THE UNIVERSITY OF BRITISH COLUMBIA
Digital Solutions
Faculty of Medicine

Standard Operating Procedure:
REDCap Project Archiving

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DOCUMENT HISTORY

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1	New Document	December 16, 2020
2	Revision: updated section 6.2.2	March 8, 2021

APPROVALS

Approver Name	Approver Signature	Date
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1. PURPOSE

1.1. To define the procedure used to archive REDCap projects supported by the Faculty of Medicine Research Data Management (DM) Team. This document focuses on the aspects of study/project archival that are the responsibility of the FoM Research 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 Research 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. RESPONSIBITILES

3.1. Principal Investigator (PI) or Project Administrator (PA) is responsible for requesting their project be archived.

3.2. FoM Research DM Team is responsible to review the project for archiving, contact the QI/PA to confirm project archival and to review archiving process.

3.3. FoM Research DM Team 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. FoM Research DM Team is responsible for doing routine checks for projects that have been inactive for 12 months or longer, and for notifying that research Team.

3.5. QI/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.

3.6. Biostatistician may be involved in the review of the archiving design and format specifications for some of the components.

4. RELATED SOPS/DOCUMENTS

FoM Research DM Clinical Research Study Archiving Guidelines

5. DEFINITIONS

5.1. **Principal Investigator (QI)/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 QI/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 QI 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. **REDCap Project Archiving:** Procedure in which a completed REDCap project is removed from access by Research/Project Team. 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. Preparation

6.1.1. QI/PA is responsible for initiating the archiving process, by requesting the project be archived by the FOM Research DM Team.

6.1.2. FoM Research DM Team discusses the FoM Research DM archiving process with QI and/or PA.

6.1.3. FoM Research DM Team and QI and/or PA approve the project for archiving in writing or electronically. Approval is documented in the Project Lifecycle tool, together with a copy of the approval documentation, if necessary.

6.2. Archiving

6.2.1. FoM Research DM Team ensures that the responsible parties have finished the project and downloaded the project data in the appropriate format (*See Clinical Research Study Archiving Guidelines)*.

6.2.2. FoM Research DM Team sets the expiration dates on all user accounts in the project to the archiving date to ensure no users can directly access an achieved project. This process also disables all API tokens.
6.2.3. FoM Research DM Team moves the project to 'Archive' status.
6.2.4. FoM Research DM Team updates the necessary information in the Project Life Cycle.

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. QI and/or PA requests the project be unarchived and returned to "active" status.
6.3.3. Upon approval from the FoM Research DM Team, the requested project is unarchived.
6.3.4. FoM Research DM Team notifies the QI/PA or Research Team that the requested project is unarchived.
6.3.5. Once the project is completed, the archival process is repeated.

7. REFERENCES

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