STANDARD OPERATING PROCEDURE 23
Archiving

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Revision Chronology:	Effective date:	Reason for change:
Version 4.0	18 Oct 2023	Biennial review: Additional information added to cover archiving of different types of documents including email. Minor format changes.
Version 3.0	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.
Version 2.0	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
Version 1.4	15 August 2013	Addition of requirement to archive staff training records and study related electronic data files.
Version 1.3	19 March 2012	Format change to comply with SOP 1.
Version 1.2	15 March 2010	Biennial review: Web page links updated. Text to explain what documents need to be archived moved from section 3.3.3 to 3.3.1.
Version 1.1	31 January 2008	Biennial review: Format change. Amendment to text to reflect new legislation. Correction of typographical errors.

STANDARD OPERATING PROCEDURE 23
Archiving

1. Purpose and Scope

The purpose of this Standard Operating Procedure (SOP) is to detail the legal requirements covering the archiving of paper and electronic records (inc. data) generated from University of Warwick (UoW) sponsored studies and to describe procedures for its implementation. For co-sponsored studies responsibility for archiving should be clearly defined in the co-sponsorship agreement. Where a study is sponsored by other organisations, it is their responsibility to arrange archiving provision unless detailed in the agreement. *The process for archiving of the Investigator Site File (ISF) should be done in accordance with both the protocol and local investigator site policies. It is the Principal investigators responsibility to ensure it is retained in line with these.*

2. Definitions

Archiving	Archiving of a study refers to the long term retention of the essential documents contained within the TMF and any other associated documents or data that allows for the accurate re-construction of activity.
Essential Documents	The documents which individually and collectively permit evaluation of the conduct of a clinical study, and the quality of the data produced. These documents serve to demonstrate the compliance of the investigator or sponsor with the standards of GCP and with applicable regulatory requirements. see SOP 11 'Essential Documentation' for more details.
Named Archivist(s)	Named individual(s) responsible for archiving records which have been contained in the Trial Master File (TMF).
'Archived'	For records to be considered 'archived' custody should be restricted to the Named Archivist(s)
Clinical Data Management System (CDMS)	A tool used for the collection, tracking, processing and storage of data used in clinical research.

3. Background

The International Conference on Harmonisation (ICH) Good Clinical Practice (GCP) Guidelines say that essential documents should be filed in an organised way that will facilitate management of the clinical trial, audit and inspection and should be accessible in a TMF. Essential documents must be retained (archived) for sufficient periods to allow for audit and inspection by regulatory authorities and should be readily available upon request.

It is a requirement of the Medicines for Human Use (Clinical Trials) Regulations that for Clinical Trials of Investigational Medicinal Products (CTIMPS), the sponsor appoints an individual or individuals within the organisation who are responsible for archiving the documents which are in the TMF at the conclusion of the trial and that these documents are retained for a minimum of five years unless a longer period is defined by the Sponsor organisation or other contractual requirements.

4. Procedure

4.1 Responsibilities

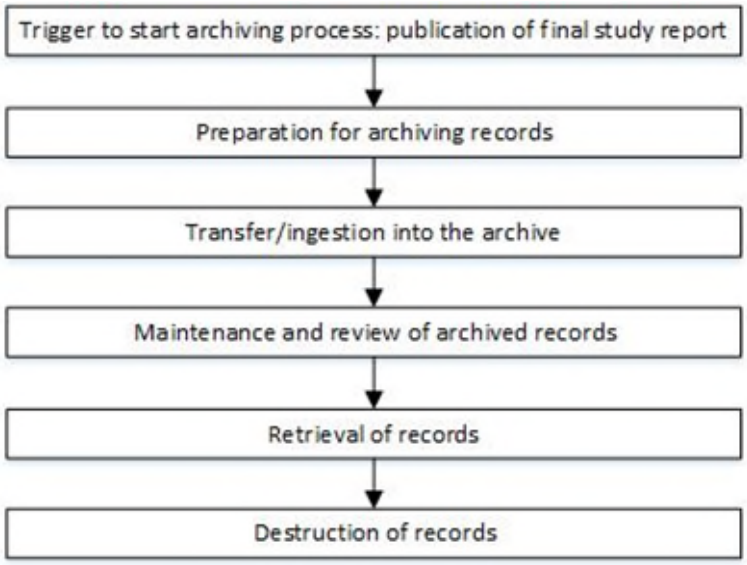
Sponsor	Archiving of the study at the coordinating centre. This activity can be delegated to appropriately trained individuals.
Chief Investigator (CI)	Responsible for ensuring there is provision for long term retention of documents in accordance with the this SOP. Where Warwick Clinical Trials Unit (WCTU) are managing a UoW sponsored study, the CI is responsible for ensuring all essential documents are collated prior to transfer to the archivist.
Named Archivist(s)	Responsible for the safe and secure archiving of the TMF (Including the clinical data), maintaining the archive log, monitoring for digital obsolescence, control of retrievals, implementation of destruction and oversight of any archive providers. The named archivists for studies managed by WCTU are the QA Managers and the Programming Team Manager.

4.2 When?

Archiving should be considered from the beginning of a study. Costings for archiving must be included in initial grant applications and the requirements for archiving for both the sponsors TMF and ISF(s) should be detailed in the study protocol.

Archiving of a completed trial should be triggered upon publication of the final study report. Once the records have been ingested into the archive the continued retention and any maintenance requirements should be reviewed at an agreed review date.

4.3 How?



4.3.1 Preparation for archiving records

Prior to the archiving, it may be the case that the TMF is not all in one place. This is acceptable practice but it should be clear where each of the essential documents are located if kept separately in electronic files or in other geographical locations. The TMF index and map (T26) can be used to record the locations of all essential document repositories. When it comes to archiving, the same principles apply and it should be clear where each element of the TMF is archived. Examples of items which may be held externally to the main TMF folder include:

- Programming documentation: Functional Requirement Specifications (FRS), database testing and sprint documentation
- Quality Control (QC) checks of data entry
- Study data and associated audit trails
- Statistical analysis scripts
- Emails documenting key decisions or demonstrating evidence of activity for reconstruction
- Electronic approvals contained within the Q-Pulse Electronic Quality Management System (EQMS)

Considerations prior to archiving:

Check content of all repositories of the TMF	• Eessential documents complete and legible • Emails filed as per the TMF index, correspondence should be filed within the section of the TMF file/inbox to which the decisions or activity relates.
Anonymisation of data and records	• Check for personal data that there is no longer a purpose to retain. Legitimate purposes for retention may include: o Long term follow-up o Reconstruction of activity • Check the PIS to ensure compliance with all data retention and deletion information • Deletion of personal data from the CDMS should be requested via a WCTU Programming HelpDesk request. • It is good practice at this point to create and retain an anonymised dataset and associated materials for the purpose of onward sharing if requests are made.
Update Information Asset Register	• Updates should reflect the level of personal data retained at the point of archiving. • The retention date should be added and the status changed to 'Archived'
Document the media types in each repository of the TMF	• It is good practice to provide the archivist with a list of systems and applications that are applicable to any electronic records in the TMF to facilitate the archivist with review of obsolescence. • For considerations of how to prepare certain data formats see table below.
Review contracts	• All contracts should be reviewed prior to archiving. • Expiry of any active Data Sharing Contracts should be reflected on the Information Asset Register.

Once these steps are complete, the format of documents should be assessed to check they are appropriate for long term retention. The transfer should be documented in writing and evidence of acceptance by the archivist retained by the CI or their delegate in the trial team.

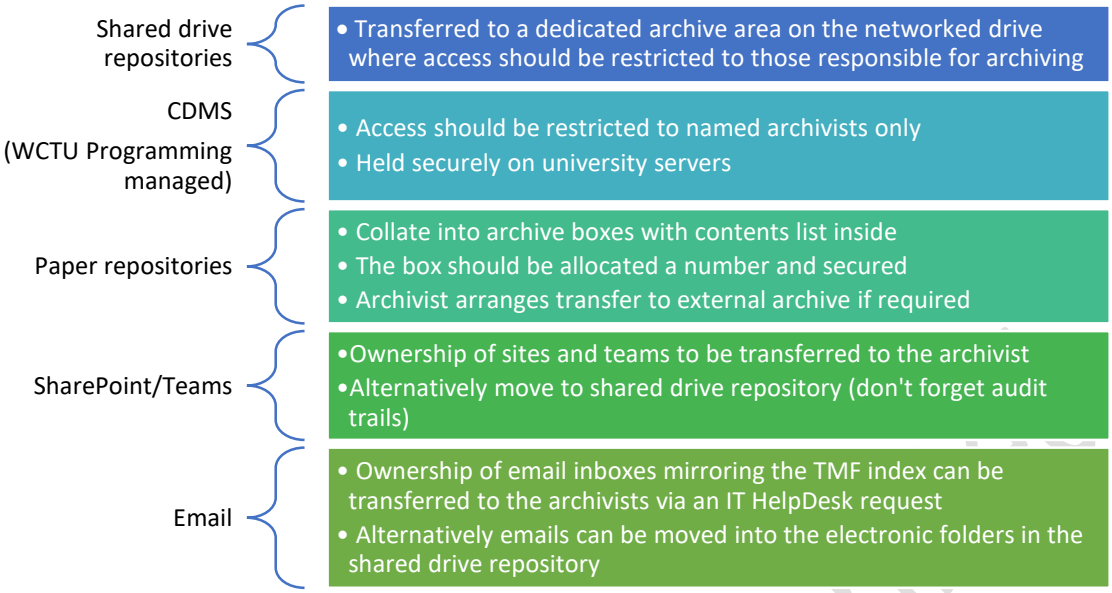
Examples of formatting considerations for long term storage are included in the table below:

Media type	**Suggested actions**
Paper	Removal of items that may cause damage to documents over a long period of time: - rubber bands - plastic wallets - paper clips/staples Check for contamination that could worsen over time and would benefit from transfer to another type of media as a certified copy.

	For non-CTIMP studies, digitisation of documentation may be considered. Digitisation but be done in line with UoW Information Governance Policy IG03.
Electronic Docs (Inc. audit trials)	Transfer documents to Portable Document Format (PDF) where possible. This will preserve documents in a format that will be less likely to be subject to ongoing compatibility issues caused by software updates. Conversion to PDF can cause problems with audit trails and metadata so this should be checked. Any data/documents held on temporary storage devices such as CDs, USB flash drives and floppy disks should be transferred to university servers to ensure ongoing compatibility for the retention period required. Passwords on any electronic documents will need to be removed
CDMS	Should be held on university servers with all edit access removed. If the CDMS or elements of this are in systems or applications not managed by the WCTU Programming Team, individual arrangements according to the software will need to be arranged to ensure all data is on the servers and edit access is restricted.
Other	Assess for any items that might be subject to rapid deterioration and require transferring to other media more appropriate for long term storage: e.g. Thermochromic paper which may fade over time. Photographs and films may also need scanning or uploading to university servers to improve stability.

4.3.2 Transfer/ingestion into the archive

- Electronic files from all TMF repositories will need to be archived and should be clear from the TMF map or index. Archiving does not necessarily mean moving the physical location of an asset but appropriately restricting the access and recoding its location if the need for retrieval arises. Details of archiving locations, its contents and any software required to run or open any records (inc. associated version) should be listed in the archiving log. For all records, an appropriate review date should be added to the log to ensure that documents continue to be compatible with current software to ensure documents remain retrievable throughout the archiving period.
- For WCTU studies, the archivist is responsible for arranging the transfer to the appropriate archive space. The transfer should be documented in writing and that documentation retained by the QA Team. Where paper records will be transferred to an external provider, the archivist should obtain evidence of collection.
- Details of archiving arrangements for different repositories are outlined below:



4.3.3 Maintenance and review of archived records

Throughout the archive period, the security and retrievability of documents should continue to be assessed by the CI (or the archivist where a study is managed through WCTU). At the point of transfer to the archive, a review date should be set to ensure this. Particularly in relation to electronic records, computer systems change through time as new software or hardware is introduced. It is vital that the records can always be retrieved, so it may be necessary to change the format or mechanism of storage from time to time, to take account of changes in computer equipment. Once in storage, personal data are subject to applicable elements of the UK GDPR and any information supplied to participants regarding the destruction or removal or any personal data or certain identifiers should be reflected in the review/destruction dates and complied with.

4.3.4 Retrieval of records

- Prompt retrieval of any document whether it be electronic or paper should be possible if required in the event of an audit or inspection.
- For WCTU studies, requests for retrieval should be made in writing to the named archivists and approval from the Head of Operations (or their delegate) should be documented before recall of records is instigated.
- Any documents that are on loan from the archive should be tracked, location of storage documented and the loan period specified and monitored by the archivist.
- Retrieval of electronic documents should be in 'read only' format and under no circumstances should any document retrieved from the archive be amended in any way.
- Any change in the ownership and location of the documentation should be documented in order to allow tracking of the stored records.

4.3.5 Destruction of records

- For CTIMP studies not being used to support marketing authorisations, it is a legal requirement for records within the TMF and investigator files (paper or electronic) to be retained for a minimum period of 5 years after the conclusion of the study.

- Studies should define in their protocol the length of retention based on any legal and funding requirements but for WCTU studies the minimum retention should be 5 years. Any longer and justification should be provided.
- The conclusion of the study for the purposes of archiving is defined as publication of the final study report.
  For CTIMPs where the data are used to support a marketing authorisation or studies involving minors or pregnant women are subject to further retention requirements and you should refer to the current legislation if this is applicable to the study.
- The CI (or archivist for WCTU studies) should ensure that essential documents are not destroyed before the minimum retention period.
- Once the minimum retention period is reached, the CI or archivist should notify any PIs in writing if upon review, they wish to inform investigator sites that there is no longer an obligation to retain their records.
- If the decision is made that records held by the sponsor/coordinating centre no longer need to be retained, the reasons for destruction of essential documents should be documented and signed by the Head or Deputy Head of Operations.
- This record/certificate of destruction should be retained (by the WCTU QA team for WCTU managed studies) for a further five years from the date that the essential documents were destroyed. There is no need to destroy documents after the minimum archive period is reached as long as all commitments regarding personal data have been met and there is sufficient funding available.

4.3.6 Considerations for location and oversight of archiving

Adequate and suitable space should be provided for the secure storage of all essential documents upon study completion. When archiving both paper and electronic documents, there must be systems to prevent accidental destruction and to ensure that they can always be retrieved.

The following should be taken into account when considering if a location is suitable for archiving of paper and electronic records:

- **Security** – Measures should be in place to restrict unauthorised access
- **Location** – Consider activities taking place in adjacent rooms and what runs in the ceiling and floor voids, is there risks of burst pipes or fire?
- **Size** – Is it large enough to accommodate the documents in a complete and legible format throughout the period of archiving?
- **Environmental factors** – Are there risks from excessive temperature, humidity, sunlight, contamination (dust, fumes, smoke)?
- **Pests** – Are there risk of rodents or insects?
- **Obsolescence** – Measures should be in place to monitor for changes in software that may render records or their associated metadata unavailable.

The majority of paper documents for WCTU managed studies are transferred to a commercial archive contractor but the ultimate responsibility for the quality, integrity, confidentiality and retrievability of the documents resides with the named archivist on behalf of the sponsor. This means that the named archivist should audit the site and satisfy themselves and the sponsor that the storage is appropriate and document it. There should be a formal contract in place between the sponsor and any paper or electronic archive company. Periodic re-visits to audit the facility should be considered and any problems escalated to the Sponsor's Office in R&IS via sponsorship@warwick.ac.uk.

4.3.7 If investigator sites are no longer able to store their essential documents

If an investigator site becomes unable to store their essential documents, the sponsor/study organisers should be notified in writing so that alternative storage arrangements can be agreed. If the PI is no longer able to maintain custody of their essential documents, the sponsor or sponsor's representative should be notified in writing and the investigator/institution should ensure that appropriate arrangements are made. The sponsor should never have sole control of the ISF unless the sponsor is also an investigator site.

4.3.8 Change of ownership of documentation

Where there is a change of ownership (e.g. change of sponsor) of the data or documents connected with a study then the sponsor must record the transfer and the new owner must be responsible for data retention and archiving. This should also be reflected in updated contractual agreements.

4.3.9 Retention of Training Records from WCTU staff leaving the University

Training records of study staff will be retained for 5 years after a staff member leaves the university in case they are required for audit or inspection.

4.3.10 Named Archivist Arrangements

The named archivists should have training relating to archiving documented in their training record. A clear and detailed handover plan should be prepared where an archivist leaves the role. Access records should reflect these changes accurately.

List of abbreviations

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