Standard Operating Procedure

ARCHIVING OF RESEARCH RECORDS

SETTING Trust-wide and external locations participating in UHBW Sponsored research and Trust-wide locations participating in UHBW hosted research

AUDIENCE Research staff at UHBW and external locations participating in UHBW Sponsored research and research staff at UHBW participating in UHBW hosted research

ISSUE Research records must be archived appropriately and in accordance with applicable legislation.

QUERIES Contact the Research & Development Department via research@uhbw.nhs.uk

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Version Number	Reason for change
Original V1.0	N/A – original
V1.1	Minor clarifications and updates
V1.2	Minor update – change of wording from Appendices to Standalone templates
V1.3	Minor clarifications and updates
V1.4	Minor clarifications and updates
V1.5	Minor updates and clarifications as part of biennial review.
V2.0	Major update on arrangements for electronic filing
V2.1	Minor updates – corrections of typos, update to nominated archivist, formatting updates and clarifications for hosted research.
V2.2	Departmental name change from Research & Innovation to Research & Development. Updated throughout SOP as a minor amendment.
V2.3	Minor clarifications and updates as part of biennial review
V3.0	Major update to include updates required bythe Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025' in terminology, to describe process where PI/CI is no longer available during archiving period and further clarifications on requirements for readability of data and when data can be destroyed.

1. Introduction

Clinical Trial of an Investigational Medicinal Product (CTIMP)

It is a legal requirement of the Medicines for Human Use (Clinical Trials) Regulations (2004) [SI 1031] and subsequent amendments including the Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025), that essential records and the medical records of trial participants are retained following the end of a CTIMP (Clinical Trial of an Investigational Medicinal Product) in order to allow reconstruction of a trial, potential further analysis of project data and to enable MHRA inspection and monitoring.

Retention periods for the Trial Master File and medical records are set out in *GD_009 Guidance on Retention Period.*

The sponsor of a CTIMP must have in place a **nominated archivist**, defined as the person/s who has oversight within the Trust for the archiving of CTIMP records.

Archived material comprises project records for closed studies (i.e. studies where all patient activity and data analysis are completed) and which are no longer in the custody of the Principal or Chief Investigator (PI/CI). With reference to CTIMPs, they are records which have been put into external storage following the procedure set out in this SOP. The external storage facility used by UHBW is Restore (see section 6.3).

Non-CTIMP studies

At UHBW non-CTIMP studies should also be archived and put into external storage following the procedure set out in this SOP as a requirement of Good Clinical Practice.

Occasionally, there may be situations where records for active studies need to be put into external storage. The term 'archived' should not be applied in such cases.

2. Purpose

The purpose of this SOP is to describe the procedure for archiving the project records for UHBW hosted and sponsored CTIMPs, as required under the Medicines for Human Use (Clinical Trials) Regulations (and any amendments including the Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025),) and to describe the procedure for archiving hosted and sponsored non-CTIMP research project records..

3. Scope

In Scope:

- CTIMPs sponsored by UHBW.
- CTIMPs hosted by UHBW and where provision for third party archiving is not made by the sponsor.
- Non-CTIMPs sponsored by UHBW.
- Non-CTIMPs hosted by UHBW and where provision for third party archiving is not made by the sponsor.

Out of scope: All other externally sponsored research and non-research related records.

4. Abbreviations and Definitions

Abbreviations	
BHOC	Bristol Haematology and Oncology Centre
CI	Chief Investigator
CIMD	Clinical Investigation of a Medical Device
CTIMP	Clinical Trial of an Investigational Medicinal Product
GCP	Good Clinical Practice
ISF	Investigator Site File
PARF	Project Archiving Record Form
PI	Principal Investigator
SOP	Standard Operating Procedure
SUMP	Study Set up and Management Plan
TMF	Trial Master File
UHBW	University Hospitals Bristol and Weston NHS Foundation Trust

Definitions	
Third Party Archiving	Storage of records at a sub-contracted storage facility which is independent of the sponsor
Trial Master File (TMF)	A TMF is the collection of records that allows the conduct of the clinical trial, the integrity of the trial data and the compliance of the trial with GCP to be evaluated The Trial Master File may comprise of a sponsor file and a master file held by the Chief Investigator or a trials unit (for CTIMPs). For the sake of clarity, this SOP distinguishes between 'TMF' (when referring to the entire TMF) and a sponsor file.
Investigator Site File	The ISF is the part of the TMF which is held at the location by the PI. The PI maintains control of the ISF.
Trial location	In relation to a clinical trial, this means a hospital, health centre, surgery or other establishment, or facility or premises at or from which a clinical trial, or any part of such a trial, is conducted. (taken from HRA website) 'Site' was the previous terminology used. However this is an update required from the Medicines for Human Use Clinical Trial (Amendment) 2025 regulations to reflect research activity may take place at a number of locations not necessarily in hospital site setting.

5.0 Responsibilities

5.1 Sponsor

- The Sponsor has overall responsibility for ensuring that the TMF files are archived appropriately. The task of ensuring that the ISF records are prepared for archiving and placed into a storage facility (as applicable) is delegated to the host location, as set out in the Division of Responsibilities in the Site Agreement (for CTIMPs, CIMD's and complex non-CTIMPs) and OID or other agreement for non-CTIMPs.
- The sponsor, or the CI/trials unit if delegated by the Sponsor, is responsible for notifying locations when archived material may be destroyed. Until such notice is received, measures should be taken by the PI to prevent accidental loss or destruction of the ISF. Arrangements for destruction of the TMF of UHBW sponsored CTIMPs and non-CTIMPs should be documented by the R&D Department in the EDGE workflows.

5.2 Nominated Archivist

- The sponsor is responsible for identifying a nominated archivist for its sponsored CTIMPs.
- At UHBW the role of nominated archivist is jointly undertaken by the Trust Director of Corporate Governance (lead) and the Chief Information Officer (specialist advisor). The day-to-day operational management is delegated to the Research Management Facilitator Team Leader in the R&D Department.

- The archivist is responsible for maintaining an archive log, controlling access of material in and out of external storage and overseeing destruction of archived material for UHBW sponsored and hosted studies. The archivist is not responsible for the content of the archived material.

Nominated Archivist		Delegated individual
Director of Corporate Governance	Chief Information Officer	R&D Research Management Facilitator Team Leader

5.3 Chief/Principal Investigator

- The CI (for UHBW Sponsored studies) or PI for hosted studies is responsible for archiving the data generated at UHBW in accordance with this SOP and applicable legislation.
- If the PI/CI leaves their employing organisation during the designated archiving period s/he is responsible for ensuring that there is a documented handover of responsibility to another clinician or other suitably qualified person (e.g. lead research nurse) and informing the R&D Department of the handover arrangements.
  For situations where this has not been implemented or the designated member of staff can not be identified, the delegated archivist in R&D should identify a suitable senior member of staff to fulfil this role within the team, e.g. Lead Research Nurse, Clinical Trial Manager, etc.
- For multi-centre trials sponsored by UHBW, the site agreement delegates responsibility to the participating locations for archiving and for ensuring that data and records are available for the purposes of monitoring and inspection.

5.4 R&D Department

- The R&D department maintains a record in its research management system of all its archived studies, which includes a signed Project Archiving Record Form (TMPL_045 *Project Archiving Record Form)*, the location of the ISF and TMF (for UHBW sponsored CTIMPs) and the due date of destruction.
- The R&D Department is responsible for recouping archiving costs and raising invoices for commercial studies with the exception of commercial studies run by the Bristol Haematology and Oncology Centre Clinical Trials Unit.
- The day-to-day responsibilities of the nominated archivist are delegated to a named person in the R&D Department. These responsibilities include:

    - Ensuring there is a process in place for obtaining a completed Project Archiving Record for all closed studies in the e-study folder and that the information is entered on EDGE
    - Maintaining a record of the transfer of the ISF and sponsor file into external storage.
    - Maintaining a record and controlling the transfer of records out of external storage.
    - Maintaining a record of due destruction dates for studies put into external storage.
    - Oversight of arrangements for destruction of a) the ISF of non-UHBW sponsored CTIMPs hosted at UHBW and b) the ISF and TMF of UHBW sponsored CTIMPs at UHBW and other participating locations.

Exceptions: Bristol Haematology and Oncology Centre

- BHOC is responsible for the transfer of BHOC studies in and out of external storage and for ensuring compliance with this SOP. The R&D Department retains overall responsibility for the transfer arrangements of the TMF of UHBW sponsored CTIMPs run through BHOC.

- BHOC is responsible for gaining sponsor and PI authorisation to destroy the ISF (including the associated pharmacy files) at the end of the archiving period.
- BHOC should notify all the relevant pharmacy departments that it has requested authorisation for destruction. The R&D Department should authorise to proceed with destruction on receipt of authorisations.

6. Standards for archiving

The trial data and relevant metadata should be archived in a way that allows for their retrieval and readability and should be protected from unauthorised access and alterations throughout the retention period.

6.1 Preparation of TMF and ISF - overview

- The standards which a TMF is expected to comply with are set out in section 7 of *SOP-014 Essential Research Records*.
- All archived material must be complete, legible and recorded so that it is traceable at all times and readily accessible to the authorities upon request. It is the PI's responsibility to ensure that the archived material complies with the standards set out in this SOP and *SOP-014 Essential Research Records*. For UHBW sponsored studies, the CI must retain oversight of TMF and ISF archiving and ensure that PIs at external locations are aware of their responsibilities to archive appropriately.
- The PI, by signing off the Project Archiving Record Form, is providing confirmation that they are satisfied that these standards have been met.
- The TMF may comprise records held by the main study team, the R&D Department, support departments and external suppliers. When the study is ready to be archived, the TMF should ideally be brought together as a single file (refer to Section 8 of *SOP_014 Essential Research Recordss*). If it is not possible to physically store all the records in one place (for example, research data held on electronic databases), then the location of these records should be clearly flagged in the TMF and arrangements should be made so that they can be readily accessed for the purpose of monitoring and inspection.
- Databases and associated records (e.g. metadata) may be archived separately from the main TMF. It is anticipated that the database would usually be held by the trials unit or study team on their university or NHS server, although for some studies it may be more appropriate to be held on the R&D Department's server. This should be reviewed on a case-by-case basis and, for sponsored CTIMPs or other complex trials, should be captured in the Study Set up and Management Plan (SUMP) or the sponsor's study closure checklist.
- The TMF and ISF of UHBW sponsored studies should be archived separately, except where it has been previously agreed with the R&D Department that they may be archived together (see Essential Research Records SOP_014). If the TMF and ISF are archived together, this should be clearly stated on the Project Archiving Record Form (PARF).
- For UHBW sponsored CTIMPs, the sponsor and the trials unit/CI (as applicable) should check that the TMF includes all necessary **evidence of sponsor oversight** (section 6.1.2 *SOP_014 Essential Research Records*).
- For UHBW sponsored CTIMPs and CIMDs the research data held on electronic databases is considered to be part of the TMF (*TMPL _043 CTIMP Trial Master File Contents Index Template)*.
- See *SOP_012 Study Data* for standards on database locking.
- The transfer of project records between parties (i.e. the PI, the nominated/delegated archivist and the external storage facility) should be properly documented. This is also known as 'the chain of custody'.

- The MHRA requires that sponsors need to make reasonable effort ensure readability of data during and for the life of the study archive retention period.

- The following issues need to be considered when archiving electronic filing ('e-filing'):
    - Access to software which allows the data to be read for the duration of the period of retention.
    - Ensuring that data is not locked in proprietary or end-of-life systems. Essential data should be accessible and portable.
    - Controlled access to data.
    - Disaster Recovery Plan in the event of loss of data
    - Sponsor permission for use of e-filing or conversion of paper filing into e-files.

Further information is available in *GD_018 Essential Research Records*.

6.2 Paper filing: preparation

- Paper records should be removed from ring binders or lever arch files to keep storage space to a minimum.
- Records may be held together by plastic archiving clips, but plastic wallets and all paper clips, staples or metallic means of combining sheets should be removed to prevent rusting or other chemical deterioration. It may not always be practical to remove metallic staples if it is considered that there is a reasonable risk of damaging the records. In this instance the Sponsor should be notified.
- Duplicate copies of paper records should be destroyed.
- Post-it notes may be mis-placed and should therefore be removed and typed up as file notes as appropriate.
- Records vulnerable to deterioration should be identified and appropriate arrangements put in place. For example, thermochromic paper should not be put into storage as this will deteriorate; instead certified copies should be made or alternative arrangements made for long term storage.
- Consideration should be given to potential risk of obsolescence of data held in non-paper format e.g. film or magnetic tape and whether this can, or should, be transferred to a different media format before putting into archiving.
- For health and safety reasons, it is recommended that the upper weight limit of packed archiving boxes is 15 kilos. Archiving boxes going into external storage should be sized between 1.00 and 1.3 cubic feet. These can be sourced from the R&D department.

6.3 Paper filing - storage facilities

- Research data must be stored in a physical location that is weatherproof, pest-proof, secure at all times and environmentally controlled/protected. A reputable external storage facility provider should be able to satisfy these criteria.
- The Trust holds a contract with Restore, an external storage facility, for storing research records and medical records. The head office details for Restore are:

  Restore Storage Group, Unit 5, Redhill Distribution Centre, Salbrook Road, Salfords, Redhill, Surrey, RH1 5DY.

- The Trust expects Restore, as a data processor, to maintain the necessary standards for storing records. The Trust aims to conduct monitoring visits at Restore at least twice a year. The Trust may undertake checks which cover but are not limited to: suitability of the physical environment, security of records during transportation and storage, authorised movement of recordss, timely destruction of archived material and General Data Protection Regulation (GDPR) compliance. In addition, the R&D Department will conduct test retrievals and the frequency of these audits should be no more than 24 months apart.
- External sponsors may choose to make their own arrangements for the storage of ISFs. For CTIMPs, these must be third party archiving facilities in order to prevent unauthorised access by the sponsor to original location data.
- It is preferable that arrangements for archiving are identified and addressed at study set up by the study team, in consultation with the sponsor. For UHBW sponsored CTIMPs, this should be documented in the study setup and management plan (SUMP).

6.4 Electronic filing: preparation and storage

- E-filing which forms part of the ISF should be held on a UHBW server. Exceptionally, and in agreement with the R&D Department, they may be held elsewhere. Records forming part of the ISF should not be held on the sponsor's server or their agent's server.
- The study team should specify the exact location of the e-files in the PARF. The R&D Department should complete the e-filing field in the Archiving attribute on EDGE.
- The nominated delegated archivist should contact the IT Help Desk to arrange for access to be restricted to the nominated delegated archivist and their line manager.

6.5 Duration

- Records must be retained for the minimum length of time stipulated in the regulations and guidance (see *GD_009 Guidance on retention period for study records*), whilst at the same time taking full account of the principles enshrined in data protection legislation that personal data should be held for no longer than is absolutely necessary.
- Some studies are abandoned before they start or before a patient is consented into the study. In such cases, the PI should seek guidance from the sponsor about archiving requirements and/or follow any advice as set out in the protocol and/or the site agreement between the sponsor and UHBW.

6.6 Archiving of Standard Operating Procedures (SOPs) and related documentation

- Study specific SOPs and related documentation (guidance documents etc.) that were in place during study conduct should be appropriately archived. It is recommended that all applicable SOPs and related documents are filed either in the TMF or ISF as applicable. These should therefore be archived as described above.
- All SOPs produced by UHBW R&D and subsequently superseded should be archived at departmental level within R&D electronic folders with a clear audit trial to demonstrate which SOPs were effective at a given time point if required (i.e., for inspection purposes). Only current, in date SOPs should remain on the R&D website and Trust document management system.

- For UHBW sponsored research the CI should be informed of any major revisions to R&D SOPs and the CI, or delegated other, is responsible for onward cascade to research sites (as applicable). Sites should either file superseded versions of applicable SOPs in the ISF and these should be archived as described above, or a file note should be inserted in the ISF describing the location of these SOPs with appropriate contact details for access as required
- It is the responsibility of UHBW research units to ensure there is a documented process for archiving departmental SOPs. These must be retrievable and have a clear audit trail (i.e. for monitoring or inspection).

7.0 Procedures for archiving site records

- For UHBW sponsored studies, the CI or trials unit has delegated responsibility for initiating archiving procedures of the ISF at all participating sites.
- For UHBW sponsored studies and non-UHBW sponsored studies, the PI is responsible for undertaking the following procedures or delegating them to appropriately qualified staff in their team:
    - Liaise with the sponsor to initiate archiving procedures and obtain approval to archive the study records.
    - Ensure that the essential records listed in the ISF template provided by the sponsor are present and appropriately filed (see section 6 above)
    - Create a contents log of the archived material and append this to the Project Archiving Record Form
    - Place a copy of the contents log inside each archiving box or attach to the inside lid of the box. A copy of the contents log may also be held in the site research team's office
    - Complete and return the Project Archiving Record Form (PARF) to the R&D Department.
    - Place a copy of the signed and completed PARF form in all boxes being archived, if more than one box is required for the archive.
    - For studies going into external storage, complete the *New Intake/Returns form (TMPL_047*) and send this by email to Restore to arrange collection (copied to the R&D Department).
    - All storage boxes going into external storage should be labelled using the R&D *TMPL_046 Label* Template. This states the R&D reference number, the due destruction date, the box number, and the total number of boxes, for example CH/2008/2315 Box 2/5, destroy 20/10/2023. If the sponsor requires additional information, this should also be included. Boxes going into external storage should be labelled on both the long and the short end of the box in order to aid retrieval.
    - In addition, each box should also be allocated a unique Restore barcode (supplied by R&D) and attached to the R&D label on the top of the box. This/these barcode number(s) should be recorded on the PARF form.

    - Once the R&D Department has received confirmation that the TMF/ISF has been prepared for archiving (paper and/or e-filing), the Research Projects Assistant should:

    (i) Request the collection of the archive to be stored at Restore via the central Restore electronic portal.

    (ii) Update both the Archiving attribute on EDGE and the spreadsheet of studies sent to Restore (held on the R&D Department's shared drive "R&D Group").

8.0 Retrievals

- The retrieval of records from external storage should be kept to an absolute minimum. Retrieval is controlled by the nominated archivist (or delegated person) and requires their authorisation before records can be taken out of storage.
- After authorisation has been obtained, the research team should complete *a Retrieval Request form (TMPL_048*) and return the form to the external storage facility, copied to the R&D Department.
- When the records are ready to return to storage, the research team should complete the *New Intake/Returns form (TMPL_047*), copied to the R&D Department.
- For UHBW sponsored CTIMPs where archiving has been arranged by another party (e.g. the trials unit or CI), any retrievals should only be arranged in consultation with the Trust's nominated archivist (or delegated person). Such arrangements should be specified in the SUMP.
- The movement of records in and out of storage should be recorded by the R&D Department.
- If the retrieval has been requested by an external Sponsor, the cost of retrieval should be met by the Sponsor.

9.0 Destruction of archived material

- The trial data and metadata may be permanently destroyed when no longer required as determined by applicable regulatory requirements.
- The R&D Department should monitor due destruction dates of studies put into external storage. This may be done via reports provided by Restore or through its online portal. Additionally, R&D may use routine reports generated on EDGE. For studies which use e-archiving in part, or exclusively, due destruction dates are identifiable via the EDGE routine reports.
- The R&D Department or the local research team should contact the CI (for UHBW Sponsored studies) or the PI and the sponsor (for hosted studies) at least one month before the due date for destruction to seek authorisation for destruction. If the sponsor cannot be contacted or fails to provide a response after several attempts, the R&D Department may authorise destruction. The R&D Department or the local research team should arrange destruction of records put into external storage and/or e-filing stored on the Trust's server and inform the sponsor and PI (where contactable) that this has been done. The R&D Department should record the date of destruction in its research management system For UHBW sponsored CTIMPs the date of destruction should also be recorded on EDGE.
- For UHBW sponsored CTIMPs, the R&D Department should authorise destruction of the TMF and is responsible for informing sites about arrangements for destruction.

10.0 Dissemination and training in the SOP

This SOP should be disseminated to applicable research staff (including the R&D Department) and should be available on the R&D website.

Plan Elements	Plan Details
The Dissemination Lead is:	Research Operations Manager
Is this document: A – replacing the same titled, expired SOP, B – replacing an alternative SOP, C – a new SOP:	A-replacing the same titled, expired SOP
If answer above is B: Alternative documentation this SOP will replace (if applicable):	
This document is to be disseminated to:	All applicable research staff (including R&D)
Method of dissemination:	For major updates to the SOP dissemination should be: 1. To Chief Investigators of UHBW Sponsored CTIMPs 2. Research Unit leads across UHBW 3. Head of Research Governance at UoB (where SOP is applicable) All updates (major and minor to the SOP) should be: 1. Updated on the trust MyStaffApp 2. Updated on the R&D website 3. Cascaded in R&D communications
Is Training required:	All staff whose activities are subject to this SOP should ensure that they read and understand the content of the SOP. The personal training log of the individual (and the Investigator Site File/Trial Master File if required) should be completed to document that the content of this SOP has been read and understood as described in *SOP_007 Research Training UHBW*

REFERENCES	Medicines for Human Use (Clinical Trials) Regulations (2004) [SI 1031] as amended by the Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025
RELATED DOCUMENTS AND PAGES	• GD_009 Guidance on retention period for study records • SOP_007 Research Training • SOP_014 Essential Research Records • TMPL_045 R&D Project Archiving Record Form • TMPL_046 Label Template • TMPL_047 New Intake/Returns form • TMPL_048 Retrieval Request Form

	Latest versions of these are located on the Research & Development section of UHBW's website: http://www.uhbristol.nhs.uk/research-innovation/for-researchers/templates-and-sops/ UHBW Research & Development - Home (sharepoint.com)
AUTHORISING BODY	Trust Research Group
SAFETY	N/A
QUERIES AND CONTACT	Research & Development department via email: research@uhbw.nhs.uk
AUDIT REQUIREMENTS	R&D departmental Quality Management System audits are undertaken annually.