STU-SOP-TC-001 – Standard Operating Procedure on Preparation and Management of Archived Clinical Research Data

1. Purpose

This Standard Operating Procedure (SOP) describes the procedure for archiving, retrieval and destruction of research project documentation for projects adopted by Swansea Trials Unit (STU). Further information on adoption can be found in STU-SOP-ADM-005 Adoption.

The procedure for archiving may vary depending on the sponsor organisation. However, STU will ensure that appropriate arrangements are in place for archiving research documentation in accordance with their delegated duties, applicable legislation and guidelines.

Retention of research project documentation is a regulatory requirement for Clinical Trial of Investigational Medical Product (CTIMPs).

Within STU, project documentation must be retained so that data are accessible after a project has completed to enable, for example:

- Further analysis of project data
- Inspection by a regulatory body such as the Medicines and Health Care products Regulatory Agency (MHRA)
- Funder or contractual requirements

2. Background

Archiving arrangements, including a retention period for any research project are the responsibility of the Sponsor taking into account legal requirements where applicable.

Research Sponsor's usually delegate responsibility for archiving to the Chief Investigator (CI) of a project. The associated tasks and liaison with Principal Investigators (PI) at research sites is usually completed by the Trial Manager (TM). All delegations between sponsor, CI and PIs will be recorded in agreements as appropriate.

Research project documentation consists of all documents and data. This can include a sponsor oversight file, Trial Master File (TMF), Investigator Site Files (ISF) and pharmacy files. All component parts of the TMF must be archived at the end of the project as determined by the protocol or early termination.

The Good Clinical Practice (GCP) guideline details which documents comprise the **minimum** list of essential documents required for the TMF and these are detailed in the TMF SOP (STU-SOP-TM-002). Any documentation created during the research project that helps reconstruct and evaluate project conduct must be filed in the TMF.

Research project documentation may be generated in electronic or paper form. Source documents may be original documents, data and records held at any organisation involved in the research project (e.g. hospital records, laboratory notes, participant diaries, completed questionnaires or files, pharmacy records, data or scans recorded from automated instruments, copies or transcriptions certified as being accurate copies).

For CTIMPs, clinical trial regulations require a named archivist with documented responsibilities. The regulations dictate that all clinical trial information shall be recorded, handled and stored in a way that allows its accurate reporting, interpretation and verification and that confidentiality of records that could identify participants shall be protected, respecting the privacy and confidentiality rules in accordance with the requirements of the Data Protection Act.

Funder and sponsor requirements may result in an increase but not decrease in these retention times.

3. Roles and Responsibilities

The **Sponsor** has overall responsibility for appointing a named archivist and ensuring there are appropriate procedures in place for archiving, and that staff comply with the process. Sponsor are also responsible for ensuring that appropriate and adequate archive facilities are in place, or appropriate contracted facilities are available.

The **Chief Investigator (**CI), when delegated, has responsibility for the logistics and arrangements necessary for archiving of the TMF. It is the responsibility of the CI to ensure that the TMF is not kept longer than stated on the Research Ethics Committee (REC) application, nor destroyed prior to the end of the retention period. The CI is responsible for seeking agreement for any required retention period extensions from the Sponsor, REC and funder.

The CI is also responsible for ensuring that the delegation of archive responsibilities are documented in a trial delegation log (STU-AD-TMP-019), for maintaining adequate oversight and ensuring that the TMF is made available for audit or inspection on request during the archive period.

If the CI leaves their employment post during the archive period, they are responsible for advising the Sponsor of their intentions. The CI must inform the Sponsor of the change in responsibility. Further information is available in STU-SOP-TM-014 Managing a Change of CI.

The **Trial Manager** (TM) is usually delegated the role of preparing the project TMF for archive.

The TM must establish if the project can be archived in the STU facility or if alternative arrangements will be required.

The TM is responsible for ensuring that all documentation required in the TMF (including site, laboratory, pharmacy and vendor files as appropriate) are available, adequately prepared, recorded and transferred to the archive facility. For a multicentre project, organisation and oversight of the process at sites will be required.

The TM must ensure that all documentation is complete, legible, traceable and readily accessible upon request. They will complete an archive transfer form (STU-AD-FRM-001) which should contain sufficient detail to support the retrieval, review and destruction of archived material in the future.

The TM must ensure that all documents are prepared for archive as described in the guidelines for archive preparation (STU-AD-GDN-001).

In a multicentre project, the TM must liaise with the local Principal Investigator (PI) or delegate to ensure that the ISF is complete, archived appropriately with documentation received to clarify. It is usual for the ISF to be archived at the host organisation.

The site **Principal Investigator (**PI) has delegated responsibility for ensuring that all data in the ISF required for retention are available, adequately prepared, recorded and archived appropriately. PIs who plan to leave their employer are responsible for notifying the sponsor of any archived research project they have responsibility for. Alternative arrangements for responsibility of data retention will need to be agreed and documented by the sponsor.

The **STU archivist** is responsible for agreeing to the research project being stored in the STU archive facility after review of the archive transfer form (STU-AD-FRM-001).

The STU archivist or delegate will ensure that all boxes or files to be archived have the appropriate Box Label Template (STU-AD-TMP-001) and will advise of the date when the boxes can be received.

The STU archivist or delegate is responsible for ensuring that research project data are received and stored securely in appropriate archive facilities. They will ensure appropriate environmental conditions, vector control and controlled access procedures are restricted to authorised personnel only within the STU archive facility.

The STU archivist or delegate will ensure that removal, request for review, relocation or return of material held in the STU archive is adequately documented and authorised (STU-AD-FRM-002 Retrieval form and STU-AD-TMP-044 Retrieval Log).

The STU archivist or delegate is responsible for ensuring the disposal or destruction of material held in the STU archive (STU-AD-FRM-003, Destruction form).

The STU archivist or delegate will ensure that any third party facilities used for the archive of CTIMPs are managed by a reputable provider in premises with appropriate environmental conditions, vector control and access restricted to authorised personnel. Further information can be found in STU-SOP-TS-004 Vendors.

External use of SOP: this SOP and Associated Documents (AD) may be used for research projects not adopted by STU where Swansea University (SU) staff and associated NHS organisations require guidance. In such instances, oversight responsibility for any associated tasks will not be the responsibility of STU.

4. Procedure

4.1 Archive considerations during project design

Full archiving arrangements, including costs and retention period shall be documented during the design phase for a research project. Future extension of the retention period will incur additional costs whether in STU or a third party facility.

Retention periods must be documented in the Research Ethics Committee (REC) application form submitted to the REC.

STU minimum retention periods for closed research projects are:

- CTIMPs and non-CTIMPs which involve a medicinal product – 25 years
- non CTIMPs (including regulated device trials)– 5 years
- Interventions involving children – until 3 years after youngest participant reaches 18 years of age, or 5 years after project conclusion, whichever is longer

Some non-CTIMP research projects will require a longer retention period e.g. device trials, genetic studies and interventional projects involving children or because the funders terms require a longer retention period. In such circumstances, the retention period will be established on a case by case basis during the design phase and documented in the protocol.

For interventional research projects, arrangements should also be made to ensure that participant medical records and source data are retained throughout the archive period. NHS organisations may have different policies for retaining medical records.

It is essential to ensure that medical records of all participants involved in a research project are identified for retention according to local policy e.g. placing adhesive label to the medical record, setting an electronic alert. The minimum information to be recorded should be:

- Project acronym or short title
- Project ID number (REC reference and EudraCT number (CTIMPS only)
- Name of the local Principal Investigator
- Name of department and contact number
- Retention period

For multicentre research projects, the CI must determine whether the ISF shall be archived at site or returned to Sponsor. This should be documented in the protocol and TMF.

The Sponsor shall issue agreements for the research project which will delegate the responsibility for archiving of the TMF and ISF in multicentre projects, with oversight by the CI.

4.2 Archiving Process

All appropriate authorities should be notified of completion (or termination) of the research project.

The CI or TM (if delegated) shall ensure that all documents required for the TMF are available and prepared as per section 4.3.

The CI must ensure that any publications after files have been archived are added to the physical archive. This should include updating the Archive Transfer Form.

Within STU, electronic project data will be held in a defined archive area of a computerised system. Data files will be 'locked' to ensure they cannot be altered or deleted without detection, with access restricted to those authorised to view them as documented in the TMF.

When the TMF has been prepared for archive the CI or delegate should contact the STU archivist via STU@swansea.ac.uk with a single completed transfer form (STU-AD-FRM-001) and **electronic copies** of individual archive contents lists for each box to be archived to confirm the physical arrangements required.

When agreed that the project can be archived in the STU archive facility the STU archivist will issue an archive identity number for each box to be submitted.

The STU archivist or delegate will agree a date and time for the boxes to be accepted to the archive.

The CI or delegate must arrange for the boxes to be transferred to the STU archive at the agreed date and time.

On receipt of the boxes the STU archivist or delegate will return electronic copies of the individual archive contents lists to the CI updated with details of the allocated STU archive number.

Should a sponsor require offsite archiving, the STU archivist or delegate will liaise with the sponsor archivist. The principles of this SOP will be followed.

4.3 Multicentre Projects

The CI or delegate will notify the PI and coordinate the archiving of the ISF as soon as is practicable after site closure. This will usually follow a site closure visit or document assessment via a remote check.

In a multicentre project it is the responsibility of each PI to arrange archiving of paper and electronic data, in accordance with the sponsor agreement and local policies.

The PI is also responsible for complying with the terms of the project agreement, regulations and guidelines for archiving medical records, data or information or data received by them during or after project completion.

The secure storage arrangements for ISFs should be documented in the TMF.

4.4 Access to Archived Data

Access to archived documents should be arranged by completing an Archive Retrieval Form (STU-AD-FRM-002) and sending to the STU Archivist via STU@swansea.ac.uk.

On receipt of the retrieval form arrangements will be made for the box(es) to be returned to an authorised person within 10 working days of receipt of the written request.

Retrieved boxes can be kept for:

- CTIMPs – 4 WEEKS before return to the archive is required
- Non-CTIMPS – 2 MONTHS before return to the archive is required

Longer periods for access may be agreed with the STU archivist.

If removed material is not to be returned to the archive, this must be documented in an updated content index and on the archive retrieval form.

4.5 Archive Review and Disposal

When a project has reached the end of the retention time specified at initial archiving, the STU archivist shall contact the CI.

The CI will be required to decide whether to:

- Archive the data for a further period of time or,
- The data should be securely destroyed

The CI should confirm the further storage or destruction of the archived project. The STU archivist or delegate will complete the destruction form and send a copy to the CI.

5. References

- Health Research Authority website (HRA) - http://www.hra.nhs.uk/
- Medicine and Healthcare products Regulatory Agency website (MHRA) - https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency/services-information
- UK policy framework for health and social care research (2017) - https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/
- UK Medicine for Human Use (Clinical Trials) Regulations 2004 - http://www.legislation.gov.uk/uksi/2004/1031/contents/made
- Data Protection Act (1998) - https://www.gov.uk/data-protection/the-data-protection-act
- Good Clinical Practice: A Guide to Archiving – Scientific Archivists Group Second Edition (2014) http://www.sagroup.org.uk/publications/good-clinical-practice-a-guide-to-archiving
- A Guide to Archiving of Electronic Records – Scientific Archivists Group (2014) http://www.sagroup.org.uk/publications/e-archive

It is assumed that by referencing the principal regulations that all subsequent amendments are included in this citation.

6. Associated Documents

Number	Title	Location
STU-AD-GDN-001	Archive guidance	Q-Pulse
STU-AD-TMP-001	Archive Box Label Template	Q-Pulse
STU-AD-FRM-001	Archive Transfer Form	Q-Pulse
STU-AD-FRM-002	Archive Retrieval Form	Q-Pulse
STU-AD-FRM-003	Archive Destruction Form	Q-Pulse
STU-AD-TMP-044	Archive Retrieval Log	Q-Pulse

7. Abbreviations

List of Abbreviations	
CI	Chief Investigator
CRF	Case Report Forms
CTIMP	Clinical Trial of an Investigational Medicinal Product
GCP	Good Clinical Practice
ISF	Investigator Site File
MHRA	Medicines and Healthcare products Regulatory Agency
PI	Principal Investigator
REC	Research Ethics Committee
SOP	Standard Operating Procedure
STU	Swansea Trials Unit
SU	Swansea University
TM	Trial Manager
TMF	Trial/Project Master File

8. Appendices

Appendix 1: Document History

Version No:	4	**Effective Date:**	22-Apr-2024
Description of changes:	Updated to SOP Template v5		