IMPERIAL Research Governance and Integrity Team

Imperial College Healthcare NHS Trust

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Archiving Study Documents

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Version 1.0	31 May 2007	1st Edition
Version 2.0	20 Jun 2008	Annual Review
Version 3.0	08 Feb 2010	Formation of Joint Research Office
Version 4.0	14 Jul 2011	Annual Review
Version 5.0	30 Nov 2012	Annual Review
Version 6.0	18 Feb 2015	Annual Review
Version 7.0	25 Oct 2017	Annual Review
Version 8.0	19 Oct 2020	Scheduled Review Template removed & administrative changes. JRCO name change to RGIT.
Version 9.0	14 Jun 2021	Updated guidance on electronic archiving
Version 10.0	06 Feb 2024	3yr SOP review
Version 11.0	27 Apr 2026	Updates following legislative changes.

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1. PURPOSE

The purpose of this Standard Operating Procedure (SOP) is to describe the procedure for archiving study documents in a clinical trial.

2. INTRODUCTION

Study documentation must be kept so that the data is accessible after the trial is completed. This is because future studies may suggest a further period of follow-up, allegations are made of fraudulent behaviour, or concerns arise about side effects and participants need to be contacted.

In current regulations, archiving is recognised as the responsibility of the Sponsor, which may be delegated to the Chief/Principal Investigator.

The International Conference on Harmonisation of Good Clinical Practice (ICH GCP) guidelines are specific about which documents are essential for the conduct of a clinical trial (for further information, please see RGIT_SOP_005).

3. PROCEDURE

3.1. Determining the end of the study

The end of study should be defined in the protocol (please see RGIT_SOP_012), for example, when the last patient entered onto the study has their last study visit.

3.2. Who is responsible?

Clinical trial documentation should be archived by the Chief Investigator (CI) or a person delegated by the CI. At Imperial College Academic Health Science Centre (AHSC), the logistics and necessary arrangements of archiving study data should be arranged by the CI.

At a local site, the Principal Investigator (PI) should undertake these arrangements in conjunction with the CI. The Investigator has a responsibility to allow the Sponsor access to the archived data on request. The archived data can be audited by the Sponsor or competent authority on request. The management of trial documentation and study files may be the responsibility of a designated member of the research team. The Principal Investigator at the site, however, retains overall responsibility. If the Principal Investigator leaves the institution during the archival period, arrangements must be made to ensure the safekeeping and security of the archive information. Changes in personnel must be defined in the study file and handover of responsibility documented. The Sponsor must also be informed of the new arrangements.

3.3. When should documents be archived?

Essential documents should be archived as soon as practicable after the completion of the study.

3.4. What documents should be archived?

All essential documentation as defined in ICH-GCP Guidelines (including minutes from all trial related meetings), must be retained until notification from the Sponsor. Further information on the documents to be retained in the Trial Master File (TMF) can be found in (RGIT_SOP_005).

3.5. How should documents be archived?

All archived material should be stored in archive boxes that are clearly labelled with black permanent marker pen with the name and reference number of the study, Sponsor, Investigator and date to be archived until on top of the Box and at the side. The archive boxes should be stored in a secure, environmentally controlled location (i.e. fire protection without water sprinkler systems, water protection for humid conditions). Archived material should be stored in a legible condition, with fax thermal paper copied to standard paper.

Access to the material should be restricted to the CI, Sponsor and the regulatory authorities. Details of the archiving location should be recorded by the CI and notified to the Sponsor. Whenever an item is retrieved from archive, the date, item and person retrieving the item should be documented, together with the date returned to archive. **All data should be made available if requested by relevant authorities.**

3.6. How long should documents be archived?

ICH GCP section 9.5 states essential records should be retained securely by sponsors and investigators for the required period in accordance with applicable regulatory requirements. These essential records should be available to regulatory authorities, monitors, auditors and IRBs/IECs (as appropriate) upon request to enable appropriate evaluation of the trial conduct in order to ensure the reliability of trial results.

In the UK, The Medicines for Human Use (Clinical Trials) Regulations 2004, "Trial master file and archiving 31A (7)" states : The Sponsor and the chief investigator shall ensure that the documents contained, or which have been contained, in the trial master file are retained for at least **5 years** after the conclusion of the trial and that during that period they are:

a) readily available to the licensing authority on request
b) complete and legible

Following The Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025, the above has now been amended to extend the retention time to **25 years.**

The Imperial College London Retention Schedule states that primary research data should be retained for a minimum period of 10 years following completion of the study. This refers to all forms of research but for CTIMPs, this should now be for 25 years as per the above.

3.7. Imperial College archiving facilities

The College maintains archiving facilities at the Charing Cross Campus, with smaller storage facilities located on other campuses. This is managed by the Archives and Corporate Records Unit (ACRU).

To transfer documents to the College archive, contact the ACRU staff in the first instance to discuss requirements and agree the transfer (acru@imperial.ac.uk). The ACRU will organise storage and retrieval of documents at their archiving facilities. Costs of removals between campuses are the responsibility of each division and should be included in any initial project costings.

Further information on the transfer, including the transfer form can be found in Appendix 1 as well as at: College Archives and Corporate Records Unit

3.8. Electronic documentation and archiving

For any data, including study databases held electronically it should be considered prior to study start how data and metadata will be archived and how future access to records and data will be maintained. Archive arrangements must permit recovery and readability of data through the required recovery period and have a process in place for this. Archived data should be protected so that it cannot be altered or deleted and is protected against any accidental damage. Access should be suitably restricted as with paper records.

The process of archiving should also be validated and if data is transferred to other media for the purposes of archiving, then this will also require validation.

All databases should follow the appropriate database lock procedure RGIT_SOP_46 prior to any archiving taking place. For studies using OpenClinica, the eCRF archiving procedure should be followed with the Clinical Data Systems Team.

Where both physical and electronic records are stored, references should be maintained so that full verification can take place as necessary. Appropriate risk assessment should be undertaken, including if the storage medium may become obsolete, a process should be developed to ensure that data can be retrieved for the duration of the storage period and appropriately documented. Storage using external methods such as CDs or USBs is not recommended.

It should be ensured that the CI, Sponsor and Regulatory Authorities will be able to access the electronic archived data, so appropriate records on the location of the archived data should be kept and thought given to scenarios such as investigators leaving.

4. REFERENCES

The Medicines for Human Use (Clinical Trials) Regulations 2004 (Cited 24 Feb 2026)
The Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025 (Cited 24 Feb 2026)

ICH_E6(R3)_Step4_FinalGuideline_2025_0106.pdf (Cited 24 Feb 2026)

MHRA GxP Data Integrity Guide (Cited 24 Feb 2026)

Guide 5 - Data retention | Administration and support services | Imperial College London (Cited 24 Feb 2026)

5. APPENDICES

The following Appendices list the following Templates associated to this SOP which can be found on the SOP Associated Documents & Templates page:

Appendix 1: Transferring Records to the Archives and Corporate Records Unit – RGIT_TEMP_035