Standard Operating Procedure:
OpenSpecimen Collection Protocol Archiving

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DOCUMENT HISTORY

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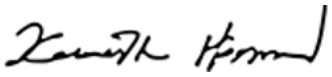
1	New Document	February 7, 2025

APPROVALS

Approver Name	Approver Signature	Date
Kenny Hammond Manager, Research Data Services UBC Faculty of Medicine		February 7, 2025
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1. PURPOSE

1.1. To define the procedure used to archive OpenSpecimen Collection Protocols supported by the Faculty of Medicine (FoM) Data Management (DM) Team. This document focuses on the aspects of project/Collection Protocol archival/closure and

deletion that are the responsibility of the FoM DM Team and not all components of a general project/Collection Protocol archival/closure/deletion.

2. SCOPE

2.1. This procedure applies to all FoM DM Team members involved in the archiving/closure/deletion responsibilities related to FoM OpenSpecimen Collection Protocols.

2.2. This procedure **does not** include the archiving responsibilities for the Research/Project Team as they relate to archiving all Collection Protocol data and project documentation outside of OpenSpecimen.

3. RESPONSIBILITIES

3.1. Archiving/Collection Protocol Closure

3.1.1. Principal Investigator (PI) or Project Administrator (PA) requests their Collection Protocol be closed and upon approval, updates the Collection Protocol access to their Research/Project Team users as necessary (see DM SOP 205 OpenSpecimen User Accounts).

3.1.2. FoM DM Team Closes Collection Protocol upon PI approval.

3.2. Collection Protocol Deletion

3.2.1. Principal Investigator (PI) or Project Administrator (PA) requests their Collection Protocol be deleted. Once deleted, the Collection Protocol will be permanently removed from the system. PI/PA is responsible for downloading/exporting all the data from the OpenSpecimen and storing all Collection Protocol data according to their own archiving protocol, including:

- Collection Protocol Events
- Participant, visit and specimen data
- Form/custom field data
- Event data (ie. transfer events, frozen events, delete events, etc.)
- Orders and shipping data
- Container design
- Consent statement data
- Queries
- Catalog requests

Research/Project Team is also responsible for archival/deletion of any associated or linked REDCap Project (see DM SOP 109 REDCap Project Archiving and DM OS CP Deletion – Study Team Instructions).

3.2.2. FoM DM Team explains the Deletion procedure to Research/Project Team and is responsible for securely sending the Research/Project Team the following:
- Collection Protocol design file in both json and csv formats
- Event and specimen mapping requirements
- Custom workflows document (if applicable)
- Manifest (if applicable)
- Collection Protocol Audit log

3.2.3. FoM DM Team deletes the Collection Protocol from OpenSpecimen upon PI confirmation and this is communicated to the PI and PA.

4. RELATED SOPS/DOCUMENTS

4.1. DM SOP 109 REDCap Project Archiving
4.2. DM SOP 205 OpenSpecimen User Accounts
4.3. FoM OpenSpecimen Collection Protocol Deletion - Study Team Instructions

5. DEFINITIONS

5.1. **Principal Investigator (PI)/Project Lead:** Primary individual in charge of and responsible for the proper conduct of a research project/Collection Protocol and/or sponsor for non-research projects/CPs.

5.2. **Project Administrator (PA):** Person responsible for the development of OpenSpecimen CP design, forms, containers, specimen requirements and overall management of the CP data.

5.3. **Research/Project Team:** Research/project assistants, nurses, data entry and other personnel involved with and granted access to the OpenSpecimen CP. The Research/Project Team members report to the PI/Project Lead but are generally directly supervised by the PA.

5.4. **FoM Data Management (DM) Team:** Manager, Research Data Services, Team Lead, Scientific Analyst and other FoM DM individuals responsible for managing CPs in

OpenSpecimen and providing support to Research/Project Teams in conducting their CP.

5.5. **OpenSpecimen Collection Protocol (CP):** Defines the details of a standardized protocol used for the collection of biospecimens. This includes any information on the approved CP such as the title of the study, institution, name of the investigator, ethics approval number, consent forms, standard operating procedures (SOPs), participant registration, specimens to be collected and processed, etc.

5.6. **Collection Protocol Closure:** Users will no longer be able to add new participants, but can still add events and specimens. Participants, events and specimens edits are also permitted.

5.7. **User accounts:** Provincial Health Services Authority/Vancouver Coastal Health/Providence Health Care (PHSA/VCH/PHC) and/or Campus Wide Login (CWL) accounts that have multifactor authentication and provide access to online systems, like FoM OpenSpecimen.

5.8. **Project Lifecycle Tool:** An active, internal project used by the FoM DM Team to track the lifecycle of projects and to assist in Data Management.

5.9. **OpenSpecimen Collection Protocol Closure (also known as Archival):** The procedure which follows data collection completion for a Collection Protocol wherein the CP is marked as Closed. In Closed status, users will no longer be able to add new participants, but can still add events and specimens. Participants, events and specimens edits are also permitted.

5.10. **OpenSpecimen Collection Protocol Deletion:** This procedure deletes all associated Collection Protocol design elements and any associated data from OpenSpecimen and is irreversible.

6. PROCEDURE

6.1. Archiving/Collection Protocol Closure

6.1.1. PI/PA requests the FoM DM Team to close their Collection Protocol.

6.1.2. FoM DM Team explains the Closure process to Research/Project Team and waits for PI approval.

6.1.3. Once PI approves, FoM DM Team moves the Collection Protocol to Closed status.

6.1.4. FoM Team communicates that the Collection Protocol has been Closed to the PI and PA.

6.1.5. PI optionally requests user /off-boarding team members as needed (see DM SOP 205 OpenSpecimen User Accounts).FoM DM Team updates the necessary information in the Project Life Cycle.

6.2. Un-archival of Collection Protocol

6.2.1. PI/PA requests the Collection Protocol be unarchived and returned to “active” status.

6.2.2. Upon approval from the FoM DM Team, the requested Collection Protocol is unarchived and moved back into “active” status.

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

6.2.4. Once the project is completed, the archival process (6.1) is repeated.

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

6.3. Collection Protocol Deletion

6.3.1. PI/PA requests to delete/archive from FoM DM Team.

6.3.2. FoM DM Team explains process to Research/Project Team and awaits PI approval.

6.3.3. PI provisionally grants the PA import/export permissions.

6.3.4. PI ensures that all data collection for the Collection Protocol has concluded and any data/Collection Protocol elements have been downloaded in the appropriate format for local long-term storage. See step 3.2.4.

6.3.5. Once PI approves, FoM DM Team downloads project design including the: Collection Protocol design, event and specimen mapping, custom workflows (if applicable), manifest(s) (if applicable), and Collection Protocol audit log. The FoM DM Team sends the corresponding files securely to the Research/Project Team.

6.3.6. Upon PI approval, the FoM DM Team deletes the Collection Protocol and communicates this to the PI and PA.

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. Biobanking Guidance – Office of Research Ethics:
https://researchethics.ubc.ca/clinical-research-ethics/biobank-guidance