RDSOP21 – Retention of Data, Off-site Archiving and Destroying of Documents.

Greater Manchester Mental Health NHS Foundation Trust
<table>
<thead>
<tr>
<th>Title of Standard Operating Procedure:</th>
<th>RDSOP21 – Retention of Data, Off site Archiving and Destroying of Documents.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Document Summary:</td>
<td>Archiving process for R &amp; I team</td>
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</table>
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| Target Audience:                    | Trust-wide, Research Community, Internal and External Researchers               |
| Consultation:                       | R&I Office, research community and R&I Committee members                        |
| Approval Committee:                 | R&I Committee                                                                  |
| Cross Reference Document(s):        | Research Approval Policy  
All Trust R&I SOPs                                                              |
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<table>
<thead>
<tr>
<th>Minimum Monitoring Requirement</th>
<th>Frequency</th>
<th>Process for monitoring</th>
<th>Evidence</th>
<th>Responsible Individual(s)</th>
<th>Response Committee(s)</th>
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<tbody>
<tr>
<td>Review of SOP content</td>
<td>Annually</td>
<td>Review by Author, redraft, submission to R &amp; I Operational Group</td>
<td>Minutes of R &amp; I Operational Group</td>
<td>Head of R&amp;I Office</td>
<td>Research &amp; Innovation Committee</td>
</tr>
</tbody>
</table>
Contents

1. Introduction ............................................................................................................. 3
2. Purpose .................................................................................................................... 3
3. Roles and Responsibilities ...................................................................................... 3
   3.1 Duties within the organisation ........................................................................ 3
3.2 Specific to this SOP .............................................................................................. 4
4. Details of Procedure .............................................................................................. 4
   4.1 Newe Department set Up ............................................................................. 4
   4.2 Archiving Procedure ...................................................................................... 5
   4.3 Cost of Archiving .......................................................................................... 5
   4.4 Destruction of Records .................................................................................. 5
   4.5 Security of premises ...................................................................................... 6
   4.6 Retention Periods .......................................................................................... 6
5. References and Bibliography ................................................................................. 7
6. Associated Trust Documents ................................................................................. 7
7. Other Trust related Policies and Procedures ......................................................... 7
Appendix 1 - Flow Chart for Procedure ................................................................. 8
Appendix 2 – Flow Chart for Destruction Procedure .............................................. 9
Appendix 3 – Link to Spreadsheet on N Drive for recording archiving .............. 10
1. Introduction

The department of Health Research Governance Framework for Health and Social Care (2005) and the Medicines for Human Use (Clinical Trial) Regulations (2004) require that Sponsors make the appropriate arrangements for the retention of research and clinical trial documentation for sufficient periods to ensure availability for future audit (for legal, regulatory or for governance reasons).

2. Purpose

To ensure that all research documentation is archived appropriately and for sufficient periods of time.

3. Roles and Responsibilities

3.1 Duties within the organisation

It is the responsibility of the Research & Innovation Office to make Trust R&I SOPs available to all research active staff working on Trust-approved research studies.

It is the responsibility of the study Chief Investigator (CI) or local Principal Investigator (PI) to ensure that up-to-date copies of Trust R&I SOPs are available to research staff.

It is the responsibility of the study Chief Investigator or local Principal Investigator to ensure up-to-date SOPs are filed in the Investigator Site File and are available to research staff, and to inform the Research Support Co-ordinator of the names of all research staff involved on a study so that copies of SOPs can be distributed appropriately.

It is the responsibility of the study Chief Investigator or Principal Investigator to designate if the SOPs of another organisation are to be followed for a study. For example those of a Clinical Research Network or commercial sponsor. If there is significant conflict between the external SOP and the Trust R&I SOP it is the responsibility of the CI or PI to resolve these with the Research Office prior to starting the study.

It is the personal responsibility of all staff to follow Trust (or the designated alternative organisations) procedural documents.

The Research & Innovation Office is responsible for managing Trust R&I SOPs including their approval, dissemination and archiving. All Trust R&I SOPs must be made available via Q-Pulse and published on the Trust website.
3.2 Specific to this SOP

The Principal Investigator/Study Coordinator will ensure that study files and records are filed/stored in a secure environment, and archived in accordance with legislation and this SOP. They will inform the R & I dept. of archive arrangements, location and date of destruction so a record can be held within the R & I dept.

The Sponsor will ensure archive arrangements are detailed in the sponsor agreements so it is clear from the outset whether archiving is on site, off site or electronic for example. Any associated costs will also be included within this agreement.

Each Research Active Department or Group (including Research Office) within the Trust will be fully responsible for:

- The administration and retention of data relating to archiving;
- The retrieval (as required) and/or destruction of archived material;
- Adherence to this SOP.

The R & I Officer will administer the Research Office archives, including keeping a database of existent study files.

4. Details of Procedure

4.1 New Department Set Up

A representative from a research active department must forward the following details to the R& I Officer for an individual (“Archive Coordinator”) who will be fully responsible for their departments research archives (as per 1.1 above)

- Department
- Name
- Job title
- Address
- Address
- Tel No:
- Email Address

They must inform the R & I Coordinator of the location of the archive(s) (to enable audits to be carried out) and details of the date that the records can be destroyed.
This individual must inform the R & I officer if they are transferring this responsibility to another.

The Archive Coordinators must be identified as such in the Site Responsibility Log (see RDSOP3 Definition/Delegation of Responsibilities Log) for Clinical Trials.

### 4.2 Archiving Procedure

Archiving is the responsibility of the Sponsor but may be delegated to the Trust/Principal Investigator within a contract/agreement. Research records can either be archived by the Sponsor, Research team or by the R&I Office as agreed in the contract or as indicated in the Protocol.

The following procedure should be followed:

**See Appendix 1**

Investigators must ensure that all documents pertaining to a study are archived in a secure facility (this includes the Investigator Site File, Pharmacy Site File (these should be archived with the study and not separately in pharmacy) and the Case Report Forms. All versions of documents must be archived, including CV’s of investigators.

R & I files are stored securely within the R & I Department.

Hard copy medical notes must be marked with a green sticker to notify the Clinical Records Managers that these files may have different retention requirements.

### 4.3 Costs of Archiving

Wherever possible costs of archiving should be obtained from the research grant/sponsor. Where the Trust has agreed to archive study material and no costs were agreed, the R&I Office will provide the funding.

### 4.4 Destruction of Research Data

The following procedure should be followed for destruction of research data:

**See Appendix 2**
R & I Corporate Data (e.g. HR, Personnel, Financial)

All other documentation/material used by the R & I Office in the course of its business should be stored securely and disposed of as directed by Trust Policies as outlined in section 7.0.

4.5 Security of premises

All research and personnel files should be stored in locked drawers or cabinets in one of the R & I offices, first floor, Harrop House, Prestwich site or R&I Offices and the offices should be locked when not occupied. The building is secured by key pad entry.

4.6 Retention Periods

As there are contradictions within the associated guidelines issued, for example by the Medical Research Council; the Medicines for Human Use (Clinical Trials) regulations (2004) and subsequent amendments, and the Retention of Records (NHS) Guidelines, the Trust has agreed minimum retention periods as follows:

- For all studies involving NHS patients (interventional or observational) – 15 years after completion of study
- Any studies which do not involve patients e.g. interviews with NHS staff, must be retained for a minimum of - 5 years after completion of study

The research office will notify any changes to this policy to the research community as required.

It is the responsibility of the Chief/Principal investigator to ensure that trial specific records are retained for the amount of time specified in the related legislation or study protocol.
5. References and Bibliography


6. Associated Trust Documents

RDSOP3 – Definition of Responsibilities

7. Other Trust related policies and procedures

In all instances of storage, retention, disposal and security of research related material reference should be made to up to date Trust policies and procedures and if in doubt, guidance should be obtained from IM & T or Information Governance.
Appendix 1

FLOW CHART OF PROCEDURE

Request CI/Trial Manager/RA to complete an Archiving form (Appendix 3).

Once complete a copy should be returned to the R&I Office and a copy should be placed in each box of archived documentation/material.

The R&I Office will record details of storage location, sponsor, custodian, retention period, date and process for disposal etc. in the R&I Office Archive Tracking Spreadsheet on the R&I drive.

Boxes to be archived should be sealed, labelled appropriately for RESTORE plc. Barcodes are available from archivist.

Boxes should be stored in locked R&I cupboards in Archive Room and should be marked with the project number and date of retrieval/destruction.

Boxes should be securely delivered to the R&I Office Archive Room, Rawnsley Building and archivist informed who will then arrange collection with RESTORE plc.

Date of storage and disposal should be recorded on the Tracking Spreadsheet.
Appendix 2

Flow Chart for Destruction of Data

When the date of destruction is reached, the boxes should be retrieved by the R&I Office.

The Sponsor should be notified of the action to be taken regarding disposal (as per earlier received instructions) and given 30 days to

If no response is received from the Sponsor, the R&I Office should proceed with destruction of all data/material related to the study.

Electronic data on electronic media (CDs, external hard drives, audio machines) should first be deleted from the media and then sent to the Trust IT Dept. for destruction of the media.

Paper hard copy research data should be disposed of in confidential waste.
Appendix 3 Archive Proforma

This form is an Excel formatted form and is available from the Archiving Folder on the R & I - N Drive

N:\Research and Innovation\Archiving\2018 + Archiving process