Sheffield Teaching Hospitals NHS
NHS Foundation Trust

Clinical Research & Innovation Office

# STANDARD OPERATING PROCEDURE

# STH Investigator

# Archiving of Essential Documentation Generated During Clinical Research

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| **Effective Date** | 19 February 2024 | **Author** | Alessia Dunn, Eve Dawber |
| | | | |
| **Related SOPs** | B109 Archiving for STH Clinical Research & Innovation Office | | |

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| **Approved by (name & role)** | Dipak Patel, Associate Director of R&I | **Date** | 05 February 2024 |

## Standard Operating Procedure: STH Investigator

## Archiving of Essential Documentation Generated During Clinical Research

This SOP has been produced in accordance with **Medicines for Human Use (Clinical Trials) Regulations 2004 and subsequent amendments, ICH Good Clinical Practice (GCP) & UK Policy Framework for Health and Social Care Research 2017.**

This SOP will outline the procedure to be followed by Investigators for the archiving of essential documentation generated during clinical research conducted in STH.

**Background**
In accordance with the Medicines for Human Use (Clinical Trials) Amendment Regulations 2006 and the ICH-GCP, archiving of essential documentation is mandatory for all studies involving investigational medicinal products (IMPs). The Medicines for Human Use (Clinical Trials) Amendment Regulations 2006 embrace the principles set out in the ICH-GCP guidelines relating to the handling and archiving of study documentation generated during the course of a clinical trial and these regulations apply to all those parties involved in a trial (Investigator, Monitor, Sponsor, Pharmacy).

As the sponsor and host organisation for clinical research involving IMPs, investigational devices, surgical intervention and varied non-interventional clinical research, STH has a responsibility to ensure that archiving arrangements are in place for all essential documents generated during the course of research in accordance with the standard of GCP and all applicable Regulations. See Appendix 4 for details of periods of retention for the various categories of research conducted in STH.

The requirements of ICH-GCP and the Medicines for Human Use (Clinical Trials) Amendment Regulations 2006 are:

**ICH Harmonised Tripartite Guideline for Good Clinical Practice**
*'The Investigator/Institution should maintain the trial documents as specified in Essential Documents for the Conduct of a Clinical Trial and as required by the applicable regulatory requirements. The Investigator/Institution should take measures to prevent accidental or premature destruction of these documents'*

*Essential documents should be retained until at least 2 years after the last approval of a marketing application in an ICH region and until there are no contemplated marketing applications in an ICH region or at least 2 years have elapsed since the formal discontinuation of clinical development of the investigational product. These documents should be retained for a longer period however, if required by the applicable regulatory requirements or by an agreement with the Sponsor. It is the responsibility of the Sponsor to inform the Investigator/Institution as to when these documents no longer need to be retained.'*

Section 8 of ICH-GCP details those essential documents which should be retained by the Investigator in the Investigator Site File (ISF) and those which should be kept by the study sponsor in the Trial Master File (TMF). Details of these documents are given in Appendix 3.

**Medicines for Human Use (Clinical Trials) Amendment Regulations 2006:**
*The sponsor and the chief Investigator shall ensure that the documents contained, or which have been contained, in the TMF are retained for at least 5 years after the conclusion of the trial and that during that period are—*

*(a) readily available to the licensing authority on request; and*
*(b) complete and legible*

All clinical trials of IMPs will adhere to the above regulations and guidance. At STH we will take the stance that high-risk trials of medical devices or surgical interventions will work to the same principles as trials of IMPs. All non-interventional and low risk interventional research will be required to archive

study documentation appropriately but the period of retention of documentation will be substantially less than that for high risk studies – see Appendix 4.

**Index**



**Acronyms**

| | |
|---|---|
| SOP | Standard Operating Procedure |
| STH | Sheffield Teaching Hospitals |
| ICH-GCP | International Committee of Harmonisation – Good Clinical Practice |
| IMP | Investigational Medicinal Product |
| R&D | Research & Development |
| CTRU | Clinical Trials Research Unit |
| TMF | Trial Master File |
| ISF | Investigator Site File |
| CRIO | Clincal Research & Innovation Office |
| CRFs | Case Report Forms |

**Definitions**

**Archiving** in the context of clinical research relates to the collection for long-term storage of **essential documents** that individually and collectively permit the evaluation of the conduct of a trial and the quality of the data produced. Section 8 of ICH-GCP lists those documents which are, considered to be, essential documents. Investigator and archiving delegate refer to individuals named on the delegation log or named departmental archiving delegates who are responsible for confirming that the relevant documentation is archived according to STH Policy – Code of Practice for the Management of Records (Appendix 1), and retained for the appropriate duration.

**Procedure**

## 1. Clinical Trials of Investigational Medicinal Products (IMPs)

### 1.1 STH Sponsored IMP Trials

***Prior to Confirmation of Capacity and Capability***

1.1.1 For single centre studies the Investigator completes the Single Site Internal Study Management Arrangements Form at the request of the Clinical Research & Innovation Office Coordinator, providing details of the proposed archiving arrangements for the trial. For multi-centre studies, the CRIO Coordinator will ensure that archiving arrangements are delegated accordingly in the CTRU/CRO collaboration agreement and in site agreements.

1.1.2 The CRIO Coordinator confirms that the arrangements are satisfactory with the CRIO Archiving Lead. The following guidance, which reflects the requirements of the UK Medicines for Human Use (Clinical Trials) Amendment Regulations 2006 and produced using the guidelines prepared by the European Forum for Good Clinical Practice, will be used to gauge the suitability of an archiving facility.

1.1.3 The CRIO Coordinator will confirm that the proposed archiving arrangements are satisfactory with the Investigator. For STH sponsored IMP studies, where proposed arrangements are not satisfactory, the CRIO Coordinator will require the Investigator to use the Clinical Research & Innovation Office's preferred off-site archiving facility, RESTORE Document Management in Leeds – see Appendix 7 for contact details.

1.1.4 The Investigator must ensure that there will be sufficient funds available to cover the cost of employing an off-site archiving facility at the end of a trial. As such, the cost of archiving trial documentation must be accounted for when costing a trial.

1.1.5 If the Investigator is to employ an off-site archiving facility, other than RESTORE Document Management, they will file a copy of the service level agreement between the off-site archiving provider and the Investigator in the ISF. It may not be possible to set up the contract until near the end of a trial, but Investigators must note that as part of the ongoing monitoring of STH sponsored IMP trials, the Clinical Research & Innovation Office will expect to see a contract in place before the end of the trial so that arrangements are in place for the safe archiving of trial documentation as soon as required.

Investigators can use the label in Appendix 6 to identify files/boxes containing archived documents.

***During the Trial***

1.1.6 The CRIO Coordinator will conduct a monitoring visit of the trial site when recruitment to the trial commences. As part of the routine monitoring visit, the CRIO Coordinator will assess where the ISF is located and note whether storage arrangements are satisfactory and in line with the arrangements advised by the Investigator prior to Sponsor Green Light in the Study Monitoring and Management Plan. The expected standards for an archiving facility are detailed in point 2 above.

1.1.7 If the interim storage of the ISF is found not to be in accordance with regulations (refer to Principles of Storage), these will be noted as a finding in the Monitoring study report and the Investigator will have to take immediate action to ensure that the site file is stored appropriately.

***When the Trial has ended***

*For the purposes of archiving of essential documentation, the end of the trial will be considered to be the point at which all data analysis is complete, and the trial documentation no longer needs to be accessed by the Investigator.*

1.1.8 The Investigator will notify the CRIO Coordinator of the end of the trial (see above definition).

1.1.9. The Investigator will liaise with any STH support departments involved in the trial (Pharmacy, Radiology, Laboratory Medicine etc.) regarding any trial documentation (both electronic and/or hard copy) that these departments hold, which can be archived with the ISF.

1.1.10 The CRIO Coordinator will confirm with the Investigator that all data analysis is complete and whether the site file and electronic data can be archived. If the site file is ready to be archived, the Investigator or delegate will complete the log of archived documents and label for archived documents (Appendices 5 & 6) including the location of electronically archived data. A copy of the log will be sent to the STH Clinical Research & Innovation Office. Upon receipt of the form, the CRIO Coordinator or delegate will file a copy in the R&D Master File and update the Archiving status on the STH Clinical Research & Innovation Office database, provided the archiving has been carried out by the Investigator. If archiving is to be facilitated by the Clinical Research & Innovation Office, the status is updated when the boxes have been successfully transferred to the off-site storage facility RESTORE.

1.1.11 The CRIO Coordinator or delegate will archive the R&D Master File with RESTORE Document Management at least five years after the study has ended. The STH Clinical Research & Innovation Office database and diary page will be updated accordingly.

1.1.12 The Investigator will be informed by the CRIO Coordinator as to when the archived ISF can be destroyed. The destruction of essential documents should be documented by the Investigator and the STH Clinical Research & Innovation Office. This record should be retained at the investigator site, and a copy should be retained by the STH Clinical Research & Innovation Office, for a further five years from the date that the essential documents were destroyed. See Appendix 4 for the period of retention for documents generated during STH sponsored IMP trials.

**1.2 Non-Commercially Sponsored IMP Trials (external to STH)**

For trials which are non-commercially sponsored, the responsibilities for defining the requirements of archiving arrangements lies with the trial sponsor which is in accordance with the regulations. Investigators with support from the CRIO Coordinator liaise with the funders of such trials to confirm that the necessary funding will be provided to cover archiving of trial documentation.

***Prior to Confirmation of Capacity and Capability***

1.2.1 The CRIO Coordinator on behalf of Investigators will establish with Research Councils, Charitable Bodies, Academic Institutions, or other NHS Organisations who will be the sponsor of the research.

1.2.2 The CRIO Coordinator and Research Accountant on behalf of the Investigator will establish the funding that will be available to cover the cost of archiving at the end of the trial.

1.2.3 The archiving arrangements for the trial will be agreed upon between the sponsor and the STH Clinical Research & Innovation Office prior to commencement of the trial and delegated responsibilities documented in the site agreement.

***When the Trial has ended***

*It is the responsibility of the trial sponsor to notify the Investigator of what they consider to be the end of the trial.*

1.2.4 The Investigator or delegate will determine from the study sponsor what is to be considered the end of the trial and when trial documentation can be archived and establish the duration of the retention of the documents.

1.2.5 Following confirmation from the trial sponsor the Investigator will notify the CRIO Coordinator of the end of the trial. The Investigator will arrange for the site files to be archived either in an appropriate location on site or at an off-site archiving facility as approved by the study sponsor. If the STH approved off-site archiving facility RESTORE is not approved by the study sponsor during set up of the trial, the study sponsor must provide adequate storage locations and transportation of study documents.

1.2.6 The Investigator or delegate will liaise with any STH support departments involved in the trial (Pharmacy, Radiology, Laboratory Medicine etc.) regarding any trial documentation (electronic and/or hard copy) that these departments hold, which can be archived with the ISF.

1.2.7 The Investigator or delegate should complete and retain a log of archived documents as provided by the Sponsor and provide a copy of this to the Clinical Research & Innovation Office (example templates are provided in Appendix 5 & 6 if required). The Investigator is requested to inform the Clinical Research & Innovation Office that the ISF has been archived internally or by Sponsor collection, upon which the CRIO Coordinator will update the archiving status on the Clinical Research & Innovation Office database. If the study documents are to be archived facilitated by the Clinical Research & Innovation Office, Appendix 5 must be received ahead of transporting archiving documents to the Clinical Research & Innovation Office. Once the study has been transferred to the off-site archiving facility RESTORE the CRIO Archiving lead or delegate will update the archiving status on the Clinical Research & Innovation Office database.

1.2.8 The Sponsor should notify the Investigator of when the archived site files can be destroyed, and the Investigator should notify the CRIO Coordinator of the expected date of destruction. Where the study files have been archived for the expected duration and the Sponsor has not informed the Investigator that the site files can be destroyed, the Investigator in conjunction with the CRIO Coordinator will notify the Sponsor contact of intention to destroy the site files. Upon confirmation from the Sponsor, the Investigator will arrange for the files to be destroyed per Trust confidential waste policy for files archived on site. Where site files are archived by RESTORE Document Management, the Clinical Research & Innovation Office will request destruction of the documents. RESTORE will provide a certificate of destruction which is to be sent to the Sponsor, Investigator and retained by the Clinical Research & Innovation Office.

## 1.3 Commercially Sponsored Trials

***Prior to Confirmation of Capacity and Capability***

1.3.1 The Sponsor will confirm archiving arrangements with the Investigator and will inform the Investigator of the required period of retention of documents and the date when documents may be destroyed.

1.3.2 If the Sponsor has delegated the responsibility to archive the site file to the Investigator, the CRIO Coordinator with the assistance of the Research Accountant will review the Clinical Trials Agreement and negotiate with the Sponsor the provision of funds to cover the cost of the archiving of the ISF following the end of the study.

1.3.3 The Research Accountant will ensure that where agreed by the Sponsor, the costs of archiving are covered in the Clinical Trial Agreement.

***When the Trial has ended***

1.3.4 The Sponsor representative will notify the Investigator of the end of the trial and arrange a site close out visit.

1.3.5 Following the site close out by the Sponsor representative, Investigators who have been delegated the responsibility to archive site files by the Sponsor will arrange for documents to be archived. The Investigator will arrange for the site files to be archived either in an appropriate location on site or at the Trust preferred off-site archiving facility, RESTORE. Archiving boxes and RESTORE Document Management contact details will be provided by the Clinical Research & Innovation Office upon request by the Investigator.

1.3.6 The Investigator or delegate will liaise with any STH support departments involved in the trial (Pharmacy, Radiology, Laboratory Medicine etc.) regarding trial documentation (electronic and/or hard copy) that these departments hold, which can be archived with the ISF and CRFs.

1.3.7 The Investigator should complete and retain a log of archived documents as provided by the Sponsor and provide a copy to the Clinical Research & Innovation Office (example templates are provided in Appendix 5 & 6 if required). The Investigator is requested to inform the Clinical Research & Innovation Office that the site files have been archived internally or by Sponsor collection. The CRIO Coordinator will then update the archiving status on the Clinical Research & Innovation Office database. If archiving of the boxes is to be facilitated by the Clinical Research & Innovation Office, the Clinical Research & Innovation Office database is updated upon sending boxes to the off-site archiving facility RESTORE

1.3.8 The Sponsor should notify the Investigator of when the archived site files can be destroyed, and the Investigator should notify the CRIO Coordinator of the expected date of destruction. Where the study files have been archived for the expected duration and the Sponsor has not informed the Investigator that the site files can be destroyed, the Investigator in conjunction with the CRIO Coordinator will notify the Sponsor contact of intention to destroy the site files. Upon confirmation from the Sponsor, the Investigator will arrange for the files to be destroyed per Trust confidential waste policy for files archived on site. Where site files are archived by RESTORE Document Management, the Clinical Research & Innovation Office will request destruction of the documents. RESTORE will provide a certificate of destruction which is to be sent to the Sponsor, Investigator and retained by the Clinical Research & Innovation Office.

## 2. Principles for Trials of Devices and Surgical Intervention

Given the risk associated with trials investigating the use of devices and surgical procedures, the Clinical Research & Innovation Office will adopt the same principles and procedures as for IMP studies. See sections 1.1 -1.3 above for details of the principles and procedures to be followed when archiving trial documentation generated during trials of medical devices and surgical interventions. See Appendix 4 for details of the recommended periods of document retention for device and surgical intervention trials.

## 3. Principles for Non-interventional and Low Risk Interventional Research

3.1 Investigators are responsible for arranging for the site files for non-interventional studies to be archived following the end of a study and, as for interventional research, must consider the need for an archiving facility prior to commencing their research.

3.2 Investigators will confirm archiving requirements with the study Sponsor prior to the research commencing. The Sponsor will confirm for how long documents will need to be archived following the end of a study – see Appendix 4 for guidance.

3.3 The Investigator will notify the Clinical Research & Innovation Office of the end of the study and intention to archive essential documents as confirmed with the study Sponsor (the point at which access to study documentation is no longer required and the documents can be placed in an archive).

3.4 The Investigator will arrange for the ISF and electronic data to be archived in a suitable location, either on STH/University premises if appropriate for the purpose or at an off-site facility as agreed by the study Sponsor. The Investigator or delegate should complete and retain a log of archived documents as provided by the Sponsor, retain a copy with the archived documents, and provide a copy to CRIO for saving on the Clinical Research & Innovation Office Database. The location of any archived electronic data must also be provided (example templates are provided in Appendix 5 & 6 if required).

3.5 The Investigator or delegate is requested to inform the Clinical Research & Innovation Office that the ISF and electronic data has been archived. If archived internally, the CRIO Coordinator will update the archiving status on the Clinical Research & Innovation Office database. If archiving is to be facilitated by the Research Office, the archiving delegate will update the status upon successful transfer to the off-site storage facility RESTORE.

3.6 The Sponsor should notify the Investigator of when the archived site files can be destroyed, and the Investigator should notify the CRIO Coordinator of the expected date of destruction. Where the study files have been archived for the expected duration and the Sponsor has not informed the Investigator that the site files can be destroyed, the Investigator in conjunction with the CRIO Coordinator will notify the Sponsor contact of intention to destroy the site files. Upon confirmation from the Sponsor, the Investigator will arrange for the files to be destroyed per Trust confidential waste policy for files archived on site. Where site files are archived by RESTORE Document Management, the Clinical Research & Innovation Office will request destruction of the documents. RESTORE will provide a certificate of destruction which is to be sent to the Sponsor, Investigator and retained by the Clinical Research & Innovation Office.

## 4. Advanced Therapy Medicinal Products (ATMPs)

4.1 *STH Sponsored ATMP Trials*

The Principles for STH Sponsored CTIMP Trials should be followed although further confirmations on Study requirements should be assessed by the CRIO Coordinator, the Archiving Lead, and the Research Manager on a case-by-case basis.

4.2 *Non-Commercially Sponsored ATMP Trials*

Clarification should be sort from the Sponsor as to additional requirements on a case-by-case basis prior to study Confirmation of Capacity and Capability

4.3 *Commercially Sponsored ATMP Trials*

Clarification should be sort from the Sponsor as to additional requirements on a case-by-case basis prior to study Confirmation of Capacity and Capability.

## 5. Principles of Storage

5.1 *Confidentiality & Security*

Filing space should be available for the storage of TMF and local ISF during the conduct of the clinical trial. ISFs will normally be stored in an Investigator's office or local filing area. At the end of the trial the files must be transferred to a suitable on-site archiving facility, provided the Investigator has access to one, or transferred off STH premises to a dedicated off-site archiving facility. Investigators should contact the Clinical Research and Innovation Office to discuss

suitable on-site facilities or arrange transfer to the STH approved archiving facility RESTORE if off-site storage is required.

5.2 *Record Keeping*

Investigators must ensure that data are recorded and stored correctly and accurately. This not only includes data recorded on Case Report Forms (CRFs) but also all original source data (patient medical notes for example), laboratory test results, radiological images and pharmacy data both electronic and physical (drug dispensing records and drug accountability records for example) and any relevant emails relating to the study. A copy of the delegation log and enrolment log must be retained at site securely. Further requirements for archiving of electronic and physical data are outlined below.

5.3 *Environmental Conditions*

The minimum requirement is for documentation to be stored in conditions that minimise the risk of damage or loss of information. The risk of damage from water should be reduced by storing documentation above floor level and away from overhead water pipes. Documentation should be located in areas with minimal variation in temperature and humidity if stored for long periods of time.

5.4 *Period of Document Retention*

The sponsor and the Chief Investigator shall ensure that the documents contained, or which have been contained, in the TMF and ISF are retained for at least 5 years after the conclusion of the trial. The sponsor and chief Investigator shall ensure that the medical files of trial subjects are retained for at least 5 years after the conclusion of the trial.

5.5 *Archiving of Paper Documents*

Efforts should be made to maximise the use of each box whilst ensuring the boxes and documents are maintained in good order and are not crushed or over tightly packed. Documentation for multiple trials may be stored in a single archive box subject to having the same destruction date and that the contents of the box are clearly documented on the Record of Archiving form. Where multiple studies are stored in one box, all contents of a study must be retained within one box.

Remove all bulky storage items, such as ring binders or hanging files / folders, and ensure all plastic, binders or wallets are removed. . Create a copy of source data which may not be suitable for storage over time, for example ECGs or film documents. Secure documents with treasury tags to replicate the structure of the file wherever possible.

Place the documents in an appropriate box for storage. RESTORE branded boxes may be provided by the Clinical Research & Innovation Office, on request. The “Record of Archiving Essential Documentation for a Clinical Trial” (Appendix 5) form signed by the Investigator or delegate must be retained on site, within the box and a copy must be sent to the Clinical Research & Innovation Office for storage on the Clinical Research & Innovation Office database. This must be sent prior to sending the archiving boxes to the Clinical Research & Innovation Office. Complete the “Label for Archived Documents” (Appendix 6) with a brief and accurate box description. Attach to the top of the box securely. The box should be sealed with tape to ensure that documents remain secure during transportation.

5.6 *Archiving of Electronic Documents*

Electronic source data stored on directorate computer systems or other mediums must be archived with the same care and duration as physical documents (Appendix 1). The Investigator and study team delegates must ensure that electronic data is correctly stored and archived according to the expectations outlined below. Databases provided by external sources will undergo a “Data Lock” to ensure that all relevant material is captured and removed from research facility computers and transferred to the Sponsor. Relevant emails stored on network

drives should either be printed and archived with the hard copy data or saved electronically according to the principles outlined below.

5.7 *Confidentiality*

Source data containing personal information should only be visible by authorised individuals from within the research team. Access to data outside of the research team may not be permitted as outlined in the Ethical and Information Governance approval. Access to external databases such as EDGE containing personal information should be restricted to the named recruitment contacts and individual named on the delegation log or for representatives of the research support and management teams Data containing personal information may be retained within the archiving files if documents are stored securely RESTORE in line with research governance approvals. If alternative arrangements are made for example sending to the Sponsor, discuss with the relevant CRIO Coordinator ahead of sending personal data.

5.8 *Accuracy of information*

Editable electronic documents must be converted to read only formats to maintain authenticity. By converting editable documents to PDF, the Investigator or delegate confirms that all data is present and readable.

5.9 *Back up of Data*

Electronic data extracted from computer systems must be stored in more than one format wherever possible. This may be in the format of encrypted archived data on departmental network drives and physical storage (e.g USB stick) of devices containing data at archiving facilities. It is recommended to encrypt data wherever possible and ensure that passwords and locations are stored in separate locations. Location of electronic files should be noted in the TMF/ ISF in the archiving section and reported to the Clinical Research & Innovation Office via completion of Appendix 5 when the trial has ended.

5.10 *Destruction of data*

Data must be retained in line with the outlined retention periods (Appendix 4) and efforts should be made to not store data longer than is required, however, the Investigator or delegate is not permitted to destroy data when archived data retention period is reached for externally Sponsored studies without permission from the Sponsor. The Investigator or delegate should be informed by the study Sponsor as to when the archived data can be destroyed. Once permission is received from the Sponsor or Clinical Research & Innovation office it is then the responsibility of the Investigator or delegate to permanently destroy files which have been archived and contain source data. At this point Appendix 5 signature pane 2; destruction of electronic files is to be signed by the archiving delegate and a copy is sent to the Clinical Research & Innovation Office. This will trigger destruction of all physical files if stored off-site at RESTORE. If the documents are stored internally documents must be destroyed according to the Trust's confidential waste policy. To ensure adequate destruction of electronic files saved on network drives, the Investigator or delegate should email STH IT to request permanent deletion of electronic files.

## 6. Retrieving Files from Archiving

6.1 If there is a need to retrieve archived study documentation, the requester will need to inform the Archiving Lead of the study number(s), the box reference number(s), the reason for retrieval, the location the boxes will be stored on return and the approximate required retrieval duration. Unless otherwise agreed between the requester and the Research Manager via the CRIO Archiving Lead, the retrieval duration will be four weeks.

6.2 The Archiving Lead will obtain a quote for the archiving retrieval, considering the cost of sending the archived study documentation back to RESTORE for re-archiving. The requester will confirm if this cost can be covered by the Investigator, sponsor (if applicable) or other available funds.

6.3 Once the funding for retrieval has been confirmed, the CRIO Archiving Lead will request the archived study documentation from RESTORE Document Management. The archived study documentation is normally delivered to the STH Clinical Research & Innovation Office, but if there is a large amount of archived study documentation, delivery directly to the requester can be arranged.

6.4 The requester must ensure that the archived study documentation containing confidential information is kept securely and away from any potential fire or water damage, as reasonably possible.

6.5 The requester will inform the CRIO Archiving Lead when they have finished with the retrieved archived study documentation. The CRIO Archiving Lead will then arrange for RESTORE Document Management to pick up the archived study documentation to be re-archived.

6.6 If the requester requires the retrieved archived study documentation for longer than was agreed, the Archiving Lead will discuss with the Research Manager to decide if this is appropriate.

6.7 On receipt of the invoice from RESTORE, the Archiving Lead will confirm with the Research Accountant the agreed relevant funding sources.

## Appendix 1
## Documents Associated with the SOP

| | Document | Create | S-drive | Website | Database | Who |
|---|---|---|---|---|---|---|
| 1 | STH Policy – Code of Practice for the Management of Records | | No | STH Website | No | N/A |

## Appendix 2
## SOP Revisions and History

| *SOP number* | *Effective date* | *Reason for change* | *Author* |
|---|---|---|---|
| *THIS SOP* | | | |
| A127 | 19 February 2024 | Updated name of archiving company, destruction process, and principles of storage. | ED/ AD |
| *PREVIOUS SOPs* | | | |
| A127 | 01 August 2014 | | ZW |
| A127 | 03 June 2013 | | JDM |
| A127 | April 2011 | | GM |

## Appendix 3
## Essential Documents for the Conduct of a Clinical Trial Involving IMPs

**In accordance with ICP GCP, the following documents should be kept within the Investigator site file and the Sponsor's files.**

| **Documents**<br>***Documents to be in files before a trial starts:*** | **Located in the Files of the Investigator** | **Located in the Files of the Sponsor** |
|---|---|---|
| 1. Investigators brochure | ✓ | ✓ |
| 2. Protocol and amendments and a sample case report form (CRF) | ✓ | ✓ |
| 3. Information given to trial subjects<br>3.1 Informed consent form<br>(including translations)<br>3.2 Information sheet<br>3.3 Adverts for recruits | <br>✓<br>✓<br>✓ | <br>✓<br>✓<br>✓ |
| 51. Financial Agreement<br>Grant Award Letter | ✓ | ✓ |
| 5. Insurance statement<br>5.1 Indemnity form | ✓ | ✓ |
| 6. Signed agreements (between involved parties) | ✓ | ✓ |
| 7. Dated documented approval of all trial related documents.<br>7.1 By REC<br>7.2 Composition of REC (where available) | <br>✓<br>✓ | <br>✓<br>✓ |
| 8. Regulatory Authority approval/ Authorisation (where required) | ✓ | ✓ |
| 9. CV's of the following:<br>9.1 Investigator<br>9.2 Co-investigator<br>9.3 Research Nurse | <br>✓<br>✓<br>✓ | <br>✓<br>✓<br>✓ |
| 10 Normal values and ranges for medical/ laboratory/technical procedures /tests included in the protocol | ✓ | ✓ |
| 11. Certification/accreditation for medical/ laboratory/technical procedures/tests | ✓ | ✓ |
| 12 Sample of label(s) attached to IMP containers | | ✓ |
| 13 Instructions for handling investigational product | ✓ | ✓ |
| 14 Shipping records for investigational products | ✓ | ✓ |
| 15 Certificate of analysis of IMP shipped | | ✓ |
| 16 Decoding procedures for blinded trials | ✓ | ✓ |
| 17 Master randomisation list | | ✓ |
| 18 Pre-trial monitoring report | | ✓ |
| 19. Trial initiation monitoring report | ✓ | ✓ |
| ***Documents filed during the conduct of a study*** | | |
| 20. Relevant communications<br>20.1. Letters<br>20.2. Faxes<br>20.1 Emails | ✓<br>✓<br>✓<br>✓ | ✓<br>✓<br>✓<br>✓ |

| | | |
|---|---|---|
| 20.2 Meeting notes<br>20.3 Notes of telephone calls | ✓ | ✓ |
| 21 Monitoring visit reports | ✓ If STH sponsored | ✓ |
| 22 Certificates of analysis for new batches of IMPs | | ✓ |
| 23. Documentation of IMPs and trial-related materials shipment | ✓ | ✓ |
| 24. Updates of medical/laboratory/technical procedures & tests | ✓ | ✓ |
| 25. Updates of normal values & ranges for procedures/tests included in the protocol | ✓ | ✓ |
| 26. Signed informed consent forms | ✓ | |
| 27. Source documents | ✓ | |
| 28. Signed dated and completed Case Report Forms (CRF) | ✓ (copy) | ✓ (original) |
| 29. Documentation of CRF corrections | ✓ (copy) | ✓ (original) |
| 30. Serious Adverse Events (SAEs): Notification by originating investigator to sponsor of SAEs and related reports | ✓ | ✓ |
| 31. Serious adverse drug reactions reported by sponsor (if any) to regulatory authorities and Ethics Committees of unexpected serious adverse drug reactions and other safety information | ✓ | ✓ |
| 32. Safety information | ✓ | ✓ |
| 33. Interim or annual reports to regulatory bodies/ethics | ✓ | ✓ |
| 34.Subject screening log | ✓ | ✓ |
| 35. Subject identification code list | ✓ | |
| 36.Subject enrolment log | ✓ | |
| 37.CVs for new investigators | ✓ | ✓ |
| 38. Signature sheet | ✓ | ✓ |
| 39. IMP accountability at the site | ✓ | ✓ |
| 40. Record of retained body fluids/tissue samples | ✓ | ✓ |
| 41. Investigator brochure updates | ✓ | ✓ |
| 42.Amendments to protocol/information sheets/consent form/CRF | ✓ | ✓ |
| 43. Ethical approval of amendments/revisions | ✓ | ✓ |
| ***Documents filed at the end of a trial*** | | |
| 44. Investigation product accountability at site | ✓ | ✓ |

| | | |
|---|---|---|
| 45. Documentation relating to IMP destruction | ✓ | ✓ |
| 46. Completed subject identification code list | ✓ | |
| 47. Audit certificate (if available) | ✓ | ✓ |
| 48. Final trial close-out monitoring report | ✓ | ✓ |
| 49. Treatment allocation and decoding information | | ✓ |
| 50. Final report by investigator to regulatory bodies/ethics | ✓ | ✓ |
| 51. Clinical Study Report | ✓ | ✓ |

## Appendix 4
## Recommended Period of Archiving of Essential Documentation

The following matrix outlines the duration for which the STH Clinical Research & Innovation Office would expect the Investigator to retain the essential documentation generated during the course of a research project. For those studies involving investigational devices or surgical intervention, the same principles will be followed as for trials of IMPs to reflect the risk associated with these types of study. For studies that do not involve regulatory submissions i.e. non interventional research that does not involve the use of an IMP or a device, the minimum period for archiving should be at least five years after completion of the study in line with DHSC recommendations.

| # | Category of Study | Recommended Period of Retention of Investigator Site File | Location of Archived Investigator Site File | Point at which Site Files can be destroyed |
|---|---|---|---|---|
| 1 | IMP Study – STH Sponsored | 15 years | In a suitable location on STH premises approved by Clinical Research & Innovation Office or at an agreed off-site facility | 15 years after the declaration by PI of the end of the study. |
| 2 | IMP Study – Non-commercially Sponsored | At least 5 years (longer if sponsor requires) | Investigator or delegate should negotiate with the sponsor for the off-site storage of documents. | The sponsor will notify the PI of when documents can be destroyed. |
| 3 | IMP Study – Commercially Sponsored | At least 5 years (longer if sponsor requires) | Investigator or delegate should negotiate with the sponsor for the off-site storage of documents. | The sponsor will notify the PI of when documents can be destroyed. |
| 4 | Investigational Device Study – STH Sponsored | As for IMP studies (#1) | As for IMP studies (#1) | 15 years after the declaration by PI of the end of the study. |
| 5 | Investigational Device Study – externally Sponsored | As for IMP Studies (#2 or #3) | As for IMP Studies (#2 or #3) | As for IMP Studies (#2 or #3) |
| 6 | Surgical Intervention Study – STH sponsored | As for IMP Studies (#1) | As for IMP studies (#1) | 15 years after the declaration by PI of the end of the study. |
| 7 | Surgical Intervention Study – externally sponsored | As for IMP Studies (#2 or #3) | As for IMP Studies (#2 or #3) | As for IMP Studies (#2 or #3) |
| 9 | Low risk Interventional study – STH Sponsored | 5 years (longer if sponsor requires) | As for IMP studies (#1) | 5 years after declaration by PI of the end of study |
| 10 | Low risk Interventional study – Externally Sponsored | At least 5 years (longer if sponsor requires) | As for IMP Studies (#2 or #3) | As for IMP Studies (#2 or #3) |
| 11 | Non-interventional Study – STH Sponsored | 5 years | As for IMP studies (#1) | 5 years after declaration by PI of the end of study |
| 12 | Non-interventional Study – Externally Sponsored | At least 5 years (longer if sponsor requires) | As for IMP Studies (#2 or #3) | As for IMP Studies (#2 or #3) |
| 13 | ATMP Study – STH Sponsored | Investigator should seek confirmation from Clinical Research & Innovation Office | In a suitable location on STH premises approved by Clinical Research & Innovation Office or at an agreed off-site facility | To be confirmed by sponsor |

| | | | | |
|---|---|---|---|---|
| 14 | ATMP Study - Non-commercially Sponsored | Investigator should seek confirmation from Sponsor | Investigator or delegate should negotiate with the sponsor for the off-site storage of documents. | To be confirmed by sponsor |
| 15 | ATMP Study - commercially Sponsored | Investigator should seek confirmation from Sponsor | Investigator or delegate should negotiate with the sponsor for the off-site storage of documents. | To be confirmed by sponsor |

## Appendix 5
## Record of Archived Essential Documentation for a Clinical Trial

**Please complete and retain a copy of this form in the archived investigator site file, keep a copy at the investigator site as a record of documentation sent to archive and provide a copy to the Clinical Research & Innovation Office**

| | |
|---|---|
| STH Study No: | |
| Study Title: | |
| Study Sponsor: | |
| Investigator Name: | |

| Hardcopy Documents | Location of Archived Documents (e.g. on site/off site archive & file No/archive box No) | Date Documents Archived | Planned Destruction Date of Archived Documents | Dated Documents Destroyed |
|---|---|---|---|---|
| | | | | |
| | | | | |

| Electronic Documents | Location of Electronic Archived Documents (e.g. file location, drive & folder file name) | Date Electronic Documents Encrypted and Compressed | Planned Destruction Date of Electronic Archived Documents | Date Electronic Documents Permanently deleted |
|---|---|---|---|---|
| | | | | |
| | | | | |

**1. I can confirm that the above documents have been archived in accordance with all applicable Regulations.**

Signed…….. (Investigator's or delegate's signature)

Date…….....

**2. I can confirm that the above documents have been destroyed in accordance with all applicable Regulations.**

Signed…….. (Investigator's or delegate's signature)

Date…….....

**Please return a copy of this form to the STH Clinical Research and Innovation Office, D Floor, Royal Hallamshire Hospital, Glossop Road, S10 2JF or STH.ResearchAdministration@nhs.net**

**Appendix 6**
**Label for Archived Documents**

# ARCHIVED DOCUMENTS

| | |
|---|---|
| **Project STH Ref** | |
| **Project Title** | |
| **Principal Investigator** | |
| **Box Description** | |
| **Archive Box Number (e.g. box X of X)** | |
| **DO NOT DESTROY BEFORE** | |
| **Research Office Use** | |
| **RESTORE Account Ref** | **ST4** |
| **Research Office Box Number** | |

***NB: In the event that this box is moved from this location please inform the STH Clinical Research and Innovation Office (Tel: 0114 2265431 Fax: STH.Researchadministration@nhs.net)***

## Appendix 7
## Off-site Archiving Specialist Contact Details

RESTORE Document Management
Leeds Data Centre,
Whitehall Road Industrial Estate,
Leeds
LS12 5JB

RESTORE
http://www.restore.co.uk

0113 384 1000