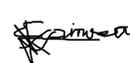


Standard Operating Procedure:
REDCap Project Archiving

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Document History

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1	New document	August 14, 2018

Approver Name	Approver Signature	Date
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1. PURPOSE

- 1.1. To outline the procedure used to archive REDCap projects managed at BC AHSN REDCap. This document focuses on the aspects of project archival that are the responsibility of the BC AHSN Data Management (DM) team and not all components of a general study archive.
- 1.2. To define the procedure for the possible re-opening of an archived 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 BC AHSN DM team members involved in the archiving responsibilities related to REDCap projects.
- 2.2. This procedure does not include the archiving responsibilities for the study team as they relate to archival of all study documents located outside of REDCap, as defined in the study close-out procedure (See N2 SOPs for reference).

3. RESPONSIBILITIES

- 3.1. The Principal Investigator (PI) or Project Administrator (PA) is responsible for requesting project archival.
- 3.2. DM Coordinator is responsible to review the project for archival, contact the PI/PA to confirm project archival and to review the archiving process.
- 3.3. DM Coordinator is responsible for setting the expiry dates on all user accounts in the project to the archival date, so that no users may access the project while it is archived.
- 3.4. DM Coordinator is responsible for doing routine checks for projects that have been inactive for 12 months or longer, and for notifying that research team of archival options.
- 3.5. PI/PA is responsible for downloading the data and the data dictionary from the project and for storing project data according to their own archival 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

- 4.1. SOP 103 – BC AHSN REDCap Service Agreement & Project Creation

5. DEFINITIONS

- 5.1. **Principal Investigator (PI):** Primary individual in charge of and responsible for the proper conduct of a research project.
- 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 team:** Research assistants/nurses, data entry personnel and other personnel involved in the clinical research study and granted access to REDCap projects. The Research team members report to the PI but are generally supervised by the PA.
- 5.4. **BC AHSN Data Management (DM) team:** team that is responsible for managing projects in REDCap and assisting research teams in conducting research studies.
- 5.5. **REDCap Project:** A set of data entry forms, surveys, schedules and other data management tools pertaining to a specific study or research project.
- 5.6. **Patient-oriented research:** Research done in partnership with patients, answers research questions that matter to patients, and aims to improve health care (See <http://www.cih-irsc.qc.ca/e/44000.html#a1.1>).
- 5.7. **Project Life Cycle Tool:** An active, internal project used by the BC AHSN DM team to track the lifecycle of projects and to assist in REDCap data management.
- 5.8. **Service Agreement:** The joint contract agreed to by both the BC AHSN DM team and the PI or PA for commencement of work and services related to REDCap project data management as outlined.
- 5.9. **REDCap Project Archiving:** Procedure in which a completed REDCap project is changed to 'Archived' status and access to the project is removed for all users. Projects should be archived when data collection and analysis are complete and projects are no longer in use. Once archived, the project can be moved back to production status by the BCCH Research DM team upon request.

6. PROCEDURE

6.1. Preparation

- a) PI/PA initiates the archival process, by emailing the BC AHSN DM team to request the project to be archived.
- b) DM Coordinator reviews the service agreement for potential specific agreements regarding BC AHSN archiving responsibility. Information is passed on to the DM team and BC AHSN IT where needed.
- c) DM Coordinator discusses the BC AHSN DM archiving process with PI/PA.
- d) DM Coordinator and PI/PA approve the project for archival in writing or electronically. Approval is documented in the Project Life Cycle tool, together with a copy of the approval documentation, if necessary.
- e) DM Coordinator will perform routine checks for projects which have shown no activity in the past 12 months or more, and contacts the PI/PA to inform them that their project should be archived.

6.1. Archival

- a) DM Coordinator ensures that the responsible parties have finished the project and downloaded the project data in the appropriate format.
- b) DM Coordinator sets the expiry dates on all user accounts in the project to the archival date to ensure no users can directly access an archived project.

- c) BC AHSN DM team moves the project to 'Archived' status.
- d) DM Coordinator updates the necessary information in the Project Life Cycle.

6.2. Unarchiving process

- a) All study data and logs remain stored in REDCap, where they can be accessed and unarchived upon request, if necessary.
- b) PI/PA requests the project be unarchived and returned to "active" (production) status.
- c) Upon approval from the DM team, the DM Coordinator unarchives the project.

7. REFERENCES

- Network of Networks (N2) resources - <http://bcchr.ca/research-support/clinical-research-support/quality-assurance>