



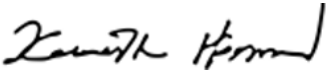

## Standard Operating Procedure: REDCap Project Data Cleanup & Analysis

SOP Number:	108
Version Number:	2.0
Approved Date:	May 24, 2024
Department/System:	Digital Solutions – Data Management /REDCap

### DOCUMENT HISTORY

Version Number:	Summary of Changes Made:	Effective Date
1	New Document	December 16, 2020
2	<ul style="list-style-type: none"> <li>• Branding updates</li> <li>• Minor procedural updates</li> <li>• SOP name change from Project Data Closure for increased clarification of SOP procedure</li> </ul>	May 24, 2024

### APPROVALS

Approver Name	Approver Signature	Date
Kenny Hammond Manager, Research Data Services UBC Faculty of Medicine		May 24, 2024
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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) Data Management (DM) Team.



## 2. SCOPE

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

## 3. RESPONSIBILITIES

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

## 4. RELATED SOPS/DOCUMENTS

- 4.1. FoM 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 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: Concluding the data collection phase and moving to the Cleanup & Analysis phase in 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. Request to move project to 'Cleanup & Analysis' phase. This will disable most project functionality, although all collected data will remain intact.
  - 6.1.2. Change all the surveys' statuses to 'Survey Offline' to prevent any new participant data entry.
  - 6.1.3. Review data quality and integrity using the Data Quality Module, which is a functionality in REDCap. Address issues that arise as necessary.
  - 6.1.4. Lock and/or e-sign forms once data has been verified so that no additional changes can be made.
  - 6.1.5. Adjust user rights to remove data entry privileges and reflect roles in the analysis phase.
  
- 6.2. PI/PA and/or biostatistician exports the data for analysis.
  - 6.2.1. PI/PA/biostatistician 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 Team can be consulted for data handling best practices.

## 7. REFERENCES

N/A