

<b>Standard Operating Procedure</b>
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<b>Version</b>	<b>Date</b>	<b>Summary of Changes</b>
2.0	January 2013	Update of web links and office details.
2.1	May 2014	Addition of version control statement for SOP
3.0	October 2015	Update of weblinks and office details
4.0	August 2016	Update of information, weblinks and office details
5.0	March 2018	Interim review and update
6.0	May 2025	Update information for retention records process
7.0	March 2026	Put into the SOP template correctly with the correct headings, font, spacing, alignment. Inserted the updated SOP introduction (2025). Updated/clarified wording. Changed archiving retention periods.

**UoMCTSOP20 Archiving version 7 27APR2026.**

01/A SOP Template version 1

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It is the responsibility of colleagues to ensure that the most recent version of the document is accessed, and the procedures stated within the document followed.

## 1 Introduction

All clinical trial activities conducted under this SOP are in line with the applicable UK legislation governing clinical trials of investigational medicinal products and/or medical devices. This includes, but is not limited to, the Medicines for Human Use (Clinical Trials) Regulations 2004 and any subsequent amendments or replacement legislation, such as the Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025, effective from 28 April 2026. All procedures will be conducted in accordance with current guidance issued by the Medicines and Healthcare products Regulatory Agency (MHRA), the Health Research Authority (HRA), relevant Research Ethics Committees (RECs) and updated GCP standards.

The Regulations define the legal requirements for archiving arrangements for both trial data and documentation.

Archiving is a legal requirement which is relevant to all trials. It means to store an inactive material in a safe location for as long as it is required, as stipulated in the study protocol. All essential documents should be archived, this includes essential documents held by Investigators, Sponsors and others involved in the conduct of a clinical trial (including services departments such as pharmacy, laboratories, and radiology). It should be noted that there will be two sets of retention periods for CTIMPs (excluding ATMP trials). Trials approved before the implementation of the UK Amended Clinical Trials Regulations; the retention period is a minimum of five years. Whereas those trials submitted after the implementation of the UK Amended Clinical Trials Regulations (28 April 2026) the new retention period will be 25 years.

The essential data for clinical trials includes all records required to reconstruct, evaluate, and verify the conduct of the trial and the quality of the data produced. This encompasses both paper and electronic records. In accordance with the updated UK Clinical Trials Regulations, the minimum retention period for the Trial Master File (TMF) and all associated essential documents is now 25 years. This represents an increase from the previous 5-year minimum.

Where trial data support a UK Marketing Authorisation, additional retention requirements apply, and records must be retained for the duration specified by the relevant regulatory and legal frameworks. All records including electronic records, metadata, audit trails, and any system required to access them must remain accessible, legible, secure, and fully retrievable for the entire retention period.

This SOP describes how the University of Manchester (UoM) will ensure compliance with these regulatory requirements, including the processes, responsibilities, and systems used to maintain the integrity and availability of essential clinical trial records throughout their mandated retention period.

## 2 Scope

This Standard Operating Procedure (SOP) applies to Clinical Trials of Investigational Medicinal Products (CTIMPs, ATIMPs, NIMPS and Medical Devices) – *i.e.* all Trials which come under the Clinical Trials Regulations, where the University of Manchester (UoM) is the Sponsor. The requirements of this SOP should be applied as a minimum to such trials and in conjunction with all applicable University policies and procedures, along with the policies and procedures of any relevant NHS Trusts.

This SOP should be used in conjunction with any local archiving arrangements, but any changes must provide an equivalent standard of provision to the procedures outlined below and agreed by the Sponsor.

The purpose of this SOP is to define the archiving processes which apply when archiving essential records of clinical trials.

## 3 Responsibilities

### 3.1 Sponsor

The Sponsor is responsible for ensuring that robust and compliant archiving arrangements are established from the outset of the trial. This includes ensuring that:

- 3.1.1 A complete and accurate Trial Master File (TMF) is maintained throughout the study and archived promptly at trial close-out.
- 3.1.2 All essential documents, trial data, and records are retained in accordance with applicable regulatory and organisational retention requirements.
- 3.1.3 Archived materials are stored under appropriate conditions that safeguard their integrity, confidentiality, and long-term accessibility for the full duration of the required retention period.
- 3.1.4 Systems and processes are in place to ensure that archived materials remain secure, retrievable, and protected from loss, damage, or unauthorised access.
- 3.1.5 Any third-party archiving providers engaged by the Sponsor are appropriately qualified, contracted, and overseen to ensure compliance with regulatory standards and Sponsor policies.

### 3.2 Chief Investigator

The Chief Investigator (CI) is responsible for ensuring that all site-held essential documents and study records are complete, accurate, and prepared for archiving at the end of the trial. This includes ensuring that:

- 3.2.1 All essential documents held at participating sites are collected, verified as complete, and returned as required.
- 3.2.2 Delegated site staff understand and follow the archiving requirements outlined in the protocol, Sponsor policies, and applicable regulations.
- 3.2.3 Both paper and electronic records are stored securely and protected from unauthorised access, loss, or damage until formal archiving takes place.
- 3.2.4 All Trial Master File (TMF) documentation and supporting records under the CI's oversight are ready for transfer to the Sponsor or designated archiving facility.
- 3.2.5 Appropriate archiving arrangements are made for both paper and electronic materials, including ensuring that long-term storage costs for the required retention period are included in the study budget.
- 3.2.6 Archiving is completed promptly following the end-of-trial activities, in accordance with Sponsor procedures and regulatory timelines.

### 3.3 Investigator Locations

Location management is responsible for providing appropriate archive facilities for the Investigator Site Files. They should ensure that supporting records such as SOPs, training records and equipment files for storage facilities are available and retained. The local policy should be followed.

### 3.4 Named Individual

(Responsible for archiving of material that is stored in Iron Mountain only). The named individual, where possible, to be a person who is independent of the trial and the line management of that trial to avoid any conflict of interest. The named individual for paper archiving at the University of Manchester is Records Management. They provide the oversight and make the arrangements for the transfer of the boxed archive material. They are responsible for coordinating with the archiving facility (Iron Mountain), ensuring that all pre archiving requirements are met, and the systems are in place to track and retrieve archived material.

## 4 Related Documents

Reference Number	Document Title
( <a href="https://www.staffnet.manchester.ac.uk/people/managers-essentials/leaving-university/">https://www.staffnet.manchester.ac.uk/people/managers-essentials/leaving-university/</a> )	Exit Checklist

## 5 Procedures

### 5.1 Forward planning

Archiving provision should be included at the grant application stage, particularly if costs for commercial storage will need to be met. Staff resources for undertaking archiving work also need to be taken in to account at this stage. The archiving arrangements for a trial should be stated in the protocol. Ongoing integrity of the storage and access of data that will be archived electronically should be considered in the trial risk assessments.

For multi-national trials, consideration must be given to the archiving in each location.

Where an archiving service external to the UoM is intended to be used, a formal contract must be put in place and a vendor assessment completed by the Sponsor prior to any archiving taking place.

The UoM uses an off-site storage provider (Iron Mountain), who are compliant with the BS 5454, environmental monitoring standard, referenced in the MHRA's guidance.

### 5.2 Preparation for Archiving

Following completion of all other trial closure activities (see UoM SOP26 'Trial Closure') trial documentation and data should be prepared for archiving.

The TMF should be checked for completeness prior to archiving. Paper documents must be within their Lever Arch files and not loose. A completed TMF checklist, or other evidence of final TMF audit or QC checked review, should be provided to the Research Governance, Ethics, and Integrity Team (RGEIT) at [clinicaltrials@manchester.ac.uk](mailto:clinicaltrials@manchester.ac.uk).

The CI (or delegated member of the trial team) need to plan for the storage ('archiving') of the complete TMF, in accordance with Good Clinical Practice and the Regulations, and as described in the REC application, protocol, data management plan, and any relevant contracts. The following sections describe how to approach this for paper and electronic records:

<https://www.staffnet.manchester.ac.uk/igo/records-information-management/off-site-record-storage/>

### 5.3 Paper-based archiving

The University uses an external contractor (Iron Mountain) to provide an off-site storage facility.

Guidance on ordering boxes and providing information about the content, including a template, can be found at

<https://www.staffnet.manchester.ac.uk/igo/records-information-management/off-site-record-storage/>.

The CI (or delegated member of the trial team) should contact the Records Management team in the Information Governance Office ([records.management@manchester.ac.uk](mailto:records.management@manchester.ac.uk)) to arrange for the TMF to be sent to off-site storage.

Trial master files should be boxed in appropriate archive boxes with sealed lids. Lids should be placed on boxes when the documents are not in use to protect the contents. The boxes need to be ordered internally by the CI (delegated member), following the required parameters as stated at Retention Records website.

Content lists for each box should be produced to ensure individual files can be located for retrieval if needed. A copy of the content list should be kept inside the box, and all content lists should be drawn together into a global list for the trial, which should be kept electronically by the Chief Investigator and IGO (Confidential Waste). A location index should also be kept recording the physical whereabouts of each box. This list will be kept by the Office of the named individual (Retention Records). Boxes should be labelled in accordance with the global list. Copies of these records will be kept with Sponsor and Faculty.

### 5.3.1 Sponsors Location Record

The Sponsor maintains a record of the files sent to the UoM designated off-site storage (Iron Mountain), so that they are aware of the location of the material and can arrange for it to be retrieved or destroyed. Arrangements are in place with the UoM off-site storage provider to ensure material will not be relocated between storage sites.

### 5.3.2 Storage Conditions

The Information Governance Office (IGO) is responsible for assuring the following to be in place for archiving.

Boxes should be stored in an auditable archive. The archive should have suitable and stable environmental conditions. The temperature should be maintained between 13°C and 18°C, relative humidity should be maintained between 45% and 65% RH.

The archive should be secure and should not be accessible to unauthorized personnel.

The archive should be appropriately protected against fire and flooding. Rooms with water pipes running through or above them should not be used, and basements should be avoided due to the increased risk of flooding.

Storage provisions should be made with regards to the ease of retrieval of the documents.

The Iron Mountain facility meets the requirements listed above and can be used if no alternative suitable archive storage is available.

It should be noted however that space within this facility is limited and those responsible for archiving arrangements should enquire as far in advance as possible as to availability of space since it is not guaranteed. The contract between Iron Mountain and the UoM ensures Iron Mountain must consult with Records Management at the University if boxes are to be relocated to a different facility.

For further information on the UoM approved onsite storage facility please contact the Records Management Office at the University. UoM off-site record storage process:

<https://www.staffnet.manchester.ac.uk/igo/records-information-management/off-site-record-storage/>

### 5.3.3 Scanning

It is not recommended that paper records are scanned and the originals destroyed, as this can lead to problems surrounding the authenticity of records. If scanning is necessary, the Sponsor must be consulted before any destruction of the original source data takes place. UoM Retention Records Management must be involved to ensure compliance with the UoM Retention Records Policy and to confirm adherence to the latest MHRA guidance for the validated scanning process. Each scanned page must be in the correct orientation and must be complete and legible.

### 5.3.4 Electronic Archiving

Where trials create electronic records (such as an electronic TMF or trial databases), consideration should be given to the method of preservation and storage of this data. Archive arrangements must permit recovery and readability of the data and metadata throughout the required retention period, and the process validated. Backup and recovery processes should also be validated and periodically assessed. Arrangements should be made for regular transfer of data to new media if necessary. File formats should be considered in terms of long-term access and support, and files should be translated to non-proprietary formats if necessary. If transfer or migration of data is required, the MHRA Data Integrity Guidance must be followed.

Software and hardware manuals relating to storage media used should be retained for the life of that media.

It must be ensured that the electronic archive used complies with regulatory requirements for archiving clinical trial data (see MHRA Data Integrity Guidance in references for guidance).

Please see the **Electronic record storage** section 5.5 for further information.

#### 5.4 Access to archives

Access to paper or electronic archived records is restricted to authorised personnel only. Any retrieval of documents should be properly recorded with an audit trail or chain of custody and logged with the Sponsor. Retrieved archive materials must be returned to storage as soon as possible.

When access is required, please send an email detailing the request, to the following email: [records.management@manchester.ac.uk](mailto:records.management@manchester.ac.uk) and cc the Sponsor using [clinicaltrials@manchester.ac.uk](mailto:clinicaltrials@manchester.ac.uk)

#### 5.5 Electronic records storage

The University of Manchester Research IT provides safe storage and archiving in RDS (Research Data Storage) or DSH (Data Safe Haven). The electronic TMFs, databases or data extractions are to be stored using the University of Manchester Data Storage platforms. The RDS/DSH is to be used for temporary storage of the databases and electronic files that need to be stored until a long-term electronic archiving solution is in place at the University of Manchester.

Each request for electronic archiving is to be logged with Research IT (<https://www.hrds.manchester.ac.uk/about/data-safe-haven/>), who will generate a ticket for the request and provide guidance on the archiving.

The data capacity in DSH is limited, the quantity of data would need to be less than 100 GB. The RDS has capacity 8TB. For situations where the data is expected to exceed the stated maximum, the Research IT will advise on the next steps.

#### 5.6 Retention periods

All archived material is given a fixed retention period, considering legal and regulatory obligations and any retention periods defined by the funding body or Sponsor.

If the trial collected human tissue samples, then the Human Tissue Act requirements for the storage of the human tissue must be adhered to.

### 5.6.1 CTIMP Trials

For trials involving investigational medicinal products, records must be kept as stipulated in The Medicines for Human Use (Clinical Trials) Amendment Regulations 2006 (regulation 18 section 31A) and GCP requirements. All essential documents must be archived to ensure the integrity of the data and compliance with regulatory requirements. This includes documents held by investigators, sponsors, and other parties involved in the trial. The trial related documents and TMF need to be kept for minimum of 25 years after conclusion of the trial. This is acceptable for UoM sponsored trials, where there is valid marketing authorisation in place. For Clinical Trials where valid marketing authorisation is yet to be received, the minimum retention period is 25 years after the conclusion of the trial or at least 2 years after the last marketing application or for at least 2 years after formal discontinuation of clinical development of the investigational product. Directive 2005/28/EC (GCP Directive), Article 17 and the Medicines for Human Use (Clinical Trials) Regulations 2004 (as amended), which implement Directive 2005/28/EC into UK law.

The MHRA Archiving and Retention of Clinical Trial Records, indicates when a trial involves minors (under 18 years of age) essential documents must be retained until the young person reaches 18.

This means: -

- If a participant is 16, documents must be kept at least 2 more years, plus the usual CTIMP retention period.
- If a participant is 5, documents must be kept at least 13 more years, plus the usual CTIMP retention period. The Sponsors applies this rule because:
  - A minor cannot bring a legal claim until they reach adulthood.
  - Limitation periods (e.g., 3 years for personal injury) begin at age 18.

Therefore, documents must be retained at least until the participant turns 18, and then for the standard CTIMP retention period.

This is consistent with MHRA expectations.

### 5.6.2 Clinical Investigations of Medical Devices

For Clinical Investigations of Medical Devices, the archiving duration will be determined on a risk-based approach, in line with HRA and GCP expectations. Essential documents for medical device trials are expected to be archived for the devices expected lifetime and at least 15 years for implantable devices, after the completion of the trial.

### 5.6.3 Advanced Therapy Investigational Medicinal Product (ATIMPs)

For clinical trials involving an Advanced Therapy Investigational Medicinal Product (ATIMP), the Sponsor, manufacturer, and Chief Investigator/institution must retain all records relating to ATIMP

traceability — including essential documents and medical files of trial subjects — for a minimum of 30 years after the expiry date of the product, in accordance with Regulation (EC) No 1394/2007. The agreed retention period must be documented in regulatory submissions, contracts, and study agreements. MHRA Guidance on ATMPs adopts the same requirement in the UK following Regulation 1394/2007. Non CTIMP Trials Essential documents and medical files of trial subjects must be retained for a minimum of five years after the completion of the trial.

## 5.7 Destruction of records

Destruction of Archived documents and boxes can only proceed if the Sponsor/someone on behalf of the Sponsor gives approval in writing. (The Sponsor/ Sponsor designee should notify investigators in writing when their trial records can be destroyed.)

When archived records reach the end of their retention period they should be securely destroyed, with the appropriate Dean of the Faculty informed in advance by the Named Individual. A record of this destruction and the reasons should be created and retained for a period of 7 years from the date of destruction. The record of destruction should clearly list which records have been destroyed. This list will be shared with the appropriate Dean of the Faculty by the Named Individual.

If the CI leaves the University of Manchester, the Exit Checklist (<https://www.staffnet.manchester.ac.uk/people/managers-essentials/leaving-university/>) is to be completed, to transfer the data ownership and any responsibilities. If the CI is unable to continue their role prior to a plan being established, the Head of School will appoint a replacement. This follows the UoM IGO guidance in place.

## 6 References

UK Clinical Trial Regulations

<https://www.legislation.gov.uk/ukxi/2006/1928/regulation/18/made>

For guidance only: EMA Guideline on the content, management and archiving of the clinical trial master file (paper and/or electronic):

- [https://www.ema.europa.eu/en/documents/scientific-guideline/guideline-content-management-archiving-clinical-trial-master-file-paper/electronic\\_en.pdf](https://www.ema.europa.eu/en/documents/scientific-guideline/guideline-content-management-archiving-clinical-trial-master-file-paper/electronic_en.pdf)
- <https://www.ct-toolkit.ac.uk/routemap/archiving>
- <https://research-it.manchester.ac.uk/services/>
- <https://www.staffnet.manchester.ac.uk/igo/records-information-management/retention-schedule/>

- MHRA Data Integrity Guidance  
[https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/687246/MHRA GxP data integrity guide March edited Final.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/687246/MHRA_GxP_data_integrity_guide_March_edited_Final.pdf)
- <https://www.ukri.org/wp-content/uploads/2023/03/MRC-100323-RegulatorySupportCentre-RetentionFrameworkResearchDataRecords.pdf>
- <https://documents.manchester.ac.uk/display.aspx?DocID=42605>
- [Archiving and retention of clinical trial records - GOV.UK](#)
- EU Regulation (EC) No 1394/2007 on Advanced Therapy Medicinal Products, Article 15 (Traceability)

**\* Transitional arrangements for Good Clinical Practice**

- **Old rules clinical trials**
- *From 28 April 2026, Part 4 (Good practice and the conduct of clinical trials) of the amended Clinical Trials Regulations will apply to old rules clinical trials (i.e. where the application to approve the trial was submitted before 28 April 2026), with the exception of the amended regulation 31A(7) (retention of the trial master file), which does not apply. Instead, regulation 31A (7) immediately in force before 28 April 2026 applies, which requires the trial master file to be retained for at least 5 years after the trial concludes.*
- **New rules clinical trials**
- *For new rules clinical trials (i.e. where the application to approve the trial was submitted on or after 28 April 2026), Part 4 of the amended Clinical Trials Regulations apply.*
- <https://www.gov.uk/guidance/clinical-trials-regulations-transitional-arrangements> 2 March 2026