NHS
Gloucestershire Hospitals
NHS Foundation Trust

Trial Delivery 05 – Trial Archiving

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 Staff must ensure that they are adequately trained in the new procedure and must make sure that all copies of superseded version are promptly withdrawn from use unless notified otherwise by the SOP Controller.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:

http://www.gloshospitals.nhs.uk/en/About-Us/Research--Development/

SOP reference:	R&D SOP TD05	
Version:	3.0	
Author:	Janet Forkes Sue Woods	signature
Reviewed by Associate Director of R&D	Julie Hapeshi 31/05/2018	signature
Implementation date of current version:	31/ 05 /2018	
Date of Review:	01 / 04/2020	

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

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

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 GCP 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)

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 Senior R&D Managers 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 Site 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 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 archivists are those individuals holding the post of Trust Senior Research Managers, who may delegate the day to day logistics to other members of the research team.

4.2 Trust Hosted Trials

- The 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 to a member of the trials team to liaise with the Senior Research Managers to archive ISF at an off-site facility.
- For commercial studies, the sponsor may put in place arrangements for third party archiving. However, it is the responsibility of the participating site to archive their documents. Increasingly, it is common practice for the sponsor to request the participating site to arrange third party archiving and to remunerate accordingly.

4.3 R&D trial documentation

- Senior Research Managers will liaise with the R&D department team to archive from the main office in parallel with the research teams documentation for each specific trial being archived.

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 (see R&D SOP TD 04).
- All trial data will be stored in a physical location that is weatherproof, secure at all times and environmentally controlled.
- 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 5)

5.2 Trust Hosted Trials

- On receipt of written instructions from the Sponsor the PI and the local trials team will prepare the trial essential documents for archiving. The trials team will notify R&D at this point and support will be offered as necessary.
- Where the Sponsor has stated trial data will be stored locally the Trust SOP for archiving will be followed.
- All trial data will be stored in a physical location that is weatherproof, secure at all times and environmentally controlled.
- 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 (see appendix 1). Participating patients' hospital notes will show that the patients have taken part in a clinical trial and will be annotated to indicate that the notes must not be destroyed for a specified time as stated in the trial protocol and the ethics application.

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 too off site for the length of time detailed in the Trust records retention policy.

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 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 should be recovered by the Trust and the archiving fees specified in the agreement between the Trust and the Sponsor.
- 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).
- It is acceptable to then transfer the medical files of the trial participants into another medium such as scanning or microfiching as long as the process is validated in such a way that the Trust can demonstrate these are authenticated copies of the original medical notes. 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

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.

- 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

- Paediatric Use Marketing Authorisations (PUMAs) applications can use data from published literature and this data must meet the requirements of the EU Directive 2003/63/EA.
- Data may not be used for a Marketing Authorisation Application (MAA) when the TMF has only been maintained or 5 years.
- 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 Clinical Trials Toolkit to determine if this should be extended further.

7. Electronic archiving

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.

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 checked 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 downloaded and checked as readable onto a Trust IT system server and onto transportable media (ie USB drives). 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 1).

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 on the R&D archive drive.

7.3 Researchers CVs and GCP certificates

Trust R&D staff on receipt of signed and dated CVs and GCP certificates from researchers 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.

8. Retrieving Archived Documentation

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

- 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 are archived.

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 Trust R&D team. The costs for doing so must be recovered from the sponsor wherever possible.

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 Guidelines).

8.2 Electronic based data

The ongoing availability of the data will be periodically tested by the Trust Senior Research Managers. A programme of retrieval will be planned in collaboration with the Trust IT department (see Guidelines).

Access will be restricted and requests must be sent to the Trust Senior R&D Managers for access to electronic data and an audit trails will be documented.

9. Destruction of Documentation

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

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

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

The actual date of destruction will be recorded by the Trust R&D team, ongoing this will be on a spreadsheet on the RDSU drive, previously kept on a paper based system in the R&D office at Leadon House.

10. Invoicing for archiving Trust Sponsored and Trust Hosted Trials

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

11. Related SOPs and other documentation and links

'Reflection paper on expectations for electronic source data and data transcribed to electronic data collection tools in clinical trials'

http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2010/08/WC500095754.pdf

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
http://glnt313/sites/ghnhsft_policy_library/NonClinPolices/B0259.pdf

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

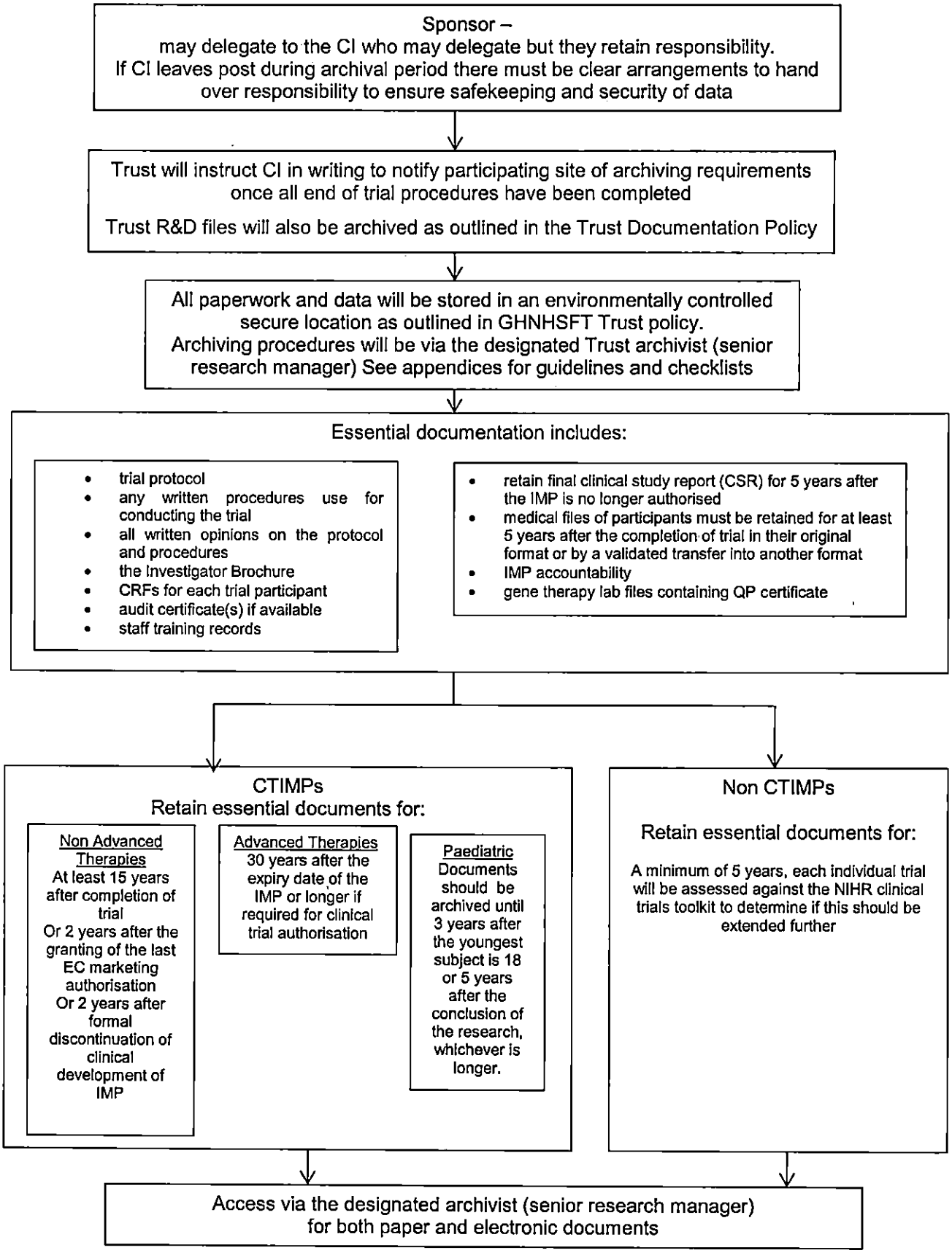
Portable IT equipment and removal media
http://glnt313/sites/ghnhsft_policy_library/Procedures/B0692.pdf

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

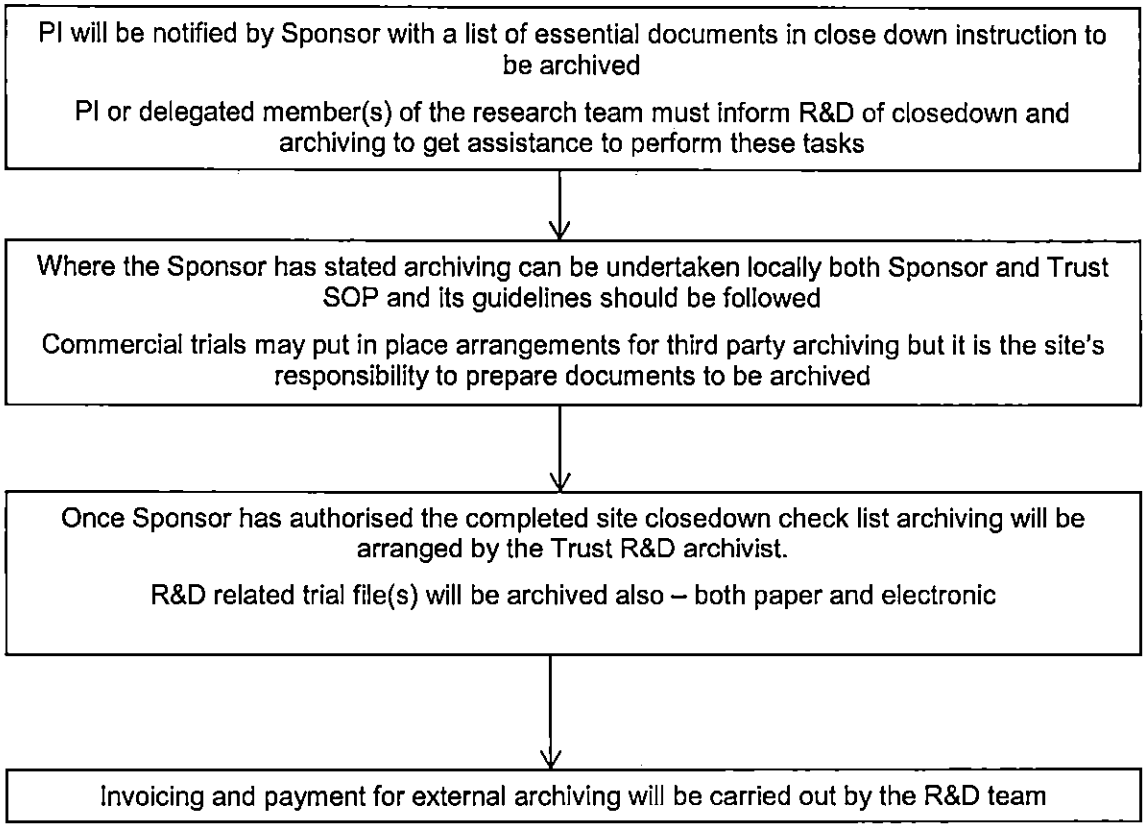
Clinical and non clinical information systems
http://glnt313/sites/ghnhsft_policy_library/NonClinPolices/B0259.pdf

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

Flow chart - Trust Sponsored Trials



Flow chart for Trust Hosted Trials



Appendix 1 - Archive Storage Boxes Template Label

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 2 - Archiving Record Form

Archiving Record Form V2. 16.02.2018
For all Commercial and Non-Commercial Research

PROJECT INFORMATION

R&D Project No:	
Short Title/ Acronym	
Title:	
Sponsor:	
Principal Investigator:	
Date Study Completed:	/ /
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 designated R&D manager *(delete as appropriate)*

FOR COMPLETION BY THE RESEARCHER

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./Crown Code)	Date Collected by Contractor *(if applicable)*	Contractor's Unique Storage Number *(if applicable)*
	/ /			/ /	

AUTHORISATIONS

Investigator or designated R&D manager(*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)

Schedule of Archived Documents

Document Type	Quantity (if applicable)	Box No	Location if not with Contractor
eg. Site file volume 1 , section 1 Protocol and superseded Protocols		*1/1*	

Schedule of Archived Documents

Document Type	Quantity (if applicable)	Box No	Location if not with Contractor

Schedule of Electronic Data

Electronic Records *(where have these been stored and who has access to them*	**Location**	**Access**
e.g. Accrual Data (dated 18.10.2010)	*Rdsu(\\Glnt000)(t:)*	*Data Manager – Name Administrator - Name*

ANY OTHER RELEVANT INFORMATION

FOR COMPLETION BY THE RESEARCH GOVERNANCE TEAM			
No. of years to be archived	Date due for Destruction	Date of Destruction	Costs Recovered?
	/ /	/ /	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 ☐			

Guidelines for 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 which do not complete and 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 as 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 section 6)*, whilst 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. Archiving boxes which are to be stored at an off-site facility should be stored within the appropriately obtained storage boxes. These are to be ordered through the Trust R&D Department team.

- CTIMP studies which are not going into a third party storage facility should be labelled using the template labels (see Appendix 2) 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 boxed, for example R&D12_099_GHT, Box 2:3, destroy by 02.07.2020, 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 the box is

placed inside the box or attached to the inside lid, a copy should also be retained by the research team and one sent to the R&D office for their information (see Appendix 4).

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

- Retrieval of one trial's documentation stored off site will be made each year in August and an audit of how long to call back and what is