

STANDARD OPERATING PROCEDURE 23

Archiving

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V5.0	19/11/2025	Biennial review: Multiple changes to text to allow for more succinct wording and to accommodate. Branding update. Minor corrections.
V4.0	18 Oct 2023	Biennial review: Additional information added to cover archiving of different types of records including email. Minor format changes.
V3.0	22 Jul 2021	Biennial review: Update to new SOP template Minor updates to text. Addition of further items to consider on ingestion to the archive.
V2.0	08 May 2019	Biennial review: update to new SOP template, clarification on scope, addition of 'named archivist' section, removal of detail regarding trials that support Marketing Authorisations. Ordering of text changed. Minor text amends. Web links updated.
August 2015		Biennial review – no changes required
V1.4	15 August 2013	Addition of requirement to archive staff training records and study related electronic data files.
V1.3	19 March 2012	Format change to comply with SOP 1.
V1.2	15 March 2010	Biennial review: Web page links updated. Text to explain what records need to be archived moved from section 3.3.3 to 3.3.1.
V1.1	31 January 2008	Biennial review: Format change. Amendment to text to reflect new legislation. Correction of typographical errors.



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1 Purpose and Scope

This SOP outlines the legal and procedural requirements for archiving paper and electronic records (including data) from UoW sponsored studies.

For co-sponsored studies, archiving responsibilities must be defined in the co-sponsorship agreement. Where another organisation is the sponsor, they are responsible for archiving unless otherwise agreed in the collaboration agreement.

Archiving of the ISF must follow the study protocol and local site policies. The Principal Investigator is responsible for ensuring ISF retention in accordance with these requirements.

2 Acronyms

CI	Chief Investigator
CDMS	Clinical Data Management System
CTIMP	Clinical Trial of an Investigational Medicinal Product
FRS	Functional Requirement Specification
ICH GCP	International Conference on Harmonisation Good Clinical Practice
ISF	Investigator Site File
PDF	Portable Document Format
PI	Principal Investigator
QA	Quality Assurance
QC	Quality Control
ROPA	Record of Processing Activities
R&IS	Research & Impact Services
SOP	Standard Operating Procedure
TMF	Trial Master File
UoW	University of Warwick
WCTU	Warwick Clinical Trials Unit

3 Definitions

Archiving	The long-term retention of the essential records contained within the TMF and any associated records that enable the accurate re-construction of study activity.
Essential Records	Records that individually and collectively allow evaluation of the study conduct and data quality. They demonstrate the compliance with GCP and with applicable regulations. See SOP 11 for more details.
Named Archivist(s)	Named individual(s) responsible for archiving records held in the TMF.
'Archived'	A record is considered 'archived' when custody is restricted to the Named Archivist(s).

Clinical Data Management System (CDMS)	A tool used to collect, track, process and store clinical research data.
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4 Background

According to ICH-GCP guidelines, essential records must be filed in an organised manner within the TMF to support trial management, audit, and inspection. These records must be retained for sufficient time to allow verification of results and regulatory review, and must be readily accessible upon request.

Under the Medicines for Human Use (Clinical Trials) Regulations, sponsors of CTIMPs must appoint one or more individuals responsible for archiving TMF records at the end of the trial which are referred to as ‘Named Archivists’.

5 Responsibilities

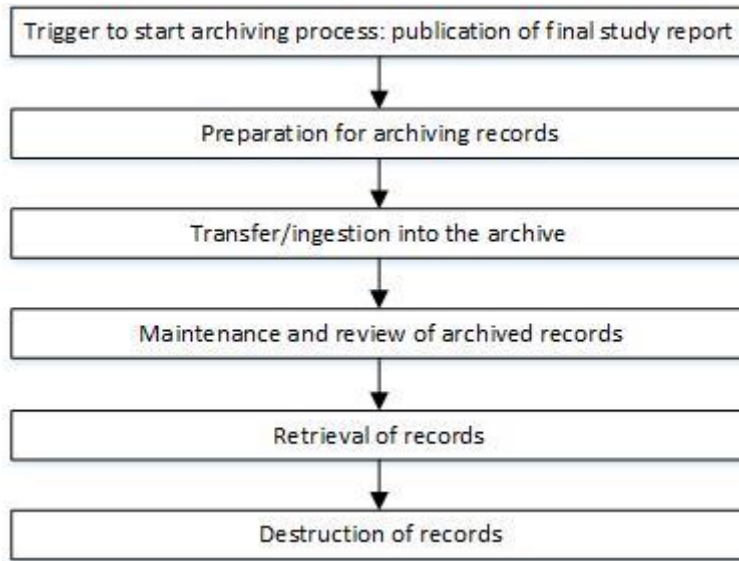
Sponsor	Ensures archiving of study records at the coordinating centre. This may be delegated to appropriately trained individuals.
Chief Investigator (CI)	Ensures long-term retention of records in accordance with this SOP. For UoW sponsored studies managed by WCTU, the CI must ensure all essential records are collated before transfer to the archivist.
Named Archivist(s)	Responsible for secure archiving of the TMF (Including the clinical data), maintaining the archive log, monitoring for digital obsolescence, managing retrievals and destruction, and overseeing archive providers. For WCTU managed studies, the named archivists are the QA Managers and the Programming Team Manager.
Head of Operations	For WCTU studies, Head of Operations should approval retrieval and destruction requests.

6 When?

Archiving should be planned from the beginning of a study. Costs must be included in initial grant applications and archiving requirements detailed in the study protocol.

Archiving should be triggered upon publication of the final study report. Once records are ingested into the archive, retention and maintenance requirements should be reviewed at an agreed date.

7 How?



7.1 Preparation for archiving records

The TMF may be stored across multiple locations or systems prior to archiving. This is acceptable, provided the location for each essential record is clearly documented. The TMF index and map (T26) should be used to record all repositories.

The same principle applies at the point of archiving. It should be clear where each TMF component is stored during archiving. Common examples of records held outside the main TMF folder include:

- Programming documentation (e.g. FRS, database testing, sprint records)
- Study data and audit trails
- Statistical analysis scripts
- Emails evidencing key decisions or activity (these should not be located in an individual’s account but a group mailbox)
- Electronic approvals, regardless of location.

Table 1: Pre-archiving checklist

Check TMF repositories	<ul style="list-style-type: none"> • Ensure essential records are complete and legible • File emails according to the TMF index, within the relevant section of the study inbox
Anonymise data	<p>Remove personal data no longer needed (unless justified, e.g. for long-term follow-up or reconstruction of results)</p> <ul style="list-style-type: none"> • Check the PIS for data retention guidance • Request deletion of personal data from the CDMS via the WCTU Programming HelpDesk.

	Create and retain an anonymised dataset and data sharing pack for potential data sharing (see Guidance G35).
Update ROPA	<ul style="list-style-type: none"> • Reflect the level of personal data retained • Add the retention date and change status to 'Archived'.
Document media types	<ul style="list-style-type: none"> • Provide the archivist with a list of systems and applications applicable to electronic records in the TMF to facilitate review of obsolescence. •
Review contracts	<ul style="list-style-type: none"> • Ensure contracts are reviewed. • Update ROPA to reflect expiry of any Data Sharing.

Once complete, assess whether the format of each record is suitable for long-term retention. Document the transfer and retain evidence of acceptance by the archivist.

Table 2: Media format considerations

Media type	Suggested actions
Paper	Removal rubber bands, plastic wallets, paper clips, and staples Check for contamination; consider certified copies if needed. Digitisation may be considered. See IMSOP03 .
Electronic Docs (Inc. audit trails)	Convert to PDF where possible, ensuring audit trails and metadata are preserved. Remove passwords on any electronic records.
CDMS	<ul style="list-style-type: none"> • Store on university servers with edit access removed. For systems not managed by WCTU Programming, ensure all data is on the servers and edit access is restricted.
Other media	<ul style="list-style-type: none"> • Identify items prone to deterioration (e.g. Thermochromic paper or photographs/scans) Transfer to university servers for stability. Photographs and films may also need scanning or uploading to university servers to improve stability.

7.2 Transfer/ingestion into the archive

- All electronic files from TMF repositories should be archived as identified in the TMF map or index. Archiving may involve restricting access rather than relocating files, provided their location is clearly documented.
- The archiving log should include:

- Location of each repository
- Contents
- Required software (including version)
- Review date to ensure ongoing compatibility and retrievability
- For WCTU managed studies:
 - The archivist should arrange transfer to the appropriate archive space (if it will be moved)
 - The QA team should retain a record of the transfer
 - Evidence of collection should be retained by the archivist for records sent to external providers for archiving.
- Details of archiving arrangements for different repositories are outlined below:



7.3 Maintenance and review of archived records

The CI (or the archivist for WCTU managed studies) must ensure that archived records remain secure and retrievable throughout the retention period. A review date should be set at the point of archiving.

Electronic records may require format updates over time due to changes in software or hardware. Regular reviews should confirm continued compatibility and accessibility.

Archived personal data remains subject to UK GDPR. Any commitments made to participants regarding data removal or destruction must be honoured and reflected in review and destruction schedules.

7.4 Retention, retrieval and destruction

7.4.1 Retention Periods:

- CTIMP records must be retained for 25 years.

- Non-CTIMP records should be retained as per protocol, reflecting sponsor and funding policies.
- The study is considered complete upon publication of the final study report.

7.4.2 Retrieval of Records:

- Archived records must be promptly retrievable for audit or inspection
- For WCTU managed studies, retrieval requests must be submitted in writing to the named archivists with approval from the Head of Operations (or delegate) documented
- Records on loan must be tracked, with location and loan period recorded
- Electronic records must be retrieved in read-only format and must not be altered.
- Any changes in ownership or location of archived records must be documented for traceability.

7.4.3 Destruction of Records:

- Essential records must not be destroyed before the minimum retention period
- After this period, the CI or archivist may notify investigator sites in writing if records no longer need to be retained
- If sponsor/coordinating centre records are to be destroyed, the rationale must be documented and signed by Head or Deputy Head of Operations.
- A certificate of destruction must be retained by the WCTU QA Team for five years post destruction.
- Records may be retained beyond the minimum period if personal data obligations are met and funding allows.

7.5 Considerations for location and oversight of archiving

Adequate and suitable space should be provided for the secure storage of all essential records upon study completion. Systems should be in place to prevent accidental destruction and ensure that they are retrievable throughout the retention period.

The following considerations apply when assessing the suitability of archiving locations:

Considerations	Paper Records	Electronic Records
Security	Locked cabinets, restricted rooms; risk of theft or fire	Role-based access, encryption, audit trails, cybersecurity controls
Location	Centralised or off-site archive; must be secure and accessible	Validated servers
Size	Requires significant physical space	Compact; scalable storage depending on system capacity
Environmental factors	Sensitive to humidity, temperature, and light	Requires climate-controlled server environments and stable power supply

Pests	Vulnerable to insects, rodents, mould	Not directly applicable; hardware may be affected by environmental hazards
Obsolescence	Format remains readable indefinitely	Risk of software or format becoming outdated; requires proactive monitoring and migration planning

For WCTU-managed studies, most paper records are transferred to a commercial archive contractor. However, the **named archivist** retains responsibility for ensuring the quality, integrity, confidentiality, and retrievability of these records on behalf of the sponsor.

The archivist must:

- Audit the archive site and document its suitability
- Ensure a formal contract is in place with any archive provider (paper or electronic)
- Consider periodic re-audits
- Escalate any concerns to the Sponsor’s Office at R&IS via sponsorship@warwick.ac.uk

7.6 Investigator sites no longer able to store essential records

If an investigator site becomes unable to store their essential records, the sponsor/study organisers should be notified in writing so that alternative storage arrangements can be agreed. The sponsor should never have sole control of the ISF unless the sponsor is also an investigator site.

7.7 Change of ownership

If ownership of the records changes (e.g. change of sponsor), the sponsor must record the transfer, and the new owner becomes responsible for data retention and archiving. This should also be reflected in updated contractual agreements.

7.8 Retention of Training Records from WCTU staff leaving the University

Training records of study staff will be retained for 25 years after a staff member leaves the university in case they are required for audit or inspection.

7.9 Named Archivist Arrangements

Named archivists must have documented training in archiving. If an archivist leaves the role, a clear handover plan should be prepared, and access records updated to reflect the change.



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