Humber Health Partnership

Archiving SOP

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This page details the version history and the main changes made for each new version.

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Version Log		
Version number and date	**Author**	**Details of significant changes**
Version 1, 27.10.10	JHP	Original SOP approved by R&D Committee on 27.10.10.
Version 2, 09.12.10	JHP	Clarification of filing of Confirmation of Receipt form for monitor on page 8.
Version 3, 14.08.13	JHP	All links checked & up-dated as necessary Added to page 4 – Who should use this SOP: • Research staff involved with HEY-sponsored non-CTIMPs may find this SOP a useful guide, although the SOP will need to be adapted for the non-CTIMP study. • Research staff involved with clinical trials sponsored by an external organisation where the sponsor has no SOP for archiving trial documents. HEY R&D SOPs are defaulted to in this case. Added to page 6, 7 & 8 - For hosted CTIMPs, investigator and pharmacy responsibilities: 'Where the sponsor is archiving on behalf of the PI, the PI should retain control of the documentation contained in the Investigator Site File and Pharmacy Study File. The ISF/PSF should never be sent to the sponsor. Documents in the ISF/PSF can only be accessed or released from the external archive with the approval of the PI and pharmacy or the Trust. The PI must check this arrangement with the archive facility.' Page 6 - Investigator responsibilities Labelling of study patients casenotes with study alert sticker on the inside front cover. We no longer use STOP-ALERT stickers on the front cover. Added to page 10 - Archivist - Hand copies of requested documents to researcher at pre-arranged time. - Complete the Retrieval Log in the R&D CTIMP archiving spreadsheet.
Version 4, 26.01.15	JHP	**Page 8** The 5yr archiving period and date of destruction of study files will be 5 years from the date in part D.1 on the Declaration of End of Trial form. **Appendices 1, 2, 5 & 6 Archiving File Notes** Head of Department to sign off if the PI cannot be

		contacted despite all efforts made to contact the PI. Head of Pharmacy to sign off should the Principal Clinical Trials Technician not be available.
Version 5, 24.04.19	JHP	Removed mention of archiving for hosted CTIMPs as this is no longer done. Removed appendices as these are now working instructions. Change of archiving organisation name from Magnum to Restore (same organisation but change in name). Added procedures for large multi-site trials managed by CTU. Added process for electronic archiving.
Version 6, 09.02.21	SM	The sections in the SOP have been reformatted and renumbered as per the new SOP template. Additional text to Section 7, Electronic archiving. Additional wording in Section 8 Archivist to include electronic archiving.
Version 7, 08.04.2024	GC	8.1.7 Added sentence to include other electronic management systems to be used as a prompt for the tracking and management of archiving of studies. R&D amended in line with new department name Research, Development and Innovation (RDI)
Version 8, DRAFT	LC	• Updated archiving retention period from 5 years to 25 years throughout the SOP, in line with updated ICH E6(R3) expectations and Sponsor requirements. (e.g., "The duration of archiving will be for at least 25 years…"). • Updated Section 3 (Background) to reflect new regulatory expectations for longer retention, particularly for IMPs in development and regulatory submissions. (Section 4.1.7) Updated Investigator responsibilities to reflect the new 25-year minimum retention period in the Archiving File Note. (Section 6.4 & 6.50 Updated Sponsor responsibilities to specify that the archiving period is now 25 years from the date in Part D.1 of the End of Trial form. (Section 5.4) Updated Pharmacy responsibilities to reflect the new 25-year retention period. (Section 8) Updated Archivist responsibilities to ensure destruction permissions and reminders align with the new 25-year retention period. • Minor wording updates to align with new departmental name (RDI) where needed. • General formatting and clarity improvements consistent with SOP template updates. •Trust name changed from Hull University Teaching Hospitals NHS Trust (HUTH) to Humber Health

		Partnership (HHP- Hull University Teaching Hospitals NHS Trust and Northern Lincolnshire and Goole NHS Foundation Trust).

Contents

Please note for definitions of acronyms refer to Appendix 1 of Management of SOPs. Refer to Appendix 2 of Management of SOPs for the standards to which clinical trials that investigate the safety and/or efficacy of a medicinal product are conducted.

All the RDI GCP SOPs are available at:
https://www.HUTH.nhs.uk/research/researchers/gcp-sops-for-HUTH-sponsored-ctimps/

1 Purpose

1.1 The purpose of this SOP is to describe the procedures for archiving the essential trial documents and data for clinical trials of investigational medicinal products (CTIMPs) sponsored by Hull University Hospitals NHS Trust (HUTH).

1.2 Ensuring essential records remain complete, legible, contemporaneous, attributable, and accessible throughout the full data lifecycle.

2 Who should use this SOP

2.1 This SOP should be used by all research staff, pharmacy staff, RDI QA staff, and medical records staff involved in HUTH-sponsored CTIMPs, and where defaulted for externally sponsored trials without sponsor SOPs.

3 Background

3.1 Essential documents include Trial Master Files (TMF), Investigator Site Files (ISF), Pharmacy Study Files (PSF), Sponsor Study Files, CRFs, and all associated data. Including electronic records, metadata, audit trails, and system outputs required to demonstrate data integrity and traceability. Essential records location index must be maintained and updated to identify where all records are located and for copies replacing originals, certified copies by dated signatures or validated processes should be used.

3.2 These records permit evaluation of trial conduct, participant safety, and reliability of trial results and are subject to MHRA inspection. A proportionate, risk-based approach to the retention and oversight of essential records.

3.3 Individually and collectively the essential documents allow the evaluation of the conduct of the trial and the quality of data and results produced. They serve to demonstrate the compliance of the investigator, sponsor and monitor with the UK Clinical Trial Regulations and are thus subject to inspection by the regulatory authority (MHRA).

3.4 Following conclusion of the trial, the essential documents and data should be archived in a

complete and legible condition for a sufficient length of time to allow for inspection by regulatory authorities and should be available upon request.

3.5 For clinical trials using IMPs with marketing authorisations, the essential documents require archiving for at least 25 years following completion of the trial.

3.6 Archiving time is longer for clinical trials involving IMPs in development prior to marketing authorisation. If trials are to be included in regulatory submissions then essential study documents should be retained until at least 2 years after the last approval of a marketing application to the EU. To meet this regulation pharmaceutical companies frequently archive for 25 years unless otherwise stated in the trial protocol.

3.7 The duration of archiving should be checked with the Sponsor, however all documentation related to significant data or security incident, breaches is critical to be retained for the required duration.

3.8 Completion of the trial is usually defined as the date of the last patient's last visit unless stated otherwise in the protocol.

3.9 After study completion, for single site/small multi-site trials archiving of all files will be the Sponsors responsibility for archiving the essential documents and data and access must be restricted to individuals appointed by the Sponsor.

3.10 Medical records of trial patients must also be retained for at least 25 years following completion of the trial.

For HUTH-sponsored CTIMPs

3.11 During the study, the essential documents should all be kept filed in the TMF, PSF, ISF, SSF (if required) and CRFs.

3.12 For single-site and small multi-site trials, RDI QA keeps the TMF, the Principal Investigator(s) keep(s) the ISF(s) and CRFs. For large multi-site trials run by a CTU, the CTU holds the TMF and each site has an ISF and CRFs. RDI QA keeps a SSF. Pharmacy maintains the PSF.

3.13 The list of contents for the TMF and PSF are available from the RDI monitor/QA be organized and centralised by the RDI monitor/QA manager. The monitor will collate the files and archive these together using the document storage company Restore. For large multi-site trials, the CTU will organize the archiving of the trial files.

3.14 The duration of archiving will be for at least 25 years following study completion. If the trial has an external Funder then it is important to check with the Funder in case they require a longer period of archiving.

3.15 During archiving, access to these files will be restricted to the RDI or CTU archivist and nominated deputy.

3.16 HHP medical records department is responsible for retaining patients' medical records.

4 Investigator responsibilities

4.1 For HUTH-sponsored CTIMPs – single-site or small multi-site managed by RDI QA

4.1.1 Investigators are responsible for maintaining ISFs and CRFs during the trial and supporting end-of-trial archiving.
Investigators must ensure records remain attributable and accessible until formal transfer to archive.

4.1.2 Labelling of trial patients paper medical records with study alert stickers and alerting electronic medical records with study details. The monitor will advise on how to do this.

4.1.3 The sticker should clearly state that the patients records should not be destroyed until the allowed date of destruction. See section 7 below for an example study sticker template.

4.1.4 Work with the monitor to submit the end of trial form (see End of Trial SOP 12) to the MHRA, REC/HRA when the study has ended (completed or terminated).

4.1.5 Work with the monitor to resolve all actions following the monitor's site closedown visit.

4.1.6 Agree a suitable date with the monitor for collection of the ISF and CRFs. Sign the RDI confirmation of receipt form when the monitor collects the files.

4.1.7 Check through and sign off the ISF Archiving File Note provided by the monitor.
The file note details;

- the files for archiving
- the duration of archiving (usually a minimum of 5 years)
- the archive organisation
- the name and contact details of the archivist
- how to retrieve documents
- the allowed date of destruction.

4.1.8 Reimburse RDI for archiving the trial files and data for the required period (at least 25 years from the end of trial). An invoice for the total duration of archiving will be sent to the Chief/Principal Investigator (CI/PI) at the start of archiving by RDI.

4.1.9 After trial documents have been archived, contact the RDI archivist to request retrieval of archived documents if necessary. The request must be confirmed by the CI/PI.

4.1.10 Permission will be sought from the CI/PI before destruction of any documents or data.

4.2 For HUTH-sponsored CTIMPs – large multi-site managed by CTU

4.2.1 Follow CTU staff instructions with regard to archiving the TMF and CRFs in both paper and electronic format. The CTU will have an archivist who will organize archiving and track any requests for retrieval of documents/data during the archive period. The CTU should have their own Archiving SOP to follow, if they do not, then this SOP will be defaulted to.

4.2.2 Permission will be sought from the CI before destruction of any documents or data.

5 Pharmacy responsibilities

For HUTH-sponsored CTIMPs

5.1 Pharmacy maintains the PSF and supports archiving following trial close-down.

Pharmacy must ensure accountability records and electronic dispensing data remain retrievable and protected.

5.2 Receipt of a copy of the end of trial form (see End of Trial SOP 12) from the RDI monitor (or CTU) as confirmation that the study has ended (completed or terminated).

5.3 Work with the RDI/CTU monitor to resolve all actions following the monitor's pharmacy closedown visit.

5.4 Check through and sign off the PSF Archiving File Note provided by the monitor.
The archiving file note details;

- the files for archiving
- the duration of archiving (usually a minimum of 5 years),
- the archive organisation
- the name and contact details of the archivist
- how to retrieve documents
- the allowed date of destruction.

5.5 Keep this file note in a secure place for future reference. A copy will be kept in the PSF and also by the archivist.

5.6 Agree a suitable date with the monitor for collection of the PSF. Sign the RDI confirmation of receipt form when the monitor collects the PSF.

5.7 Permission will be sought from the Principal Pharmacy Technician before destruction of any documents.

6 Sponsor responsibilities

For HUTH-sponsored CTIMPs

Monitor

6.1 The HHP monitor oversees completeness of TMF, ISF, and PSF.
Including confirmation that electronic systems used for trial records are suitable for long-term retention and inspection readiness.

6.2 During routine monitoring visits and at the site and pharmacy closedown visits, check for completion of the TMF and PSF. The list of contents for all study files is available from HHP R&D QA Team.

6.3 During routine monitoring visits check that patients medical records have a study alert sticker on the inside front cover with the correct information, including the correct date of destruction.

6.4 At the end of the trial, ensure that the end of trial form has been submitted to the MHRA and REC/HRA. **The archiving period will be for 25 years from the date entered in part D.1 on the end of trial form.**

6.5 At the end of the trial, prepare the TMF, ISF and PSF archiving file notes (use template Working Instruction 25). **The allowed date of destruction will be at least 25 years from the date in part D.1 on the end of trial form.**

6.6 Prepare the Receipt of Files form (WI 26) and the Archive Box Contents and Permissions Form (WI 27) ready for completion.

6.7 Ensure copies of the signed archiving file notes are filed in the TMF, ISF and PSF and that the PI and principal pharmacy technician have a copy for future reference.

6.8 Ensure the original signed archiving file notes, receipt form and ABC form are filed in the RDI office file: Archiving CTIMPs.

6.9 Check that all actions have been resolved from the site and pharmacy closedown visits.

6.10 When all actions have been resolved, organize the collection of the ISF and CRFs from site and the PSF from pharmacy. Complete and obtain signatures on the receipt form. File the original receipt form in the RDI office file: Archiving CTIMPs and place a copy in the TMF (also scan a copy and save in the eTMF).

6.11 Advise and help the archivist prepare and arrange the files in the archive boxes according to the instructions provided by Restore.

6.12 Check the Archive Box Contents (ABC) form with the archivist for each archive box.

7 **Electronic archiving** (R&D QA central electronic archiving)

For HHP -sponsored CTIMPs and site data for hosted trials.

> "The use of electronic systems for such activities as data management, statistical analysis, reporting, trial management systems and eTMFs means that electronic documentation and data are likely to need to be retained. The data may be on a server or a transportable media (for example, USB drives, CDs, tapes etc.). It is recommended that more than one copy of the data is retained: for example, where the data are archived in a specific server, this would be subject to back up, with the back-up media stored in a separate location. Consideration may be given to storing data in differing formats on different types of media or even the same media from different manufacturers." [MHRA Good Clinical Practice Guide, Section 10.7.9 Electronic archiving].

7.1 Electronic essential documents, data, and metadata must be archived in controlled systems. Systems must maintain data integrity, access control, audit trails, and long-term readability. A clear agreement between HHP(Sponsor) and the Principal Investigator is essential to determine who is responsible for archiving and maintaining the trial records. This will be stipulated within the Formal Agreement during trail set up.

7.2 Periodic checks must confirm continued accessibility. Frequency of checks should be proportionate to trial risk.

7.3 Transfers to new media or formats must be validated and documented.

7.4 For each trial archived complete Working Instruction (WI) 44. The WI will log the following:

- Trial Name
- CI/PI name
- Sponsor details
- EudraCT number
- IRAS Project ID
- R&D reference number
- CTIMP folder number e.g. eCTIMP 49 (to be entered on RDI CTIMP archiving spreadsheet)
- Password to open archived folder
- Date of archiving
- Date of first check
- List of checks to be made
- Date of move to “Deleted archive” folder
- Dates archived folder checked and by whom.

Set up a folder for each archived trial in the Archiving Folder in GCP,SOP& Forms which is separate to the RDI Trials Archived folder and accessible to only RDI QA staff. Save the completed WI in the trial specific folder.

7.5 The archived documents, data and metadata will be checked by RDI QA staff annually (this may be subject to change) to ensure they are still accessible and readable. The checks must be documented on the trial specific WI as described above in 7.4.

7.6 Should the documents and data have to be transferred to new media or a new format, the transfer should be validated and fully documented, so that it can be audited to ensure there has been no loss, change or corruption to the data or metadata.

7.7 When the Trust’s servers are decommissioned due to age, IT will send an email to all users with access to that area warning them of the move and associated downtime. Once the downtime window begins, users will be prevented from accessing and editing the files. IT will then run a command to copy the files to the new location. A log file is created confirming the success of each file that is moved. A check of the log is made for any files that have failed to move from the old server to the new server and these are moved manually if necessary. Once complete, a check is carried out to ensure that the folders in the new location contain the same number and overall size of files as the old location. Once the move is completed and all files have moved, access is granted to the users and an email is sent with the path of the new location.

7.8 The protocol or written procedures of the sponsor should contain details of the retention times for the trial documents, data and metadata.

7.9 Certain documents may need to be held for a longer period than the trial sponsor retention time. In these circumstances the Trust's SOP CP286 – Business And Corporate (Non-Clinical) Records Policy, Appendix A, Business and Corporate (Non-Clinical) Records Retention Schedule should be followed.

Please note not all files for a trial will be electronic, there may be paper files such as Pharmacy Site Files and Laboratory Files to archive as per instructions in Sections 6 and 8.

8 Archivist

For HUTH-sponsored CTIMPs (with paper files unless indicated for electronic files also)

8.1 Preparation of trial documents for archive

8.1.1 The Archivist prepares files for archiving, manages retrievals, and oversees destruction.

All actions must be auditable and authorised, with clear sponsor oversight.

8.1.2Take copies of the TMF, ISF and PSF Archiving File Notes (at the front of these files) and file in the RDI office file: Archiving CTIMPs.

8.1.3 With the monitor, prepare and arrange the files in the archive boxes.

8.1.4 Complete the Archive Box Contents (ABC) form for each archive box electronically. Ask the monitor to check. In the monitor's absence ask the QA or RDI Manager. The ABC Form can be signed either electronically using Docusign or wet-ink and then a PDF copy sent to QA for Sponsor Study records.

8.1.5 Print out a copy of the ABC form and place form in a plastic wallet at the top inside the relevant archive box and save a copy in the ABC Folder.
Clearly write the box number on the top of the Restore archive box with a black marker. Write the RDI study reference number (in contents) and box number (in box reference) on both ends of the archive box. Ask the monitor to check.

8.1.6 Complete the RDI CTIMP archiving spreadsheet (this should be completed for electronic archived files also clearly documenting that they are archived in the 'RDI Clinical Trials Archived' folder on clinicalgov Y Drive).

8.1.7 Up-date the **Edge** database by saving a copy of the ABC form/ in a folder called Archive Docs in the Document Store.

8.1.8 Set up a reminder in the RDI QA Outlook calendar to send an email to the PI/CI or principal pharmacy technician on the allowed date of destruction requesting permission for the destruction of the relevant files. The archivist, monitor, QA Manager and R&D Manager will be put on copy of this email request (for both paper and electronic archived files). Other electronic systems (such as Monday.com) could also be used.

8.1.9 Arrange for collection of the archive boxes by Restore.

8.2 Invoicing

8.2.1 Send an invoice to the Chief/Principal investigator to reimburse RDI for the cost of archiving the Trial Master File/Sponsor Study File, Investigator Site File, CRFs and pharmacy study file. This is a one-off payment to be paid at the start of archiving.

8.2.2 File invoices in the RDI office file: Archiving CTIMPs.

8.2.3 Complete the Invoice section (amount, date sent and date paid) in the CTIMP archiving spreadsheet.

8.3 Request for retrieval of documents

8.3.1 Check that the request for retrieval of study documents has been confirmed/authorized by the Chief or Principal Investigator or the Principal Pharmacy Technician or R&D Manager. This can be done via an email to the RDI QA team.

8.3.2 Discuss the request with the trial monitor, QA or RDI manager.

8.3.3 For paper files request the appropriate archive box from Restore. For electronic files print out the requested study documents.

8.3.4 For paper files photocopy the requested document(s). File the original document(s) back in the Trial Master File, Investigator Site File, CRFs, Pharmacy Study File or Sponsor Study File.

8.3.5 Make sure the researcher does not have access to the original documents in the archive box or the electronic file.

8.3.6 Hand copies of the requested documents to the researcher at a pre-arranged time.

8.3.7 Complete the Retrieval Log in the RDI CTIMP archiving spreadsheet.

8.3.8 Organize return of the archive box to Restore.

8.4 Destruction

8.4.1 At the allowed time of destruction, obtain permissions on the ABC form/WI from the Chief/Principal Investigator, Principal Pharmacy Technician and R&D Manager.

8.4.2 For paper files, when all signatures have been obtained alert Restore which boxes to destroy.

8.4.3 Complete the actual date of destruction on the ABC form.

8.4.4 For electronic files, when all signatures have been obtained the study folder should be

identified by two members of the RDI QA team to ensure the correct folder is identified. The folder will then be moved by a member of the RDI QA team to the "Deleted archive" folder which will be set up in GCP, SOPs & Forms. The actual "move" date should be documented on the study specific WI.

8.4.5 Keep all paper ABC forms and correspondence concerning destruction of the study files in the office file: Archiving CTIMPs or scan and save to .
Save all completed WIs in the in the Archiving Folder in GCP,SOP & Forms

8.4.6 Up-date the Destruction section of the R&D CTIMP archiving spreadsheet.

9 Medical records responsibilities

9.1 Patient medical records must be retained until the authorised destruction date.

Electronic health records must remain flagged for trial participation for the full retention period.

9.2 Check the sticker on the inside front cover of patients medical records for the allowed date of destruction.

9.3 An example study sticker template:

Patient involved in *(insert title)* clinical trial. Do not destroy notes until year *(insert date: last patient, last visit* + *5 years)*. Contact (*insert name and department)* tel. no *(insert tel number)* for any queries or in case of emergency admissions. Patient entered study on …… Patient completed study on ……

9.4 Retain patients' medical records in paper form until the allowed date of destruction.

9.5 Patients' electronic Health Records will have been flagged that the patient is on a trial and will remain on the Lorenzo system.

10 Implementation

10.1 Implementation will follow R&D SOP 01 Management of SOPs

Training and awareness will be provided where responsibilities change under ICH E6(R3).