THE UNIVERSITY OF BRITISH COLUMBIA
Digital Solutions
Faculty of Medicine

Standard Operating Procedure:
REDCap Project Archiving

SOP Number:	109
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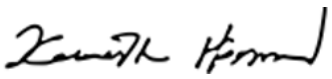
Approved Date:	October 2, 2024
Department/System:	Digital Solutions – Data Management /REDCap

DOCUMENT HISTORY

Version Number:	Summary of Changes Made:	Effective Date
1	New Document	December 16, 2020
2	Revision: updated section 6.2.2	March 8, 2021
3	• Clarified language around Archived/Completed projects and Principal Investigator • Updated branding	May 1, 2024
4	Updated language to reflect user-initiated Cleanup/Analysis and Archival.	October 2, 2024

APPROVALS

Approver Name	Approver Signature	Date
Kenny Hammond Manager, Research Data Services UBC Faculty of Medicine		October 2, 2024
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1. PURPOSE

1.1. To define the procedure used to archive REDCap projects supported by the Faculty of Medicine (FoM) Data Management (DM) Team. This document focuses on the aspects of study/project archival that are the responsibility of the FoM DM Team and not all components of a general study/project archival.

1.2. To define the procedure for the possible re-opening of an archived FoM REDCap project for the evaluation and correction of errors not addressed prior to initial archiving and the subsequent regulatory documentation that must be produced in this rare instance.

2. SCOPE

2.1. This procedure applies to all FoM DM Team members involved in the archiving responsibilities related to FoM REDCap project data.

2.2. This procedure **does not** include the archiving responsibilities for the study Team as they relate to archiving all study documents located outside of REDCap.

3. RESPONSIBILITIES

3.1. Principal Investigator (PI) or Project Administrator (PA) is responsible for requesting their project be archived. Biostatistician may be involved in the review of the archiving design and format specifications for some of the components.

3.2. PI/PA is responsible for reviewing the project and moving the project to Analysis/Cleanup status once data collection is complete.

3.3. PI is responsible for setting the expiry dates on all user accounts in the project to the archiving date, so that no users may access the project while it is archived.

3.4. PI/PA is responsible for downloading the data, the data dictionary and codebook from the project and for storing project data according to their own archiving protocol.

3.5. PI is responsible for moving the project to Complete status once the project is ready to be archived.

4. RELATED SOPS/DOCUMENTS

4.1. FoM REDCap Project Delete Form

4.2. FoM REDCap Project Unarchival 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 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 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 DM Team to track the lifecycle of projects and to assist in REDCap data management.

5.8. **REDCap Project Completion (formerly known as Project Archival):** The procedure in which a completed REDCap project is removed from access by study personnel. Projects ready for archival are marked as ‘Completed’ when data collection is complete, they have completed all analysis and are no longer in use. Once Completed, the project may be moved back to Production status by the FoM DM Team upon request.

6. PROCEDURE

6.1. Moving project to Analysis/Cleanup Status

6.1.1. PI/PA reviews project and initiates to move the project to Analysis/Cleanup status once data collection is determined to be complete.

6.1.2. In this phase, data can be queried, checked for quality/completion, and downloaded for analysis. No new records can be added.

6.2. Archiving

6.2.1. PI/PA ensures that the project has been completed, and project data has been downloaded in the appropriate format.

6.2.2. PI sets the expiration dates on all user accounts in the project to the archiving date to ensure no users can directly access an archived project. This process also disables all API tokens. PI should main their project access in the event that the project requires unarchival.

6.2.3. PI moves the project to 'Complete' status, thus archiving the project.

6.3. Unarchiving

6.3.1. All study data and logs remain stored in REDCap, where they can be accessed and unarchived upon request, if necessary.

6.3.2. PI/PA requests the project be unarchived and returned to "active" status.

6.3.3. Upon approval from the FoM DM Team, the requested project is unarchived and moved back into Analysis/Cleanup status.

6.3.4. PI/PA access is to the project is restored.

6.3.5. FoM DM Team notifies the PI/PA that the requested project is unarchived.

6.3.6. Once the project is completed, the archival process (6.2) is repeated.

6.3.7. FoM DM Team updates the necessary information in the Project Life Cycle.

7. REFERENCES

7.1. Regulation C.05.012 (4) - Guidance Document: Part C, Division 5 of the Food and Drug Regulations "Drugs for Clinical Trials Involving Human Subjects" (GUI-0100): https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/good-clinical-practices/guidance-documents/guidance-drugs-clinical-trials-human-subjects-gui-0100.html

7.2. Scholarly Integrity Policy (SC6) https://universitycounsel.ubc.ca/policies/scholarly-integrity-policy/

7.3. Study Completion – Office of Research Ethics: https://researchethics.ubc.ca/clinical-research-ethics/creb-guidance-notes/post-approval-guidance-notes#completion