Gloucestershire Hospitals
NHS Foundation Trust

SOP 06: Trial Archiving

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Version:	5.0	
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Approved by Commercial Director:	Claire Richardson	
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Date of Review:		30/10/2025

IT IS THE RESPONSIBILITY OF ALL USERS OF THIS SOP TO ENSURE THAT THE CORRECT VERSION IS BEING USED

All staff should regularly check the Research & Development Webpage for information relating to the implementation of new or revised versions. Staff must ensure that they are adequately trained in the new procedure and must make sure that all copies of superseded version are promptly withdrawn from use unless notified otherwise by the SOP Controller.

The definitive version of all Gloucestershire Hospitals NHS Foundation Trust SOPs appear online. If you are reading this in printed form, check that the version number and date below is the most recent one as shown on the R&D website:

https://www.gloshospitals.nhs.uk/about-us/research-our-hospitals

The Gloucestershire Hospitals NHS Foundation Trust wishes to acknowledge York Hospitals NHS Foundation Trust and University Hospitals Bristol NHS Foundation Trust who gave permission to use their templates in the development of these SOPs.

VERSION HISTORY LOG

This area will be updated with details of all changes made to the SOP whether due for full review or not.

Version	Details of Change	Date Implemented
1.0	Original SOP	25/06/2015
1.1	Section 7 - Updating of electronic archiving	24/08/2015
2.0	Rebranding to GHNHSFT and updating of contact details	31/03/2018
3.0	Confirmation of the duration of retention of R&D department files: inclusion of flowcharts	31/05/2018
4.0	Updating of R&D contact details and webpage link	10/02/2021 Not implemented
5.0	Correction of typographical errors Updating of website links Consideration of electronic medical notes/files Inclusion of new approval paperwork Addition of a glossary Deletion of reference to legislation following EU exit Insertion of current electronic archiving process for electronic trial files Insertion of flow-chart describing the archiving process Removal of SOP categories and change of reference codes	30/10/2023

This SOP will be reviewed every two years unless changes to any relevant legislation requires otherwise

SOPs
SOP 03 - Training
SOP 05 - End of Trial Procedures

Glossary

ATMP	Advanced Therapy Medicinal Product
CI	Chief Investigator
CTIMPS	Clinical Trials of Investigational Medicinal Products
GCP	Good Clinical Practice
iCT	interactive Costing Tool
IMP	Investigational Medicinal Product
ISF	Investigator Site File
MHRA	Medicines and Healthcare products Regulatory Agency
PI	Principal Investigator
REC	Research Ethics Committee
SoECAT	Schedule of Events Cost Attribution Tool
TMF	Trial Master File

Contents

1. Introduction, background and purpose

The purpose of this SOP is to describe the procedure for archiving trial documentation for all trials undertaken within the Trust.

Retention of trial documentation is a legal requirement for clinical trials of Investigational Medicinal Products, and it is Good Clinical Practice to treat non-interventional studies and clinical trials of medical devices similarly.

The procedure for archiving may vary depending on the sponsoring organisation. However, the Trust has a responsibility to ensure that appropriate arrangements are in place for archiving research documentation in accordance with applicable legislation and guidelines.

Trial documentation must be retained for specified periods of time so that data is accessible after a trial has completed to enable, for example

- Further analysis of trial data;
- MHRA or other inspection / monitoring to Good Clinical Practice (GCP)
- In case of late safety concerns post marketing

2. Who should use this SOP

This SOP is for all research staff working within the Trust. The responsibility of trial specific archiving process applies to Chief Investigators of trials sponsored by the Trust and Principal Investigators of trials hosted by the Trust and sponsored by an external organisation. The Head of Research & Development will have responsibility for the archiving process of the R&D Department documentation.

3. When should this SOP be used

3.1 Trust Sponsored Trials

This SOP will be referred to during the trial design and then at trial close down as soon as is practicable and no later than 12 months from the end of the trial.

3.2 Trust Hosted Trials

This SOP will be referred to during trial feasibility/ set up to ensure that the full requirements and costings of archiving have been identified and can be fully met in a timely manner. Archiving will then take place once the Sponsor has given specific instruction to the participating site to do so.

3.3 R&D Trial documentation

The R&D Department will compile a log of the duration to keep the R&D Department documentation dependent upon the type of research and the Trust wide policy on record keeping.

4. Responsibilities for Archiving

4.1 Trust Sponsored Trials

- Archiving responsibilities lie with the Sponsor who may delegate this responsibility to the CI or PI.
- In the case of multi-centre trials, the SoECAT/Model of agreement will state that the PI at each site will be responsible for archiving essential documentation and the Sponsor will be allowed access to archived data on request.
- If the CI or PI leaves their post during the archival period arrangements will be made to ensure the safekeeping and security of

information. There will be a handover of responsibilities which will be documented and stored in the TMF/ ISF.

- Costs for archiving should be considered during set up and included in any research grant application. Details will then be part of the Site Agreement.
- The Trust nominated archivist is the individual holding the post of Head of Research & Development, who may delegate the day-to-day logistics to other members of the research team.

4.2 Trust Hosted Trials

- The CI/PI is responsible for archiving ISF and data generated at a participating site and for maintaining a record of the archived material. This may be delegated by the CI/PI to a member of the research delivery team to request the Head of Research & Development/delegee archive the ISF at an off-site facility.
- For commercial studies, the sponsor may put in place arrangements for third party archiving. Increasingly, it is more common practice for the sponsor to request the participating site to arrange third party archiving and to remunerate accordingly. It remains the responsibility of the participating site to ensure the archiving their documents is completed to the legal standard for CTIMPS and to GCP standards for all other types of trials.

4.3 R&D trial documentation

- The Head of Research & Development/delegee will liaise with the R&D governance team to archive from the main office in parallel with the research delivery teams' documentation for each specific trial being archived, once the research delivery team has requested the ISF are archived. (4.2)

5 Archiving Process (see attached guideline for specifics)

5.1 Trust Sponsored Trials

- The Trust will instruct the CI in writing to notify the participating sites of the archiving requirements once all end of trial procedures have been completed (SOP 05).
- All paper trial data will be stored in a physical location that is weatherproof, secure at all times and environmentally controlled. All electronic trial data will be stored in a restricted access folder with adequate back-up and retrieval processes in place.
- Access to the research data will be restricted to authorised personnel, and should therefore be kept in a locked cabinet or in an area with swipe card, keypad or locked access.
- When it is necessary to store trials data off site then the Trust policy for off-site storage and archiving will be followed (appendix 4)

5.2 Trust Hosted Trials

- On receipt of written instructions from the Sponsor the PI and the local research delivery team will prepare the trial essential documents for archiving. The research delivery team will notify R&D at this point and support will be offered as necessary.
- Where the Sponsor has stated trial documents and data will be stored locally the Trust SOP for archiving will be followed.
- All trial documents and data will be stored in a physical location that is weatherproof, secure at all times and environmentally controlled.
- Access to the research documents and data will be restricted to authorised personnel, and should therefore be kept in a locked cabinet or in an area with swipe card, keypad or locked access.

  When it is necessary to store trials documents and data off site then the Trust policy for off-site storage and archiving will be followed (see appendix 4).

Participating patients' paper health record will show that the patients have taken part in a clinical trial and will be annotated to indicate that the health records must not be destroyed for a specified time as stated in the trial protocol and the ethics application. Currently, the Sunrise EPR configuration team are formatting a trial alert which will incorporate the archiving requirements as detailed above.

5.3 Trust R&D Documentation

- On receipt of confirmation that a specific trial can be archived the R&D documentation will be prepared for archiving to an off-site facility for the length of time detailed in the Trust records retention policy.
- These must be archived separately from the ISF/TMF.
- The eR&D files will be archived electronically on receipt of confirmation that a specific trial can be archived, in the archiving folder on the RDSU drive in the folder marked eR&D files.

6 Duration of Archiving

6.1 CTIMPs

The minimum requirements for retention of essential documents and medical files of trials participants are dependent upon research undertaken.

6.1.1 IMP not including Advanced Therapies

For commercial trials marketing authorisation applications essential documents will be retained for

- at least fifteen 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)
- or for at least 2 years after formal discontinuation of clinical development of the IMP.

- For practical purposes, commercial trial documents are usually archived for a period of 15 years. The cost of archiving commercial studies will be recovered by the Trust from the Commercial Trial Sponsor as outlined in the agreement between the Trust and the Commercial Trial Sponsor, detailed in the NIHR Interactive Costing Tool (iCT) or costing template/agreement.
- The Sponsor or other owner of the data must retain all other documentation pertaining to the trial for as long as the IMP is authorised. This will include:
    - trial protocol
    - any written procedures used for conducting the trial
    - all written opinions on the protocol and procedures
    - the Investigator Brochure
    - CRFs for each trial participant
    - final clinical study report (CSR)
    - audit certificate(s) if available
    - staff training records
    - trial participants medical files
- Additionally, the Sponsor must retain a copy of the final CSR for 5 years after the medicinal product is no longer authorised.
- The medical files of trial participants must be retained for at least 5 years after completion of the trial in their original format and for the maximum period of time permitted by the Trust (see Trust policy). To facilitate this, an alert sticker must be placed on the front of the health records, with the trial name or sticker on the inside of the front cover. Currently, a flag is being developed by the Sunrise EPR configuration team to facilitate an alert for electronic hospital notes.
- It is acceptable to then transfer the medical files of the trial participants into another medium such as scanning as long as the process is validated in such a way that the Trust can demonstrate these are authenticated copies of the original health records. The format chosen must be one that can be accessed readily in the future should the data need to be retrieved.

6.1.2 IMP for Advanced Therapies Medicinal Products (ATMPs)

All essential documentation must be retained for 30 years after the expiry date of the IMP or longer if required by the clinical trial authorisation. Further information can be found in Annex 3 of MHRA Good Clinical Practice Guide and the EU detailed guidance on GCP for ATMPs.

- This is the same information as required for all other IMPs
    - trial protocol
    - any written procedures use for conducting the trial
    - all written opinions on the protocol and procedures
    - the Investigator Brochure
    - CRFs for each trial participant
    - final clinical study report (CSR)
    - audit certificate(s) if available
    - staff training records
    - trial participants medical files
- Plus, additional documentation as follows
    - Gene therapy laboratory files which contain QP certification
    - IMP accountability

6.1.3 CTIMPs for Paediatric Use

- Where the Trust is the Sponsor and the study involves children, essential documents should be archived until three years after the youngest subject reaches 18 years old, or 5 years after the conclusion of the research, whichever is longer.

6.2 Non CTIMP trials

The archiving period is stipulated by the Sponsor and will be that detailed in the REC submission/ R&D submission. For Trust sponsored trials archiving will be a minimum of 5 years with each individual trial assessed against NIHR the Clinical Trials Toolkit to determine if this should be extended further.

7. Electronic archiving

Following advice from Countywide Trust IT support, we have a restricted access folder on the RDSU drive S:\RDSU\~ Drive Under Construction [do not delete]\ARCHIVING FOLDER for the archiving of electronic Investigator Site Files, e-e-Pharmacy Trial Files, e-Master Trial Files and e-R&D files..

On receipt from the Sponsor that archiving can occur, those teams that have access to the RDSU drive are required to transfer eISF/eTMF/ePharmacy files to the eFolder Repository [S:\RDSU\~ Drive Under Construction [do not delete]\PORTFOLIO\ 7.GOVERNANCE\ Archiving \Archving\ 1.eFOLDER REPOSITORY and inform the Research Governance Team that a file has been transferred by emailing .

Alternatively contact the IT Team to request the efolder be transferred to this location and inform the Research Governance Team.
The files will be archived by year that the study was set-up.

Consideration must be given to maintaining continued access to data possibly over a number of decades. Updating of IT systems, the hardware and software will be under the guidance of the Countywide Trust IT Support Service. New written procedures will be produced when required to identify the new systems to be used, outline the transfer and validation of the data.

This data is backed up to magnetic tape each week, which is a type of long-term backup on a physical device, as well as cloud storage backup solutions. IT has stated the current aim with the tapes is to keep them indefinitely. Each tape has a lifespan of approximately twenty years in storage, and IT has a process in place for migrating the data on expiring tapes to new tapes in order to keep them operating long term. Data on these tapes is retrievable and takes approximately 8 to 12 hours to restore and be accessible. Therefore, any data stored on the RDSU drive will be accessible indefinitely as it will be archived automatically as part of the IT archival process. This is managed as per IT policies.

7.1 Trust Sponsored trials

7.1.1 Electronic scanning and storage of data during the treatment and follow up stages of trials

Where there is insufficient storage space within the trial co-ordinating office to store all the trial documentation for each participating site then a programme of scanning documentation and off-site archiving is to be devised. This will be assessed on a trial-by-trial basis and will be in compliance with the Trust Archiving Policy.

Key considerations when drawing up the trial specific scanning programme:

- Check with IT about which drive and what storage space is available for instant access.
- The sub sections of the TMF will be replicated electronically and all documents will be stored similarly. They will not be linked to the data base containing trial data.
- All staff undertaking the scanning and verification of records will be trained and certified competent by the trial manager before working independently.
- A programme of ongoing checking for quality assurance purposes will be implemented – details of which will be set out in the specific trial guidelines for scanning.
- Where CRFs are being scanned and archived before the end of the trial, all data queries must be resolved before the CRFs are scanned and the paper copies sent to the Trust nominated archive facility.

7.2 Trust hosted trials

7.2.1 Return of data to site which has been input onto an eCRF database

The Sponsor will ensure that eCRF data is available after the end of the trial. The PI must ensure that a download of an independently verified copy of the data is provided by the Sponsor and downloaded and checked as readable onto a Trust IT system server any transportable media (i.e., USB drives) provided must be checked to ensure all the downloaded data is there. Data archived on a specific server will be backed up regularly in accordance with the Trust IT back policy. The transportable back up will be stored in accordance with Trust IT policies (see Appendix 5).

7.2.2 Pharmacy File

It is Trust practice for the pharmacy file to hold just the Trust approval letters with site file notes indicating that the full regulatory documentation is stored in the Investigator Site File as all files are brought back together when archived.

If the Sponsor requires the pharmacy file to have a full set of regulatory documentation, REC, MHRA as well as Trust approval it is acceptable to the Trust for Pharmacy to store these electronically and put in a site file note to indicate where it can be found.

7.3 Researchers CVs and GCP certificates

On receipt of signed and dated CVs and GCP certificates from researchers, Trust R&D staff will scan the documents and store them on the RDSU drive within the relevant folders. These will be stored indefinitely in line with Trust policy.
The R&D team as a whole, delivery as well as governance will store their GCP certificates on EDGE. (SOP 03 - Training)

8. Retrieving Archived Documentation

The Trust R&D governance team will maintain a log of archived:

- Trust sponsored trials,
- commercial trials where the sponsor has agreed contractual arrangements for the PI to arrange archiving with an off-site storage facility
- non-commercial CTIMP trials
- non-CTIMP studies.

All retrievals/ re-archiving will be controlled and documented. Retrievals from archive are restricted to a limited number of circumstances and should be kept to an absolute minimum.

The retrieval of any documents held at third party storage facility will require authorisation by CI/PI and the R&D governance team.

8.1 Paper based data

A programme of testing the retrieval system will be followed and modifications made as required to maintain integrity of the chain custody when required (see Appendix 4).

8.2 Electronic based data

The ongoing availability of the data will be periodically tested by the R&D governance team.

Access will be restricted, and requests must be sent to the Head of R&D for access to electronic data. All access will be documented to create and audit trail.

9. Destruction of Documentation

Essential documents will only be destroyed upon receipt of written instruction to do so from the sponsor/CI**.**

The R&D governance team may contact the Sponsor/ CI at least one month before the due date for destruction to confirm arrangements.

Destruction methods will be those outlined by the Sponsor or in accordance with the Trust policy.

The date of destruction will be recorded by the R&D governance team on a spreadsheet on the RDSU drive.

10. Invoicing for archiving Trust Sponsored and Trust Hosted Trials

Designated R&D governance team members will be responsible for invoicing or authorising payments for archiving on behalf of all research teams in the Trust.

11. References

Guideline on computerised systems and electronic data in clinical trials (europa.eu)
Completed Paediatric Studies - submission, processing and assessment - GOV.UK (www.gov.uk)
Procedures for UK Paediatric Investigation Plan (PIPs) - GOV.UK (www.gov.uk)

Trust links to relevant policies:

Countywide IT policies
Information Governance policy
http://glnt313/sites/ghnhsft_policy_library/NonClinPolices/B0413.pdf

Clinical and non clinical information systems management
http://glnt313/sites/ghnhsft_policy_library/NonClinPolices/B0259.pdf

IT Security
http://glnt313/sites/ghnhsft_policy_library/NonClinPolices/B0591.pdf

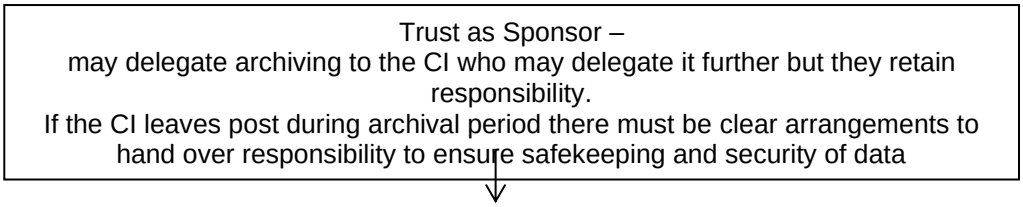
Portable IT equipment and removable media
http://glnt313/sites/ghnhsft_policy_library/Procedures/B0692.pdf

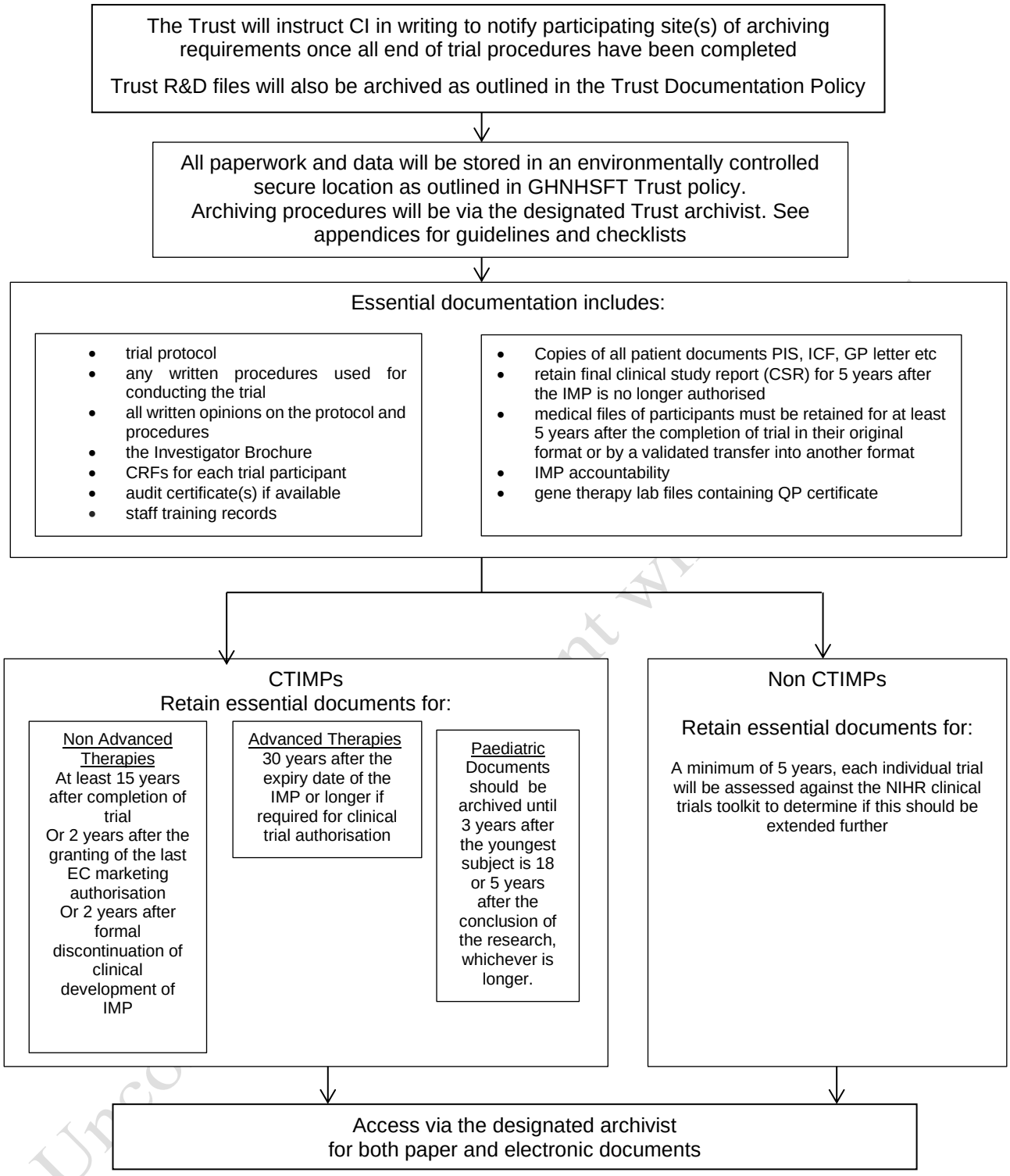
IT Forensic Readiness
http://glnt313/sites/ghnhsft_policy_library/Procedures/B0693.pdf

Data Quality
http://glnt313/sites/ghnhsft_policy_library/NonClinPolices/B0406.pdf

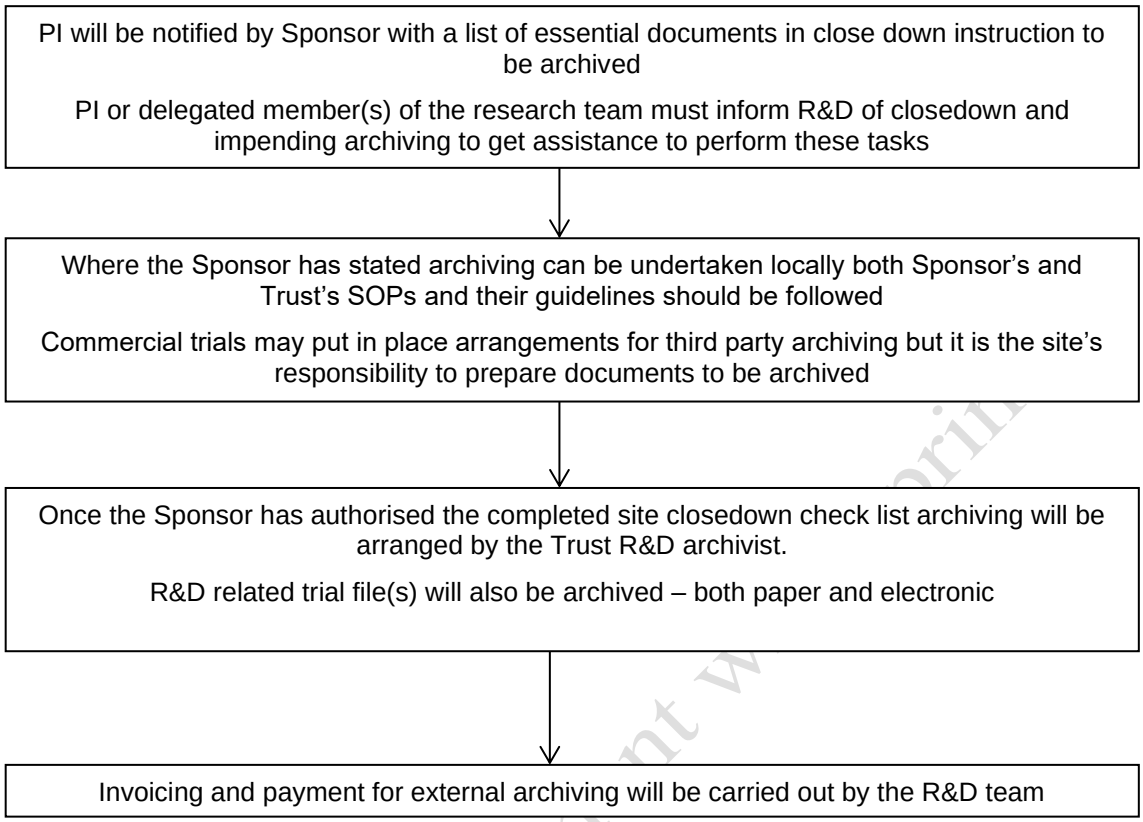
MHRA Good Clinical Practice Guide
https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-10/atmp_guidelines_en.pdf
2019

Appendix 1: Schematic diagram - Trust Sponsored Trials




The Trust will instruct CI in writing to notify participating site(s) of archiving requirements once all end of trial procedures have been completed
Trust R&D files will also be archived as outlined in the Trust Documentation Policy
All paperwork and data will be stored in an environmentally controlled secure location as outlined in GHNHSFT Trust policy.
Archiving procedures will be via the designated Trust archivist. See appendices for guidelines and checklists
Essential documentation includes:
trial protocol
any written procedures used for conducting the trial
all written opinions on the protocol and procedures
the Investigator Brochure
CRFs for each trial participant
audit certificate(s) if available
staff training records
Copies of all patient documents PIS, ICF, GP letter etc
retain final clinical study report (CSR) for 5 years after the IMP is no longer authorised
medical files of participants must be retained for at least 5 years after the completion of trial in their original format or by a validated transfer into another format
IMP accountability
gene therapy lab files containing QP certificate
CTIMPs
Retain essential documents for:
Non Advanced Therapies
At least 15 years after completion of trial
Or 2 years after the granting of the last EC marketing authorisation
Or 2 years after formal discontinuation of clinical development of IMP
Advanced Therapies
30 years after the expiry date of the IMP or longer if required for clinical trial authorisation
Paediatric
Documents should be archived until 3 years after the youngest subject is 18 or 5 years after the conclusion of the research, whichever is longer.
Non CTIMPs
Retain essential documents for:
A minimum of 5 years, each individual trial will be assessed against the NIHR clinical trials toolkit to determine if this should be extended further
Access via the designated archivist
for both paper and electronic documents

Appendix 2: Flow chart for Trust Hosted Trials



Appendix 3: Archive Storage Boxes Template Label

This will be completed by the head of R&D and R&D governance team

R&D Project Number: .....

Principal Investigator: .....

Specialty: ……..……..

Project Short Title: ..…….

Sponsor name: ……..……..

Ethics No: ……..…….....

Unique Code: ……..……..

of total boxes: ……..

Archive from:……..…….... Until: ……..

FOR ENQUIRIES CONTACT

GHNHSFT R&D Department, Leadon House, Gloucestershire Royal Hospital, Great Western Road, Gloucester, GL1 3NN, ghn-tr.glos.rdsu@nhs.net

Appendix 4: Guidelines for paper-based archiving

- All documentation must be complete, legible and recorded so that it is traceable at all times and readily accessible for inspection upon request.

- For trials/studies which are discontinued (dependent upon the stage at which the trial is terminated), some documentation may still need to be archived. The CI and PI should seek guidance from the sponsor and/or follow any advice set out in the protocol and/or the study agreement between the Sponsor and Trust

- Documents must be retained for the minimum length of time stipulated in regulations and guidance *(see sections 5 and 6 of current document),* at the same time taking full account of the principles within the Data Protection Act that personal data should be held for no longer than is absolutely necessary.

- Documents should be removed from ring binders or lever arch files to keep storage space to a minimum and reduce the risk of paperwork deteriorating from corroding metal.

- Documents may be held together by plastic archiving clips/ treasury tags but plastic wallets and all paper clips, staples or metallic means of combining sheets should be removed to prevent rusting or other chemical deterioration.

- Currently the Trust third party storage facility requires that packed archiving boxes weigh no more than 15 kilos. For health and safety reasons, it is recommended that wherever archiving boxes are stored, they do not exceed this upper limit. Archived documents which are to be stored at an off-site facility should be placed within the appropriately obtained storage boxes from the R&D team held in Leadon House.

- CTIMP studies which are not going into a third-party storage facility should be labelled using the template labels (see Appendix 3) on the Research & Development webpage. All storage boxes going into a third-party storage facility should be labelled with a unique code comprising of the R&D project number, the due destruction date, the box number and the total number of boxes, for example R&D12_099_GHT, Box 2:3, destroy by 02.07.2029, in addition to any assignment number (barcode) provide by the third-party archiving organisation. Boxes to be stored at an off-site storage facility must be labelled with a marker pen on the short end of the box, the same end as the space for the assignment number. It is also recommended that a list setting out the contents of each box is placed inside the boxes or attached to the inside lid, a copy should also be retained by the research team and one sent to the R&D governance office for their information (see Appendix 3).

- The R&D governance team will record the date of receipt of the trial Archiving Record Form and due date for destruction. R&D governance team will

retrieve one set of trial documentation stored off site each year in August and audit the process.

Appendix 5: Archiving Record Form

Archiving Record Form vV3 30/05/2023
For all Commercial and Non-Commercial Research (completed for guidance)

SECTION 1 PROJECT INFORMATION

R&D Project No:	*17/035/GHT*
Short Title/ Acronym	*B-ADENOMA*
Title:	*The B-ADENOMA Study : Bowel Scope – Accuracy of Detention using Endocuff Optimisation of Mucosal Abnormalities*
Sponsor:	*Newcastle University*
Principal Investigator:	*Dr Simon Hellier*
Date Study Completed:	*31/05/2018*
Commercial:	Is it a commercially sponsored study? Yes ☑ No ☐ If yes, will the sponsor make all the arrangements for third party archiving? Yes ☐ No ☐

If it is a commercially sponsored study and **if** the sponsor is making all the arrangements for third party archiving, then please sign and date below and return to the Research Governance Team *(do not complete the tables below)*

PI's signature …… Date ……
Or Head Of R&D *(delete as appropriate)*

SECTION 2 FOR COMPLETION BY THE TRUST ARCHIVIST

Name:

No. of Boxes Archived (*must be clearly labelled*)	Date Archived	Location of Archived Material (e.g. GHNHSFT /Contractor (please specify room number and building if on Trust or University premises)	Unique Study Code (R&D/Date of Destruction/Box No./Restore Code)	Date Collected by Contractor *(if applicable)*	Contractor's Unique Storage Number *(if applicable)*
1	*27/03/2021*	*Restore Record Management*	*17035GHT/21062034/0101/1536108/000*	*/ /*	*1536108/100*

SECTION 3 AUTHORISATIONS

Investigator or Head of R&D (*delete as appropriate*) I can confirm that the documents listed have been archived in accordance with all applicable Regulations	Signed:
	Date:
Sponsor (Trust sponsored studies only). I can confirm that the documents listed have been archived in accordance with all applicable Regulations	Signed:
	Date:

PLEASE SEE GUIDANCE (R&D SOP TD 01) ON WHAT DOCUMENTATION SHOULD BE ARCHIVED AND HOW IT SHOULD BE PACKAGED FOR ARCHIVING (R&D SOP TD 05)

SECTION 4 Schedule of Archived Documents

Document Type	Quantity (if applicable)	Box No	Location if not with Contractor
INVESTIGATOR SITE FILE [GRH]			
SECTION 1 – Contact Details			
Trial Unit Contact Details	*1*	*1*	
Site Signature and Delegation Log	*1*	*1*	
Curriculum Vitae [Local site]	*5*	*1*	
GCP Certificates [Local site]	*5*	*1*	
SECTION 2 – Protocol			
Current Protocol	*1*	*1*	
Superseded Protocol	*4*	*1*	
SECTION 3 - Study Documentation			
Participant Information Sheet	*1*	*1*	
Superseded Participant Information Sheet	*2*	*1*	
Consent Form	*1*	*1*	
Superseded Consent Form	*2*	*1*	
GP Letter / Information Sheet	*1*	*1*	
Superseded GP Letter / Information Sheet	*1*	*1*	
CRFs	*5*	*1*	
SECTION 4 – Recruitment / Screening Log			
Recruitment Log	*1*	*1*	
Screening Log	*1*	*1*	
SECTION 5 – Ethics / MHRA / Regulatory Approvals			
REC Approval	*1*	*1*	
REC Application Form	*1*	*1*	
REC Substantial Amendment Form	*2*	*1*	
REC Approval of Amendment	*2*	*1*	
MHRA Notice of Acceptance	*1*	*1*	
MHRA Notice of Acceptance of Amendment	*2*	*1*	
C&C Approval	*1*	*1*	
PARTICIPANT PACK			
Participant 001 [full pack]	*12*	*1*	
Participant 002 [full pack]	*12*	*1*	
Participant 003 [missing GP Letter]	*11*	*1*	

SECTION 5 Schedule of Electronic Data

Electronic Records	Location	Access

(where have these been stored and who has access to them)		
eCRFs	*GHT Shared (S:) RDSU/Governance/Archiving/eISF/.....*	*R&D Team*
Recruitment Log	*GHT Shared (S:) RDSU/Governance/Archiving/eISF/.....*	*R&D Team*

SECTION 6 ANY OTHER RELEVANT INFORMATION

SECTION 7 FOR COMPLETION BY THE RESEARCH GOVERNANCE TEAM

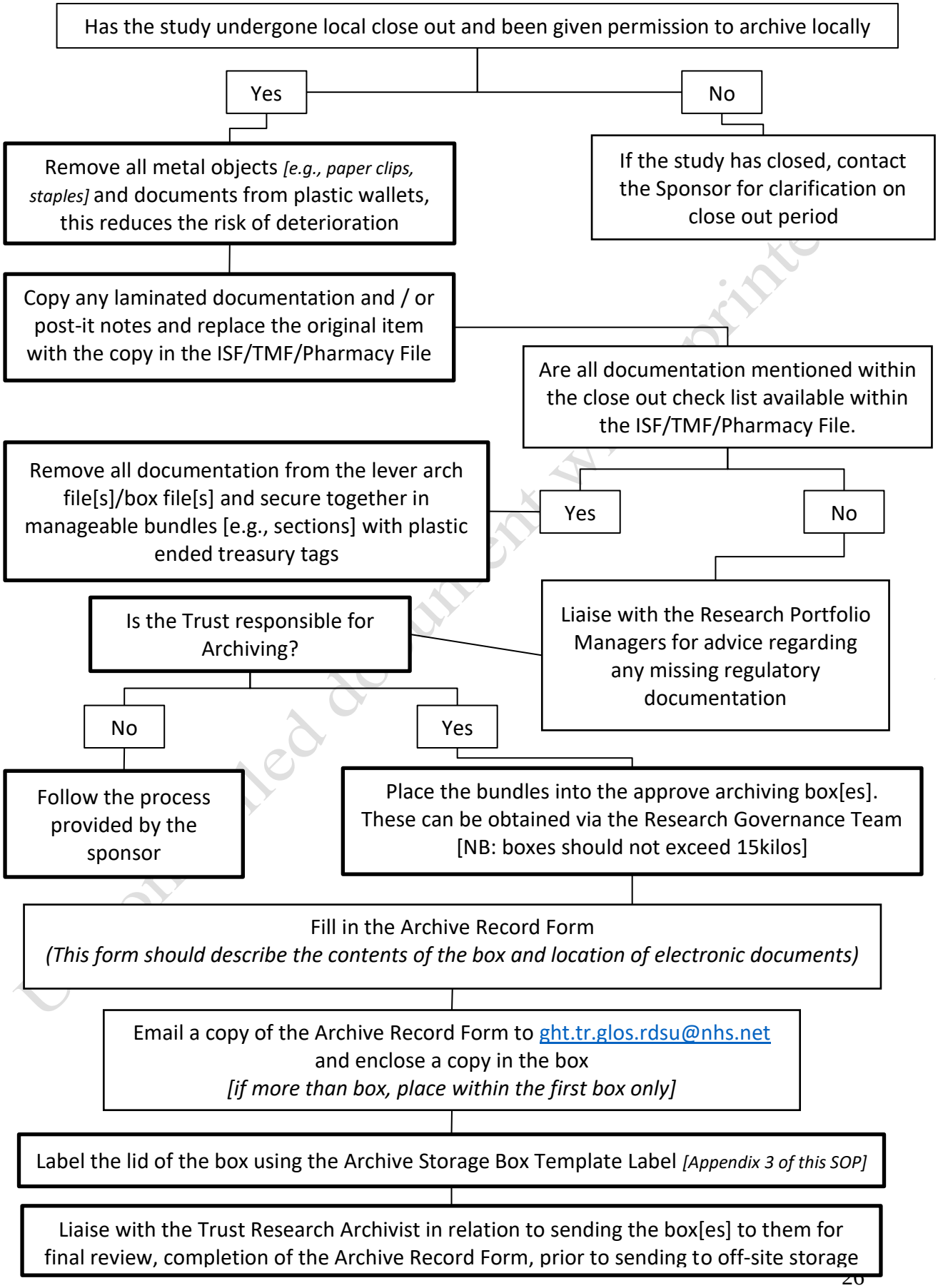
No. of years to be archived	Date due for Destruction	Date of Destruction	Costs Recovered?
16 Years	*21/06/2034*	*/ /*	Yes ☑ No ☐ Some ☐ n/a ☐

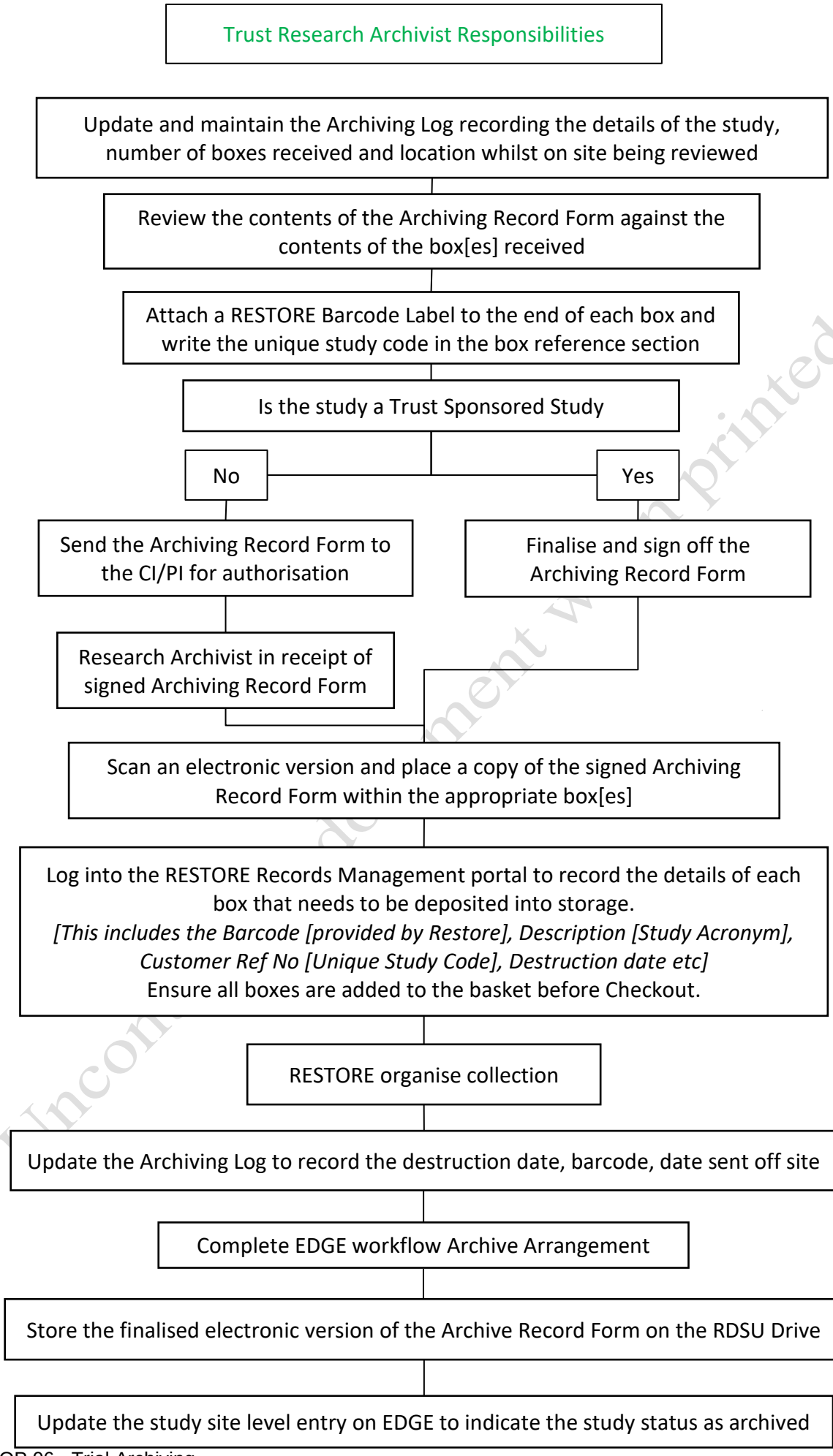
Commercially-sponsored invoices only

Sponsor invoiced Yes ☐ No ☐ n/a ☐ (Invoice number:)

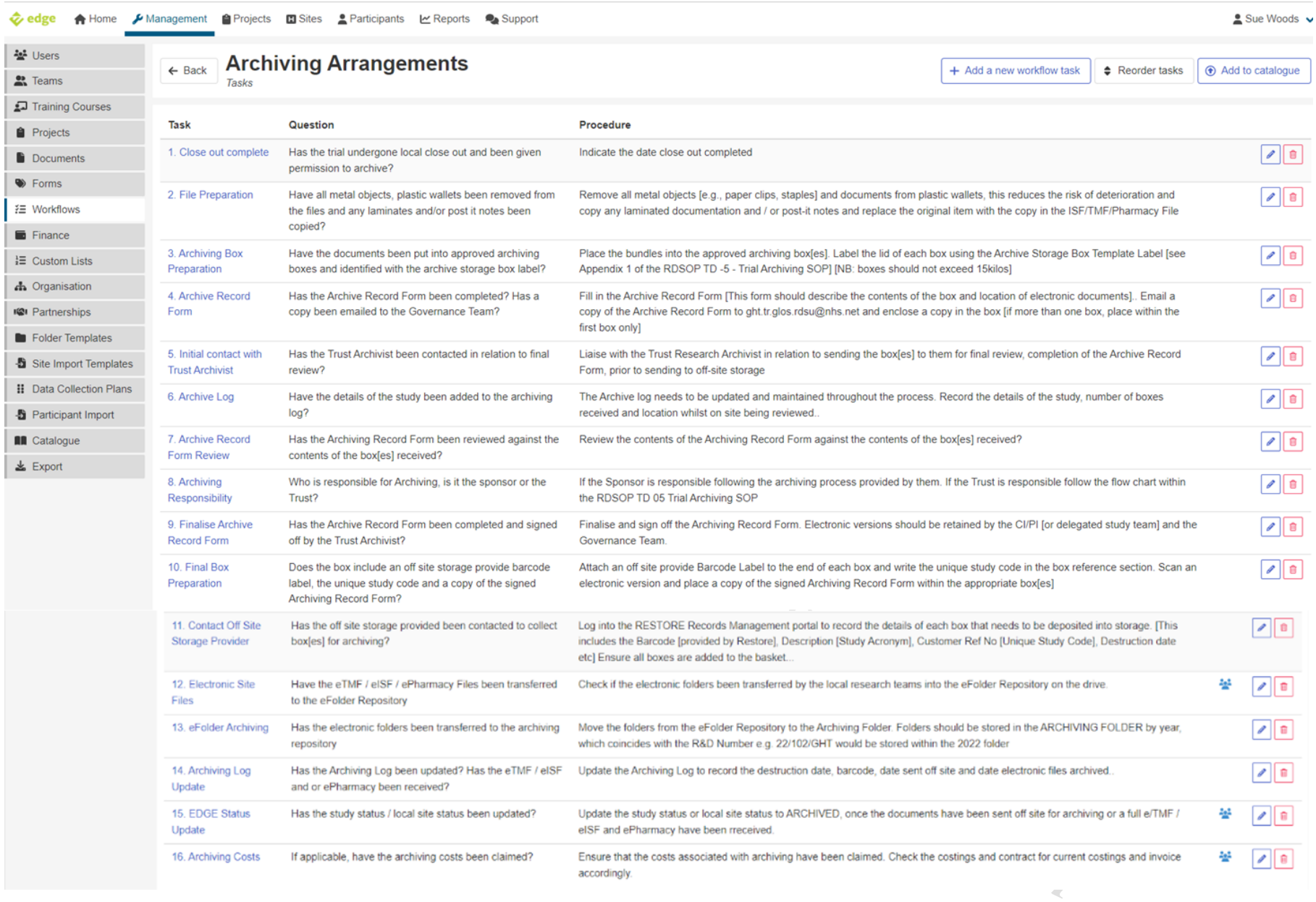
Invoice from third party storage facility authorized Yes ☐ No ☐ n/a ☐

Appendix 6: Flow-chart for Archiving




Trust Research Archivist Responsibilities
Update and maintain the Archiving Log recording the details of the study, number of boxes received and location whilst on site being reviewed
Review the contents of the Archiving Record Form against the contents of the box[es] received
Attach a RESTORE Barcode Label to the end of each box and write the unique study code in the box reference section
Is the study a Trust Sponsored Study
No
Yes
Send the Archiving Record Form to the CI/PI for authorisation
Finalise and sign off the Archiving Record Form
Research Archivist in receipt of signed Archiving Record Form
Scan an electronic version and place a copy of the signed Archiving Record Form within the appropriate box[es]
Log into the RESTORE Records Management portal to record the details of each box that needs to be deposited into storage.
[This includes the Barcode [provided by Restore], Description [Study Acronym], Customer Ref No [Unique Study Code], Destruction date etc]
Ensure all boxes are added to the basket before Checkout.
RESTORE organise collection
Update the Archiving Log to record the destruction date, barcode, date sent off site
Complete EDGE workflow Archive Arrangement
Store the finalised electronic version of the Archive Record Form on the RDSU Drive
Update the study site level entry on EDGE to indicate the study status as archived

Appendix 7: Edge workflow



Task	Question	Procedure
1. Close out complete	Has the trial undergone local close out and been given permission to archive?	Indicate the date close out completed
2. File Preparation	Have all metal objects, plastic wallets been removed from the files and any laminates and/or post it notes been copied?	Remove all metal objects [e.g., paper clips, staples] and documents from plastic wallets, this reduces the risk of deterioration and copy any laminated documentation and / or post-it notes and replace the original item with the copy in the ISF/TMF/Pharmacy File
3. Archiving Box Preparation	Have the documents been put into approved archiving boxes and identified with the archive storage box label?	Place the bundles into the approved archiving box[es]. Label the lid of each box using the Archive Storage Box Template Label [see Appendix 1 of the RDSOP TD -5 - Trial Archiving SOP] [NB: boxes should not exceed 15kilos]
4. Archive Record Form	Has the Archive Record Form been completed? Has a copy been emailed to the Governance Team?	Fill in the Archive Record Form [This form should describe the contents of the box and location of electronic documents].. Email a copy of the Archive Record Form to ght.tr.glos.rdsu@nhs.net and enclose a copy in the box [if more than one box, place within the first box only]
5. Initial contact with Trust Archivist	Has the Trust Archivist been contacted in relation to final review?	Liaise with the Trust Research Archivist in relation to sending the box[es] to them for final review, completion of the Archive Record Form, prior to sending to off-site storage
6. Archive Log	Have the details of the study been added to the archiving log?	The Archive log needs to be updated and maintained throughout the process. Record the details of the study, number of boxes received and location whilst on site being reviewed..
7. Archive Record Form Review	Has the Archiving Record Form been reviewed against the contents of the box[es] received?	Review the contents of the Archiving Record Form against the contents of the box[es] received?
8. Archiving Responsibility	Who is responsible for Archiving, is it the sponsor or the Trust?	If the Sponsor is responsible following the archiving process provided by them. If the Trust is responsible follow the flow chart within the RDSOP TD 05 Trial Archiving SOP
9. Finalise Archive Record Form	Has the Archive Record Form been completed and signed off by the Trust Archivist?	Finalise and sign off the Archiving Record Form. Electronic versions should be retained by the CI/PI [or delegated study team] and the Governance Team.
10. Final Box Preparation	Does the box include an off site storage provide barcode label, the unique study code and a copy of the signed Archiving Record Form?	Attach an off site provide Barcode Label to the end of each box and write the unique study code in the box reference section. Scan an electronic version and place a copy of the signed Archiving Record Form within the appropriate box[es]
11. Contact Off Site Storage Provider	Has the off site storage provided been contacted to collect box[es] for archiving?	Log into the RESTORE Records Management portal to record the details of each box that needs to be deposited into storage. [This includes the Barcode [provided by Restore], Description [Study Acronym], Customer Ref No [Unique Study Code], Destruction date etc] Ensure all boxes are added to the basket...
12. Electronic Site Files	Have the eTMF / eISF / ePharmacy Files been transferred to the eFolder Repository	Check if the electronic folders been transferred by the local research teams into the eFolder Repository on the drive.
13. eFolder Archiving	Has the electronic folders been transferred to the archiving repository	Move the folders from the eFolder Repository to the Archiving Folder. Folders should be stored in the ARCHIVING FOLDER by year, which coincides with the R&D Number e.g. 22/102/GHT would be stored within the 2022 folder
14. Archiving Log Update	Has the Archiving Log been updated? Has the eTMF / eISF and or ePharmacy been received?	Update the Archiving Log to record the destruction date, barcode, date sent off site and date electronic files archived..
15. EDGE Status Update	Has the study status / local site status been updated?	Update the study status or local site status to ARCHIVED, once the documents have been sent off site for archiving or a full e/TMF / eISF and ePharmacy have been rreceived.
16. Archiving Costs	If applicable, have the archiving costs been claimed?	Ensure that the costs associated with archiving have been claimed. Check the costings and contract for current costings and invoice accordingly.