SECTION

ROYAL CENTRE FOR DISEASE CONTROL

SOP No. RCDC/QMS/QSE/SOP/11.4

STANDARD OPERATING PROCEDURE FOR LONG TERM ARCHIEVING

Version 1.00

Date: 08/06/2019

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Contents

1. ACRONYMS AND DEFINITION 1
2. PURPOSE 1
3. APPLICATION 1
4. RESPONSIBILITIES 1
4.1. Section Head 1
4.2. Data Assistant/ focal person 1
4.3. Quality Assurance 2
5. PRINCIPLE 2
6. PRECAUTIONS 2
7. PROCEDURE 2
7.1. How to archive 2
7.2. Retention period 3
7.3. Conditions for withdrawal or removal of archived data 4
7.4. Closure and Succession 4
8. ANNEXURE 6
9. REFERENCE 7

1. ACRONYMS AND DEFINITION

SOP	Standard Operating Procedure
RCDC	Royal Center for Disease Control
QC	Quality Control

2. PURPOSE

To guide and support laboratory personnel in RCDC who looks after archive materials and help to assess and plan for the care and development of archive collections from a small storage cupboard to the contents of a large storeroom.

3. APPLICATION

This SOP applies to all laboratory personnel who look after data archives.

4. RESPONSIBILITIES

4.1. Section Head

Identify and submit surveillance/studies data and other documents to the data assistant for archiving.

4.2. Data Assistant/ focal person

- Develop an identification system e.g. numbering system for records and other documents.
- Create and maintain details for the archive (using information management system/excel).
- Transfer the documents to the archive.

4.3. Quality Assurance

- Assist in defining data and documents to be archived
- Verify compliance with internal procedure

5. PRINCIPLE

Data archiving is the process of storing the record of events within the system for future retrieval and analysis. An archive file captures all copy of the data and stores it in a fashion that is indexed for retrieval.

6. PRECAUTIONS

- Storage must be locked when not in use.
- Access to the storage area must be controlled and monitored and if storage areas have to be shared, archives should be clearly separated and only handled by people responsible for their care.
- Never use open fires, stoves, gas, radiant electric or paraffin heaters in an archive room.
- Smoke detectors should link to the building's main alarm system and where possible, the Fire Service.
- All depositors should ensure that data meets requirements of confidentiality and non- disclosure for data collected from human subjects.

7. PROCEDURE

7.1. How to archive

- The RCDC must appoint dedicated archivist/data assistant to collect the documents that need to be archived.

- It is recommended to password protecteddata ifarchivedin management information system/ excel sheet.
- Documents in hard copy should be archived in boxes with details such as type of Documents, reference fiscal year, department, division and date of archival neatly typed and affixed on the front of Archival box. Every box should have a Reference Number. (Annexure I)
- Documents in Electronic Form should be backed up in separate hard drive / Pendrives/CDs/ DVDs or such other secure medium with a level containing brief details of storage in such drive pasted on it. It will also have a Reference number.
- Storing of the Documents may be managed locally, in-house or outsourced to an outside agency. If outsourced to an outside agency, the security and integrity of the Documents handed over to them must be ensured.
- Documents which are no longer required byInstitute may be destroyed by the authorized person after the approval of the technical committee. The details of the Documents destroyed shall be recorded in the register to be maintained by the respective authorized Person within the respective unit. (Annexure II)

7.2. Retention period

- Deposited items will be retained for five to ten years, unless otherwise specified by the depositor, or as mandated by policies of funding agencies or by government regulations.

- Some datasets may be transferred to other repositories for long term duration and preservation of the data.

7.3. Conditions for withdrawal or removal of archived data

- Datasets may be withdrawn for any of the following reasons:
- Copyright violation
- Legal requirements and/or proven violations of legal requirements
- National security
- Falsified research
- Confidentiality concerns
- Datasets may be withdrawn at the request of the principal investigator/depositor. The following conditions may apply as negotiated between the Data Archive and the principal investigator/depositor:
- Datasets and documentation may be entirely removed from the Data Archive
- Datasets and documentation may be removed from public view/access but retained by the Data Archive
- Datasets and documentation may be transferred to another archive
- Metadata may be retained by the Data Archive but may not be searchable or available for public view/access

7.4. Closure and Succession

If the Data Archive will cease operation every effort will be made to transfer data to another appropriate archive with negotiation between

the principal investigator/depositor and in accordance with policies and regulations.

8. ANNEXURE

Annexure I

BOX FILLING

ANNEXURE – II

REGISTER OF DOCUMENTS DESTROYED

Sl No	Particulars of Documents destroyed	Date and mode of destruction	Signature of Authorized Person

9. REFERENCE

11.1 Archive Principles and Practice: an introduction to archives for non-archivists.(https://www.nationalarchives.gov.uk/documents/archives/archive-principles-and-practice-an-introduction-to-archives-for-non-archivists.pdf)

11.2 Archiving policy and procedure – paper records https://medium.com/@stangarfield/archiving-document-management-and-records-management-6622023eb488