Great Ormond Street Hospital for Children
Research and Innovation

DIRECTORATE OF RESEARCH AND INNOVATION

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	Name	Position
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1. Scope

This SOP is applicable to

- All Great Ormond Street Hospital for Children (GOSH) or UCL Great Ormond Street Institute of Child Health (ICH) staff working on research. This includes studies where GOSH and/or UCL are the Sponsor (and where these studies are managed through the Joint R&D Office for GOSH/ICH) or where there is an external Sponsor (hosted studies).
- This SOP applies to both electronic and paper essential documents.
- This SOP does not apply to medical records. For medical record management, see the Trust Health Records Management Policy.

Further to the requirements listed in this SOP, personnel must also comply with:

- Any additional study-specific requirements mandated by the CI, PI, Sponsor or R&I.

2. Purpose

The purpose of this SOP is to describe the responsibilities and procedures for archiving essential documents at the end of a research study, including retention periods, preparing studies for archiving, archiving of electronic records and paper records or transportable media, retrieving records from archive, and destruction of records.

3. Definitions/Abbreviations

Certified Copy – A copy (irrespective of the type of media used) of the original record that has been verified (i.e., by a dated signature or by generation through a validated process) to have the same information, including data that describe the context, content, and structure, as the original.

EDGE – A database used to track study progress and recruitment.

Essential Documents – Documents that allow the conduct of the study, the integrity of the study data and the compliance of the study with GCP to be evaluated. They may be paper or electronic.

GCP – Good Clinical Practice

GOSH/ICH Named Archivist(s) – named individual(s) within GOSH/ICH responsible for archiving essential documents. The lead is the Head of Governance, Clinical Trials and Contracts with support from PA(s) to Deputy Director of R&I (contact through Research Governance (Research.Governance@gosh.nhs.uk)). Access to the archived documents is restricted to these appointed individuals, PIs and auditors and/or inspectors.

Research – As per UK Framework for Health and Social Care Research and HRA/Medical Research Council (MRC) 'Is my study research?' tool.

Trial Master File (TMF) – The TMF is the collection of essential documents for the study. The documentation contained within it should be sufficient to adequately reconstruct the study activities undertaken, along with key decisions made concerning the study. The TMF is normally composed of a Sponsor file, held by the Sponsor organisation, and an Investigator Site File (ISF), held by the investigator. These files together are regarded as comprising the entire TMF for a study. Within this SOP, 'TMF' should be taken to include the ISF unless otherwise stated.

4. Responsibilities

Duties may be delegated but the responsibility always remains with those listed.

4.1 The study Sponsor is responsible for:

- Informing the investigator/institution in writing when the essential documents no longer need to be retained.
- Ensuring the TMF and essential documents are appropriately retained. The Sponsor may delegate this to the CI; this is usually applicable to GOSH/ICH sponsored studies. If the CI becomes unable to be responsible for the TMF (e.g. relocation or retirement) they must notify the Sponsor in writing and inform them to whom the responsibility has been transferred.

4.2 The study Principal Investigator (PI) is responsible for:

- Retaining the site section of the TMF (usually called the Investigator Site File (ISF)) until the Sponsor and GOSH/ICH Named Archivist informs them these are no longer needed. If the PI becomes unable to be responsible for the essential documents (e.g. relocation or retirement) the PI must notify the Sponsor, CI and GOSH/ICH Named Archivist in writing and inform them to whom the responsibility has been transferred.
- Ensuring their own and study team compliance with this SOP, the protocol, GCP and any applicable legislation, policies, procedures or guidelines.

4.3 All study staff are responsible for:

- Being aware of the specific archiving arrangements for their studies and preventing the accidental or premature destruction of essential documents.
- Preparing the essential documents for archiving.
- Ensuring their practice meets the requirements of this SOP, the protocol, GCP and any applicable legislation, policies, procedures or guidelines.

4.4 R&D Clinical Trials Team/R&D Governance team are responsible for:

- Being aware of the specific archiving arrangements for their studies and preventing the accidental or premature destruction of essential documents.
- Supporting the study team with archiving.
- Ensuring their practice meets the requirements of this SOP, the protocol, GCP and any applicable legislation, policies, procedures or guidelines.

4.5 GOSH/ICH Named Archivist is responsible for:

- Overseeing the archiving process at GOSH/ICH and ensuring compliance with this SOP.
- Maintaining the records to track and retrieve archived documents.
- Ensuring that archive facilities are secure with appropriate environmental control and adequate protection from physical damage.

5. Procedure

5.1 Retention Periods for Essential Documents

All site essential documents must be retained until there is notification from the Sponsor and GOSH/ICH Named Archivist that they may be destroyed. The minimum retention period depends on the type of study (see below), but retention may be longer if required by the Sponsor. During the retention, the essential documents must be readily available at all reasonable times for inspection/audit.

5.1.1 Clinical Trials of Investigational Medicinal Products (CTIMP)

Essential documents must be retained for at least 5 years after end of trial.

Trials where the data are used to support a marketing authorisation have additional requirements; here the essential documents must be kept for at least 15 years after completion or discontinuation of the trial, or for at least two years after the granting of the last marketing authorisation in the European Community (EC) (when there are no pending or contemplated marketing applications in the EC), or for at least two years after formal discontinuation of clinical development of the investigational product.

5.1.2 Advanced Therapy Investigational Medicinal Products (ATIMP) Trials

In addition to CTIMP requirements, records regarding ATIMP traceability must be kept for a minimum of 30 years after the expiry date of the product, or longer if required by the terms of the clinical trial authorisation.

5.1.3 Non-CTIMPs (Including Device Studies and Surgical Interventions)

Essential documents must be retained for at least 5 years after end of study.

5.1.4 Centralised Records That Are Non-Study Specific

Centralised records that are relevant to multiple studies (e.g. written procedures, staff training records, or maintenance and calibration records for equipment) must be retained for the longest applicable period as these are required in addition to the TMF to demonstrate compliance.

5.1.5 Studies That Did Not Open For Recruitment

If a study was approved but did not open for recruitment at GOSH and there was no screening of any patients, or was withdrawn before approval at GOSH, the essential documents held by the study team do not need to be archived and can be destroyed (as per section 5.4) after receiving written confirmation from the GOSH/ICH Named Archivist and PI. The R&D Office are responsible for retaining any necessary documents regarding the study set up.

5.2 Archiving Process

5.2.1 Preparation of Essential Documents for Archiving

The study team are responsible for preparing the essential documents ('study file') for archiving.

The study file can be archived once the close-out letter has been filed, and the GOSH/ICH Named Archivist has given permission (ideally, the study should be archived within three months of receiving the close out letter).

The study team does not need to wait for the final study report to archive the study. It is the Sponsor's responsibility to send out the final study report in a timely manner (see Appendix 8.2). If this is provided after the study has been archived, it will be filed electronically on EDGE by the appropriate R&D team.

If this study is archived before the final study report is received, a note to file must be included in the study file to say where the report will be stored if received (for template see section 6). This note to file must be signed by a Sponsor representative to document their agreement and this must also be communicated to the CRA/Sponsor at close out (for template see Appendix 8.3). If the final study report is received before the study is archived, then it should be filed in the study file as well as on EDGE (this means the note to file will not be required and can be removed).

If the study opened for recruitment at GOSH but the site closed without recruiting any participants, the study file can be archived once the closure agreement is filed, and the GOSH/ICH Named Archivist has given permission (ideally, the study should be archived within three months of

receiving the closure agreement). We would not expect to receive a copy of the final study report in this case.

Before the study file is archived, it must be checked to ensure that it is complete and that all necessary documents have been filed (see SOP/R/006 Study Documentation and Monitoring, Audit and Inspection). If this is not done by the study monitor at the close out visit it must be done by the study team.

If study documents are held separately to the study file (e.g. information is held on an electronic system, in a different location such as pharmacy, labs or imaging, or in a central location if the information is not study-specific), they must be collected to archive with the study file, or (if this is not possible) a file note must be filed that clearly states the location during the retention period. This alternative location must be suitable for the required retention period (check with the GOSH/ICH Named Archivist if unsure). File note templates are available (see section 6).

Before archiving, it is important to assess the contents of the study file for any records that could be disposed of (e.g. duplicates), and those that may be subject to rapid deterioration or need special handling for them to be retained (e.g. electronic media that may become obsolete, or documents stored in plastic wallets that can remove the ink).

If copies are to be made of essential documents that will replace the original document (e.g. scans or photocopies) then these must meet the definition of a 'Certified Copy', i.e. be "A copy (irrespective of the type of media used) of the original record that has been verified (i.e., by a dated signature or by generation through a validated process) to have the same information, including data that describe the context, content, and structure, as the original" (Ref: ICHE6, see section 7).

The media used to store documents needs to be such that they remain complete, legible and suitably accessible for monitoring, audit or inspection throughout the required retention period.

5.2.2 Electronic Archiving

GOSH do not have a specific electronic archive facility for electronic data. The data may be held on the original system, or transportable media if appropriate. If the system is decommissioned, the data will be transferred to a suitable secure location. More than one copy of the data should be maintained (e.g. a back-up server or media) with the copies stored separately. Archived data must have suitably restricted access and be protected from unauthorised changes. For data stored in systems, the access will be controlled via the system access controls (e.g. username/password) and protected via the Trust firewalls/security software (see Trust Information Security Policy). For transportable media, these will be protected in the same way as paper records. It's important that future access to records and data is maintained. The media must be stored under suitable conditions and the transfer of data to new media as technology advances must be considered.

5.2.3 Archiving Paper Essential Documents and/or Transportable Media

GOSH/ICH has a contract with an external archiving facility that stores all archived material securely, in an environmentally controlled location. This facility is:

Restore Document Management
Redhill Distribution Centre
Redhill
Surrey
RH1 5DY

The archiving process is as follows (see Appendix 8.1 for flow chart):

a) Once the study is complete and considered ready to archive (see section 5.2.1), the **Study Team** contact the **GOSH/ICH Named Archivist** to request permission to archive and request archiving boxes, and numbered cable ties.

b) If the **GOSH/ICH Named Archivist** gives permission for the study to be archived, the **GOSH/ICH Named Archivist (or support)** orders archiving boxes from the archiving facility, and numbered cable ties, and sends to the **Study Team**. Only the archiving facility boxes may be used to archive.

   If the study cannot be archived, the **GOSH/ICH Named Archivist** will inform the **Study Team**.

c) The **Study Team** prepare the essential documents (as per section 5.2.1 and 5.2.2) and box them using the minimum number of boxes possible. If there is more than one study to archive, avoid having more than one study per box.

   The **Study Team** must complete the 'Study Content Archive Spreadsheet' for each study detailing the contents of each box, the storage media (e.g. paper, CD), and the cable tie numbers. The completed spreadsheet must go in each archiving box for that study.

   Each archiving box must be labelled with the study R&D number and the box number (written as box x of y, where y is the total number of boxes for a study, e.g. box 2 of 5) as a minimum.

   The boxes must be sealed with numbered cable ties as a tamper proof seal.

   The **Study Team** then contact the **GOSH/ICH Named Archivist** to inform them that the boxes are ready for collection.

d) The **GOSH/ICH Named Archivist (or support)** will organise for the collection of the archiving boxes to be transported to the external archiving facility and will inform the Study Team when this collection will be.

e) Once the boxes have been collected; the **Study Team** will contact the **GOSH/ICH Named Archivist** to inform them the boxes have been collected and to submit a copy of the completed 'Study Content Archive Spreadsheet' for each study collected.

f) The **GOSH/ICH Named Archivist (or support)** will complete the Master Archiving Spreadsheet and update the necessary governance tracker(s) to confirm that study documents have been archived.

5.2.4 Retrieval of Archived Boxes from the Archiving Facility

Archived boxes may be retrieved by contacting the GOSH/ICH Named Archivist in writing, who will then contact the archiving facility for retrieval.

The transfer of boxes to site and the location while on site must be tracked on the Master Archiving Spreadsheet.

5.2.5 Returning Boxes to the Archiving Facility

When a box is returned to archive, the contents must be checked to ensure the originally archived material is still present. Any changes to the Study Content Archive Spreadsheet must be documented by hand on the print-out, signed and dated. The amended spreadsheet must be scanned and sent to the GOSH/ICH Named Archivist (to update the Master Archiving Spreadsheet) before going in the box. Box must be sealed with numbered cable ties (make sure the new numbers are recorded on the spreadsheet).

The GOSH/ICH Named Archivist (or support) will contact the archiving facility to return the box to archive. The return of the box to the facility must be tracked on the Master Archiving Spreadsheet.

5.3 Archiving Essential Documents at Sponsor's Archiving Facility

The PI must retain control of all essential documents and records generated by the site before, during, and after the study. The essential documents must not be sent to the Sponsor (except where the Sponsor and site are essentially the same). An external Sponsor can arrange archiving at an independent facility on behalf of the site/PI if:

- The archive arrangements are formally agreed and documented between the Sponsor and site (including access for GOSH/ICH and the PI).
- A formal procedure is in place such that documents are only accessed or released from the archive with the approval of the GOSH/ICH Named Archivist and PI.
- The records go directly between GOSH/ICH and the independent facility (i.e. not via the Sponsor). The Sponsor must not have uncontrolled access to the essential documents.

The Sponsor will need to provide archiving boxes and arrange for the secure transport of the essential documents to the archiving facility. A list of all archived documents must be kept with the GOSH/ICH Named Archivist and the PI.

5.4 Destruction of Essential Documents

Archived documentation must not be destroyed unless written permission has been obtained from the Sponsor (or delegate) and GOSH/ICH Named Archivist. The GOSH/ICH Named Archivist should consult with the PI if available.

Documents must be destroyed in accordance with the Trust Confidential Waste Policy and any additional Sponsor requirements.

5.5 Support and Escalation

If a staff member has questions or queries, they can ask for support from a more experienced colleague or their line manager. If the query is related to a specific study, then the study research nurse, PI, Governance officer, and/or CRA may also be able to help. If staff (or monitors) have a question regarding the archiving process in general, then they can contact the R&I QA Manager or the GOSH/ICH Named Archivist.

If a staff member becomes aware of an issue or has any concerns, then this must be escalated to the appropriate person(s) in a timely manner (see SOP/R/005 Reporting and Escalation for Research).

5.6 Compliance

Archiving will be reviewed during routine monitoring/audit. The archiving facility will be reviewed during routine vendor audit.

Systematic or persistent failure to comply with the study procedures and/or this SOP will be seen as non-compliance to GCP and must be brought to the attention of the Head of Governance, Clinical Trials and Contracts who will decide the appropriate action.

6. Related Documents

- Trust Health Records Management Policy
- GOSH/ICH/TMP/R/005B: File note template regarding final study report
- GOSH/ICH/SOP/R/006: Study Documentation and Monitoring, Audit and Inspection
- GOSH/ICH/TMP/R/005: File note template. File note templates are also available for essential documents that are routinely held outside of the TMF at GOSH, see GOSH/ICH/TMP/R/005x (where ‘x’ is a different letter for each template)
- Trust Information Security Policy
- GOSH/ICH/FRM/R/005 Study Content Archive Spreadsheet Template
- Master Archiving Spreadsheet held by Head of Governance, Clinical Trials and Contracts
- Trust Confidential Waste Policy

7. References

- Medicines for Human Use (Clinical Trials) Regulations
- Directive 2003/63/EC – relating to medicinal products for human use

- 'Recommendation on the content of the trial master file and archiving', EudraLex Vol 10 – Clinical trials, Chapter V
- NIHR Clinical Trials Toolkit, Archiving
- ICH Harmonised Guideline - Guideline For Good Clinical Practice E6(R2)
- Guidance on the Archiving of Good Clinical Practice Material 2nd Edition, May 2014, Scientific Archivist Group
- UK Policy Framework for Health and Social Care Research
- MHRA Good Clinical Practice Guide (Grey Guide) – Chapters 10.7 and Annex 3

8. Appendices

- Appendix 1 – Archiving Process Flow Chart
- Appendix 2 – Further information regarding final study report timelines
- Appendix 3 – Template reminder for Sponsor regarding final study report

8.1 Appendix 1: Archiving Process Flow Chart

Study Team

- File the study close out letter and note to file about location of final study report (see section 6), or closure agreement if no recruitment at GOSH.
- Contact **GOSH/ICH Named Archivist** to request; permission to archive, archiving boxes, and numbered cable ties.

Named Archivist

- Order archiving boxes and numbered cable ties and send to **Study Team**.

Study Team

- Prepare essential documents and box (minimal boxes, one study per box). Check the study file is complete, and that all necessary documents have been filed, including documents that have been held separately during the trial, OR that file notes have been included to explain where these documents are held. Check if any documents can be disposed of or may need special handling to be stored (see 5.1.1 and 5.1.2).
- Complete 'Study Content Archive Spreadsheet' for each study (including cable tie numbers and storage media) and place a copy in each box for that study.
- Label each box with R&D number and box number (format box x of y).
- Seal boxes with numbered cable ties.
- Tell the **GOSH/ICH Named Archivist** that boxes are ready for collection.

Named Archivist

- Organise collection of the archiving boxes and tell the **Study Team** when this will be.

Study Team

- Contact **GOSH/ICH Named Archivist** to inform them the boxes have been collected and to submit a copy of the completed 'Study Content Archive Spreadsheet' for each study collected.

Named Archivist

- Complete the Master Archiving Spreadsheet and update necessary governance tracker(s) to confirm that study documents have been archived.

8.2 Appendix 2: Further information regarding final study report timelines

Regulation 78A(13) and (14) of the Human Medicines Regulations 2012, as inserted by the Human Medicines (Amendment etc.) (EU Exit) Regulations 2019, requires that holders of a UK marketing authorisation who sponsor a study which involves use in the paediatric population in respect of the medicinal product to which that authorisation relates must submit to the Medicines and Healthcare products Regulatory Agency (MHRA) results of the study within the period of six months beginning with the day on which the trial ended.

For all other research, the time frame for publishing/submitting the summary of results to the appropriate authorities is within one year of the end of study.

Our expectation is that the site would receive a copy of the published/submitted report within the same time frame.

8.3 Appendix 3: Template reminder for Sponsor regarding final study report

Message to be sent at close out by the study team:

Dear xxx

Thank you for the final close out letter for [Study], this has been filed in the site file.

Can you let me know the know the End of Trial date for this study so that we can add this to our records? *[Only ask if the end of trial date is not known. Please note, the end of trial date is the date when the study has officially finished and is reported to the relevant authorities (such as MHRA, HRA and/or REC); it is potentially different from the site close out date.]*

Please can you let me know a suitable Sponsor contact we can use if needed now that the study has closed?

Once we have permission from our Named Archivist, we will be ready to archive the study. If the final clinical study report/summary of the results is provided after the study has been archived, it will be filed electronically (a file note will be added to the site file to say where the report will be stored if received). Please ensure a copy of the final report is sent to Research.Governance@gosh.nhs.uk for filing.

Please note:
Regulation 78A(13) and (14) of the Human Medicines Regulations 2012, as inserted by the Human Medicines (Amendment etc.) (EU Exit) Regulations 2019, requires that holders of a UK marketing authorisation who sponsor a study which involves use in the paediatric population in respect of the medicinal product to which that authorisation relates must submit to the Medicines and Healthcare products Regulatory Agency (MHRA) results of the study within the period of six months beginning with the day on which the trial ended.

For all other research, the time frame for publishing/submitting the summary of results to the appropriate authorities is within one year of the end of study.

We expect to receive a copy of the report within the same time frame.

Optional Follow up message – to be sent out by Governance officer once report is overdue

Dear xxx

As you are aware [Study] ended on [Date].

We have not yet received the final clinical study report/summary of the results for this study. Please can you let me know when we can expect to receive the final clinical study report/summary of the results?

Please note:
Regulation 78A(13) and (14) of the Human Medicines Regulations 2012, as inserted by the Human Medicines (Amendment etc.) (EU Exit) Regulations 2019, requires that holders of a UK marketing authorisation who sponsor a study which involves use in the paediatric population in respect of the medicinal product to which that authorisation relates must submit to the Medicines and Healthcare products Regulatory Agency (MHRA) results of the study within the period of six months beginning with the day on which the trial ended.

For all other research, the time frame for publishing/submitting the summary of results to the appropriate authorities is within one year of the end of study.

We expect to receive a copy of the report within the same time frame.