Standard Operating Procedure

ARCHIVING OF RESEARCH DOCUMENTATION

SETTING Trustwide and external sites participating in UH Bristol Sponsored research

AUDIENCE Research staff at UH Bristol and external sites participating in UH Bristol Sponsored research

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

QUERIES Contact Research Operations Manager, Research Projects Manager or Research Management Facilitators on 0117 34 20233

SOP number	SOP 015	**SOP Version**	1.3
Effective Date	20/FEB/2018	**Review Date**	20/FEB/2020

Document History

Review date	Version number	Version date	Effective date	Author/ Reviewer	Authorised by
-	V1.0	09/OCT/2015	03/NOV/2015	Katharine Wale	Diana Benton
November 2016	V1.1	06/FEB/2017	06/FEB/2017	Katharine Wale	Jess Bisset
October 2017	V1.2	18/OCT/2017	19/OCT/2017	Katharine Wale	Diana Benton
January 2018	V1.3	25/JAN/2018	20/FEB/2018	Katharine Wale	Jess Bisset

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

1. Introduction

For CTIMPs it is a legal requirement of the Medicines for Human Use (Clinical Trials) Regulations (2004) [SI 1031] that the essential documents (usually comprising the Trial Master File (TMF), the Investigator Site File (s) (ISF) and the medical records of trial participants) are retained following the end of a CTIMP in order to allow reconstruction of a trial, potential further analysis of project data and to enable MHRA inspection and monitoring in accordance with SI 2004/1031 and Good Clinical Practice.

Retention periods for the TMF/ISF and medical records, including the final study report, range from a minimum of five years from end of study date to up to five years beyond the lifetime of a product authorisation (refers to sponsor requirement to retain final study report). The retention period for Advanced Therapy Investigational Medicinal Products (ATIMP) is 30 years.

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

Non-CTIMP studies may be archived without going into external storage, although external storage is strongly recommended. In such cases, the archived material should still be retained according to the standards set out in this SOP.

Occasionally, there may be situations where documents 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 documentation for UH Bristol hosted and sponsored CTIMPs (Clinical Trial of an Investigational Medicinal Product), as required under the Medicines for Human Use (Clinical Trials) Regulations (and any amendments) and to describe the procedure for archiving hosted and sponsored non CTIMP research project documentation within UH Bristol.

3. Scope

In Scope: Applicable documentation for CTIMPs sponsored or hosted by UH Bristol where provision for third party archiving is not made by the sponsor (if not UH Bristol). Applicable documentation for non CTIMPs sponsored or hosted by UHBristol, where provision for third party archiving is not made by the sponsor (if not UH Bristol).
Out scope: All other externally sponsored research and non-research related documentation

4. Responsibilities

4.1 Sponsor

- The Sponsor has overall responsibility for ensuring that the TMF and the ISF are archived appropriately. The task of ensuring that the ISF documents are prepared for archiving and placed into a storage facility (as applicable) is delegated by the sponsor to the host site in accordance with the following sections and the Division of Responsibilities in the Site Agreement (where applicable).
- The sponsor or the CI/trials unit, if delegated by the Sponsor is responsible for notifying sites when archived material may be destroyed. Until such notice is received, measures should be taken to prevent accidental loss or destruction of the ISF by the PI.

4.2 Nominated Archivist

- The role of nominated archivist is jointly undertaken by the Trust Secretary (lead) and the Head of IM&T (specialist advisor). The day to day operational management is delegated to the Research Projects Manager in the R&I Department.
- The archivist is responsible for maintaining an archive log, controlling access of material in and out of storage, and destruction of archived material. The archivist is not responsible for the content of the archived material.

Named Archivist		Delegated individual
Trust Secretary	Head of IM&T	R&I Research Projects Manager

4.3 Principal Investigator

- The PI is responsible for archiving the data generated at the site appropriately in accordance with this SOP and applicable legislation.
- If the PI/CI leaves their employing organisation during the designated archiving period arrangements, s/he is responsible for ensuring that there is a documented handover of responsibility to another clinician and, for all UH Bristol hosted studies and UH Bristol sponsored studies, informing R&I of the handover arrangements.
- For multi-centre trials sponsored by UH Bristol, the site agreement delegates responsibility for archiving to the participating sites and stipulates that the PI should allow UH Bristol and the regulatory authorities access to archived data upon request.

4.4 R&I Department

- The R&I department will maintain a record on its research management system for all hosted studies, which will include a signed *Project Archiving Record Form (TMPL_045)*, the location of the ISF and the due date of destruction.
- The R&I Department is responsible for recouping archiving costs and raising invoices for commercial studies.
- The day-to-day responsibilities of the nominated archivist are delegated to a named person in the R&I Department and these responsibilities include:
    - Ensuring there is a completed *Project Archiving Record Forms (TMPL_045)* for all closed studies in the e-study folder and entering the details on EDGE
    - Maintaining a record of the transfer of thhe ISF and TMF in and out of external storage
    - Controlling documents going in and out of storage
    - Maintaining a record of due destruction dates for studies put into external storage Oversight of arrangements for destruction of documents.

Exceptions: Bristol Haematology and Oncology Centre

- BHOC will be responsible for the transfer of BHOC studies in and out of external storage and for ensuring compliance with this SOP (except for UH Bristol sponsored CTIMPs which will remain the responsibility of R&I)
- BHOC will be responsible for gaining sponsor and PI authorisation prior to destruction of records. The R&I will authorise destruction on receipt of authorisations.

5. Abbreviations and Definitions

Abbreviations	
ATIMP	Advanced Therapy Investigational Medicinal Product
CTIMP	Clinical Trial of an Investigational Medicinal Product
GCP	Good Clinical Practice
CI	Chief Investigator
PI	Principal Investigator
R&I	Research & Innovation department
BHOC	Bristol Haematology and Oncology Centre
TMF	Trial Master File
ISF	Investigator Site File

Definitions	
Applicable documentation	This refers to all documents as described in the UH Bristol R&I Essential Research Documents SOP
Third party archiving	Storage of documentation at a sub-contracted storage facility which is independent of the sponsor

6. Procedure

6.1 Standards of retention

6.1.1 Storage facilities

- It is important that research data are 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. For those studies which are not being put into external storage, access to the research data should be restricted to authorised personnel with controlled access, for example in a locked cabinet or in an area with swipe card access.
- The Trust holds a contract with Restore, an external storage facility, for storing research documentation 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.

- As part of its contracting and monitoring arrangements, the Trust expects Restore to maintain the necessary standards for storing records.
- External sponsors may 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 site data.
- Arrangements for archiving at the end of the research should ideally be identified at study set up by the study team. For UH Bristol sponsored CTIMPs, this should be documented in the study setup and management plan.

6.1.2 Documentation

- For non-CTIMPs sponsored by UH Bristol, the UH Bristol ISF and the TMF may be archived together. This should be clearly specified on the *Project Archiving Record Form (TMPL_045)*.
- The transfer of project documentation 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'.
- 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 these standards. For UH Bristol sponsored studies, the CI must retain oversight and ensure that PIs at external sites take are aware of their responsibilities to archive appropriately.
- For UH Bristol hosted studies, the PI should sign off the *Project Archiving Record Form (TMPL_045)* as confirmation that they are satisfied that these standards have been met.
- The TMF may comprise documentation held by the main study team, the R&I 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 *SOP_014 Essential*

Research Documents). If it is not possible to physically store all the documentation 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 for ease of access to these records as and when required (for example, regulatory inspection).

6.1.3 Duration

- Documents must be retained for the minimum length of time stipulated in the regulations and guidance (see *GD_015 Guidance on retention period for study documentation*), 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 UH Bristol.

6.1.4 Preparation of documents

- Documents should be removed from ring binders or lever arch files to keep storage space to a minimum.
- Documents 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 therefore (and in accordance with sponsor requirements) they may not be removed unless it is considered that there is a reasonable risk of damaging the records.
- Post-it notes may be mis-placed and should therefore be removed and typed up as file notes as appropriate. Thermal paper should not be put into storage as this will deteriorate; instead it should be copied or other arrangements made for long term storage.
- 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&I department.
- Files which are not going into an external storage facility should be appropriately labelled. *TMPL_046 Label Template* is available on the R&I webpages.
- All storage boxes going into external storage should be labelled with a unique code comprising the R&I 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 with a marker pen on both the long and the short end of the box in order to aid retrieval.
- A contents log for each box must be placed inside the box or attached to the inside lid of the box and a copy of the record may be held in the research team's office to facilitate.
- Electronic filing ('e-filing') is permissible, provided that issues relating to e-filing have been fully addressed. These include, but are not limited to:
    - Access to software which allows the data to be read for the duration of the period of retention
    - Controlled access to e-filing
    - 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
    - Acceptability of e-consent signatures
    - Robust Electronic Data Management System (EDMS) for storing the source data (which may include medical notes). e.g. which includes the facility for audit trails, controlled access to data and ease of access to data.

6.2 Procedures for archiving site documentation

- For UH Bristol sponsored studies, the CI/trials unit in consultation with the Sponsor is responsible for initiating archiving procedures of the ISF at all participating sites.
- For non-UHBristol 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
    - Ensure that the essential documents described in the ISF template as provided by sponsor are present and appropriately filed.
    - Create a contents log of the archived material held in each archive box. This might be a copy of the ISF template. Complete and return the *Project Archiving Record Form (TMPL_045)*.
    - For studies going into external storage, complete the *New Intake/Returns form (TMPL_047*) and send this by email to the external storage facility to arrange collection (copied to the R&I Department)

6.3 Retrievals

- The retrieval of documents 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 documents can be taken out of storage.
- After authorisation has been obtained, the research team completes *a Retrieval Request form (TMPL_048*) and returns the form to the external storage facility (copied to R&I).
- When the documents are ready to return to storage, the research team completes the *New Intake/Returns form (TMPL_047*), copied to R&I.
- The movement of documents in and out of storage will be recorded by R&I.
- If the retrieval has been requested by an external Sponsor, the cost of retrieval should be met by the Sponsor.

6.4 Destruction of archived material

- R&I contacts the PI and the sponsor (where applicable) 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, R&I may authorise destruction.
- R&I arranges destruction of documents, records the date of destruction and informs the sponsor and PI (where applicable).

7. Dissemination and training in the SOP

This SOP will be disseminated to applicable research staff (including R&I) and will be available on the R&I website.

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*.

8. Related documents

- GD_015 Guidance on retention period for study documentation
- SOP_007 Research Training
- SOP_014 Essential Research Documents
- TMPL_045 R&I Project Archiving Record Form
- TMPL_046 Label Template
- TMPL_047 New Intake/Returns form
- TMPL_048 Retrieval Request Form