

3. RESPONSIBILITIES

3.1. Principal Investigator (PI) or Project Administrator (PA) is responsible for closing data collection and following the recommended guidelines, once the data entry process has concluded or for interim analysis.

4. RELATED SOPS/DOCUMENTS

4.1. FoM Research DM SOP 101 REDCap Project Lifecycle

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.

6. PROCEDURE

Note: Closing the data collection phase on a REDCap project is fundamental to preventing inadvertent or unauthorized changes before the final analysis and reporting of the data have begun. Although important in all studies/projects, data collection closure is even more critical to preserve the integrity of regulated clinical trials, particularly randomized trials after the blind seal has been broken.

6.1. Once a project has completed data collection, either through survey, data entry, data import, or the Mobile App, the PI/PA prepares the project for analysis by doing the following:

6.1.1. Change all the surveys' statuses to 'Survey Offline' to prevent any new participant to enter data.

6.1.2. Verify data quality and integrity using the Data Quality Module, which is a functionality in REDCap. Address issues that arise as necessary.

6.1.3. Lock and/or e- sign forms once data has been verified so that no additional changes can be made.

6.1.4. Adjust user rights to remove data entry privileges and reflect roles in the analysis phase.

6.2. PI/PA exports the data for analysis.

6.2.1. PI/PA must ensure appropriate security for storage and transfer of the data files extracted from REDCap, as well as appropriate authorizations for data access. There may be Sponsor, REB and/or Privacy Regulatory and Institutional requirements for data management and storage. FoM DM Research Team can be consulted for data handling best practices.

7. REFERENCES

7.1. Network of Networks (N2) resources - Network of Networks (N2) Standard Operating Procedures, Version 8. Effective May 2019.