The University of Manchester

Standard Operating Procedure

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Title:	Archiving		
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Version	Date	Summary of Changes
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 Further information added for electronic archiving Consideration for multi-national trials added Consideration for external archiving vendors added Added evidence of TMF check to Sponsor Updates to structure, references and minor clarifications.

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1.0 Background

The European Clinical Trials Directive 2001/20/EC ("the Directive") was introduced to establish standardisation of research activity in Clinical Trials throughout the European Union. It was transposed into UK law as the Medicines for Human Use (Clinical Trial) Regulations 2004 (SI 2004/1031), which came into force on 1st May 2004. The Medicines for Human Use (Clinical Trials) Regulations together with subsequent amendments will be referred to as "the Regulations" in the rest of the document.

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 and 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).

2.0 Purpose

This Standard Operating Procedure (SOP) applies to Clinical Trials of Investigational Medicinal Products (CTIMPs, ATIMPs, NIMS and Medical Devices) – i.e. all Trials which come under the 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, and the policies and procedures of relevant NHS Trusts.

This SOP should be interpreted with regard to local existing archiving arrangements, but any variations should aim to provide an equivalent standard of provision to the procedures outlined below and agreed by Sponsor.

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

3.0 Roles and responsibilities

Sponsor
The trial Sponsor is responsible for ensuring that trial data is retained and maintained in appropriate conditions with regard to integrity and accessibility, and that appropriate retention policies are applied to such records.

Chief Investigator
The Chief Investigator (CI) is responsible for ensuring that all appropriate Trial Master Files documentation and supporting records are available for archiving and organise the archiving of the TMFs at the end of the study.
The CI is responsible for appropriate arrangements to be made at the beginning of the trial for both, paper and electronic data storage, assuring the cost of the archiving is

covered. It is responsibility of the CI to assure prompt archiving of files upon conclusion of the trial.

Investigator Site
Local site management is responsible for providing appropriate archive facilities for the Investigator Site Files. They should ensure that supporting records such as SOPs, personnel records and equipment maintenance records for storage facilities are available and retained. Local policy should be followed.

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

Electronic archiving is overseen by Research IT

4.0 Procedures

4.1 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 account of at this stage. The archiving arrangements for a trial should be stated in the protocol at the trial outset. Ongoing integrity of the storage and access of data that will be archived electronically should be considered in the trial risk assessment.
For multi-national trials, consideration should be given to archiving of country-level files.
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 archiving taking place.
The UoM uses off-site storage provider Iron Mountain, who are compliant with BS 5454, environmental monitoring standard, referenced at the MHRA's guidance.

4.2 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. 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.

The CI (or delegated member of the trial team) need to make arrangements 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/

4.3 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) 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.

4.3.1 Location record

The Sponsor must keep 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.
Arrangements have been made with the UoM off-site storage provider so that material will not be moved between different storage sites.

4.3.2 Storage conditions

The Information Governance Office is responsible for assuring the following to be in place for appropriate archiving storage.

Boxes should be stored in an appropriate location. The storage area should have suitable and stable environmental conditions. Temperature should be constant and between 13o and 18°C, humidity should be constant and between 45% and 65% Relative Humidity.

The storage area should be secure and should not be accessible to unauthorized personnel.

The storage area should be appropriately protected against fire and flood. Rooms with water pipes running through them should not be used, and in general basements should be avoided due to the risk of flooding.

Storage provisions should be made with regard to the ease of retrieval of documents where necessary.

The Iron Mountain facility meets the requirements listed above and can be utilised 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 likely provision before assuming that this will be the final destination of archived records. The contract with Iron Mountain ensures Iron Mountain must liaise with Records Management at the University of Manchester if files are to be moved to another facility.

For further information on the 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/

4.3.3 Scanning

It is not recommended that paper records be scanned and the originals destroyed, as this can lead to problems surrounding the authenticity of records. If scanning is absolutely necessary, the Sponsor must be contacted and consulted before any destruction of the original source data takes place. UoM Retention Records Management will 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.

4.3.4 Electronic records storage

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 tested. 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 for storage for further information.

4.4 Access to archives

Access to paper or electronic archived trial records is to be restricted to authorised personnel only. Any retrieval of documents should be properly recorded. Retrieved files should be returned to storage as soon as possible.
When access is needed, please send an email detailing what you need to, to the following email: records.management@manchester.ac.uk

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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 at 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 archiving solution is in place at University of Manchester.

Each request for electronic archiving is to be logged with Research IT, 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 to exceed the stated maximum, the Research IT will advise on appropriate steps.

4.5 Retention periods

All archived material should be 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 that are retained for use in future research, the consent forms must be retained to fulfil Human Tissue Act consent requirements.

4.5.1 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 5 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 15 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.
A higher retention period will be also required for CTIMPs, where participants are under the age of 18 years of age. The appropriate retention period is to be agreed by CTMG at trial design stage.

4.5.2 Medical Devices

For medical device trials, archiving duration will be determined on a risk-based approach, in line with HRA and GCP expectations. Essential documents for medical device trials should be archived for at least 5 years after the completion of the trial1. This period may be extended if the data is used to support a marketing authorisation.

4.5.3 Advanced therapy trials (ATIMPs)

For trials involving advanced therapy investigational medicinal product (ATIMP), the sponsor of the trial, manufacturer, and chief investigator/institution must keep their records related to the traceability of the ATIMP (including essential documents and

medical files of trial subjects) for a minimum of 30 years after expiry date of the product. The retention period must be stated in regulatory documents and study contract the University has agreed to contractually.

4.5.4 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.

4.6 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 for it 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 is to be completed, to transfer the data ownership and any responsibilities. If the CI is unable to continue their role prior to plan being established, the Head of School will appoint replacement. This follows the UoM IGO guidance in place*.

References

UK Clinical Trial Regulations
https://www.legislation.gov.uk/uksi/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.ct-toolkit.ac.uk/routemap/archiving
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