ECTU Central Office WPD_TM_W2: Archiving of Essential Study Documentation

Version No:	4.0
Issue Date:	20 Nov 2023
Effective Date:	04 Dec 2023

Authorship and Approval			
Name and Designation	Author/Reviewer/Approval/ Authorisation	Date	Signature
Lisa Derr, Trial Manager	Author	16 Nov 2023	See retained email approval sent on 16 Nov 2023
Stephanie Cholbi, Assistant Trial Manager	Reviewer	16 Nov 2023	See retained email approval sent on 16 Nov 2023
Gina Cranswick, Trial Management Team Lead	Approver	20 Nov 2023	See retained email approval sent on 20 Nov 2023
Tanya Tharakan QA Manager	QA Authorisation	16 Nov 2023	See retained email approval sent on 16 Nov 2023

Document Revision History		
Version No.	Effective Date	Summary of Revisions
1.0	6 June 2018	Initial creation
2.0	15 April 2021	Removal of reference to ECTU clinical team, clarification of where the box contents list should be saved, clarification of TM responsibilities for archiving throughout
3.0	30 April 2021	Section 2.5, ISG Files - updated to clarify archiving of ISG files
4.0	04 Dec 2023	WPD moved to the new template. Section 2.5 updated with responsibility for archiving of electronic files. ACCORD SOP AD001 has been renamed by the sponsor. The reference to this SOP has been updated accordingly.

1. INTRODUCTION

This Working Practice Document (WPD) provides guidance on preparing study documentation to be archived at the end of trial and arrangements to consider before this process begins.

This WPD applies to studies within ECTU with an assigned Trial Manager (TM) who will be responsible for overseeing the archiving process.

2. INSTRUCTIONS and GUIDANCE

2.1 Funding for Archiving

The Chief Investigator is responsible for ensuring that funding is available to archive the study data. The Sponsor is responsible for facilitating the archiving process but do not bear financial responsibility for this. Finances must be in place before a request to archive is made as these costs must be paid in advance.

In practice, archiving usually takes place after the study grant has closed. Archiving costs can be charged to the grant in advance. This should be discussed and agreed with the Sponsor prior to the end of the grant, when study close down is initiated.

2.2 Archiving Period and Sponsor Requirements

The study protocol should be checked initially for the study retention period. If this is not specified in the protocol, the TM should check if the funder has specified the retention period. This information may be found in the grant terms and conditions. If the funder does not specify this, the archiving period will be decided by the study Sponsor. For NHSL/ UoE sponsored studies, guidance is available from ACCORD (see section 3).

The Sponsor guidance should also be checked for specific instructions on initiating and completing an archiving request as well as advice on archiving costs, supplies and arrangements for off-site management of the archived data.

2.3 Essential Study Documentation

The following should be considered for inclusion when archiving documentation (as applicable, depending on study requirements):

- Trial Master File (TMF)
- Investigator Site File (ISF)
- Pharmacy File
- Study Data (including electronic CRFs, paper CRFs, data collection sheets, clinical reports (for example, lab reports, scan reports etc.)
- Data Management Files

- Statistics Master File
- Health Economics Files
- Clinical Files (participant files specific to any contact with clinical team may include consent forms, lab reports etc.)
- ISG (Investigational Supplies Group) Files (CTIMPS only)

2.4 Assessment of Documentation

Before the archiving process begins, the types, volume and location of the various documents held throughout the study should be assessed and who will be responsible for ensuring these are prepared for archiving should be determined. Arrangements for archiving are often detailed within the site agreement. The TM is responsible for checking the relevant agreements for archiving requirements.

It is important that the volume and type of documentation to be archived is assessed by the trial manager or delegate prior to making an official request to NHS Lothian R&D for Accord sponsored studies, as this will allow an estimate to be made regarding the number of archiving boxes that will be required. For studies not sponsored by Accord, the TM or delegate should contact the Sponsor to make archiving arrangements. Archiving is charged on a per box, per year basis and this assessment will assist in the initial cost estimate for off-site archiving.

2.5 Responsibilities & Procedure

The TM will generally be responsible for overseeing and co-ordinating the archiving process and ensuring all relevant documents are archived, with specific tasks delegated to sites or other staff within ECTU, and other relevant study staff out with ECTU, for example, WTCRF staff, pharmacy staff etc.

Sites will usually be responsible for archiving any documentation they hold (for example, ISF, CRFs etc.) in accordance with local procedures but the site agreement will specify what their exact responsibilities are.

The following details who is responsible for preparing the documentation for archiving. Where Sponsor is mentioned, these duties may be delegated to the TM as applicable:

2.5.1 **Trial Master File** – The TM or designee is responsible for ensuring that the TMF is maintained throughout the trial and that all essential documents are filed correctly. The Sponsor is responsible for reviewing the TMF prior to archiving. This will usually be done at the Close-Out visit for the study, but if the trial is not monitored by the Sponsor, the TM is responsible for ensuring the TMF is complete before archiving.

2.5.2 **Investigator Site File** – The Principal Investigator (PI) at site is responsible for ensuring that the ISF is maintained throughout the trial and that all essential documents are filed correctly. The Sponsor is responsible for reviewing the ISF prior to archiving at the Site Close-Out Visit. If the trial is not monitored by the Sponsor, the TM is responsible for ensuring the ISF is complete before archiving at the site. The PI will then be responsible for archiving this in accordance with local procedures.

2.5.3 **Pharmacy File** – As with ISF detailed above.

2.5.4 **Study Data** – In most cases study data will be held on the study database. The database should be locked and access removed for all users as part of the close-out process. In the event that study data is held on paper CRFs these will be archived by the site in accordance with local procedures.

When study data is held at ECTU, the TM or designee will be responsible for preparing the data for archiving. All patient identifiable data should be anonymised prior to archiving (see section 2.6 for further guidance on anonymization).

Note: Ensure that all study data is collated prior to archiving, including any pCRFs held by the Research Nurses (see 2.5.9 Clinical Files)

2.5.5 **Data Management Files** – Documentation in relation to the specification, build and maintenance of the trial database is kept by the Data Management and IT team throughout the trial. The TM or designee should ensure that these files are retrieved and included as part of the study archiving. The IT programmer is responsible for ensuring that these are up to date prior to being handed over for archiving.

2.5.6 **Statistics Master File** – The Statistics Master File is regarded as being part of the Trial Master File. The Statistics Master Files cannot be archived until after the final statistical report has been completely finalised. The Trial Statistician will advise when the files can be archived and they will be responsible for ensuring that all the documentation is present and correct in the file before handing it over to the TM or designee for archiving.

2.5.7 **Health Economics Files** – If Health Economic analysis is being carried out as part of the study, the TM should discuss the archiving of any files with the Health Economist before the process begins.

2.5.8 **Data Monitoring Committee Minutes** - The TM or designee should arrange for any minutes from closed sessions (where unblinded data is reviewed) of DMC Meetings

to be collected and archived along with the trial data after the final statistical report has been finalised. These minutes will usually be held by the DMC Chairperson.

Note: These minutes cannot be viewed by the TM or trial staff whilst the trial is ongoing. It is important that these are not retrieved prior to finalisation of the final report.

2.5.9 **Clinical Files** – Where an external clinical care team was involved in the recruitment and follow-up of participants, the TM will liaise with the appropriate contact and ensure any clinical files are ready to be archived.

2.5.10 **ISG Files** – If the study is a CTIMP and the Investigational Supplies Group have been involved in the supply of the study drug, the ISG file can be archived either with the sponsor file (held by ACCORD), or with the TMF. The TM or designee should contact ISG to arrange where the ISG file is to be archived. If the ISG file is to be archived with the ACCORD file, this should be documented in a file note which should be retained in the TMF. If the ISG is to be archived with the TMF, the TM or designee is responsible for arranging for the files to be transferred to ECTU for archiving. The Qualified Person(QP) in charge of the study at ISG will be responsible for ensuring that the files are complete before submitting them for archiving.

If IMP is supplied from an external company, the TM is responsible for ensuring copies of the relevant documentation are collected for inclusion in the TMF.

2.5.11 **Electronic Files-** Some electronic documents such as the trackers used by the ECTU TM team may be too large to print. The TM or designee should ensure that the documents are saved to a USB stick or similar and archived along with the TMF. This also applies to any other electronic files such as site training videos.

2.5.12 Trial Database: Refer to ECTU SOP OP 20 Requests to Lock and Unlock a Study Database.

2.6 Anonymisation of Study Data

Patient identifiable data will be collected for each participant in study in some form. Patient identifiable data can include full name, address, date of birth and CHI/Hospital number. Depending on the design of the study, this information may be collected on a separate paper CRF designed specifically for this purpose or as part of another CRF (for example, at Screening or Baseline). Patient identifiers (such as initials and date of birth) may also be

included on individual CRFs as a way of ensuring information is recorded correctly for each patient.

Prior to archiving study data, every effort should be made to ensure that patient identifiable data is fully anonymised prior to being removed off-site to protect patient confidentiality.

Anonymisation can be done by either redacting the document or sealing the data in envelopes.

2.6.1 **Redaction** – redacting a document simply means to obscure sensitive or confidential data so that it cannot be read. This can be done using permanent black markers or opaque labels. Redaction is most appropriately used to obscure patient name and address stickers placed on pCRFs during study visits. Obscuring this data with redaction does not affect the readability of the rest of the document and the information on this will usually have been collected separately (on a Screening CRF, for example).

2.6.2 **Sealed data** – If patient identifiable data is collected on a single separate CRF or data collection sheet, redaction of the document will not be appropriate. In this case, the document should not be altered but sealed in envelopes before being archived. The envelopes should be labelled as containing patient identifiable data and what this relates to (for example, Envelope contains Patient Identifiable Data for XXXXX Study – Patient Contact Forms Pt 110001-110050)

Consent Forms – Consent Forms should not be redacted in any way even if this is possible (for example, form only contains patient name as identifier). Consent Forms should always be archived in sealed envelopes at the end of trial.

For electronic versions of study data, the TM or delegate should follow the Sponsor's guidance.

2.7 Preparation of Archiving Boxes

Archiving boxes should be filled to maximum capacity allowed. This will sometimes be indicated on the box but the boxes should be easily lifted and transported.

Specific instructions relating to the packing and labelling of archiving boxes may be provided by the Sponsor or the Records Management company and this should be checked before the boxes are packed, however the following general guidance should be followed:

- Removing data from binders or folders they are held in will help to minimise the amount of archiving boxes that are required; however it is important that the data is kept secure and intact should it need to be retrieved for any reason and this may warrant holding

paperwork in document wallets when archiving. The document wallets should be clearly labelled.

- Remove any unnecessary paper-clips, bulldog clips, staples, post-it notes etc. from paperwork.
- Number each archiving box in sequential order (for example, Box 1, Box 2, Box 3 etc.) in addition to any barcodes or identifiers from the Records Management company.
- Each numbered box should contain a Box Contents List () detailing exactly what is contained in the box. An electronic copy of this will be retained in the TMF file structure held on the ECTU server.

Note: The Sponsor may also require a less detailed list of what is contained in each box but this should also be kept for auditing and future retrieval of data should it be required.

- An Archiving Inventory should be kept detailing the number of boxes and a summary of the contents of each. This will be retained electronically in the TMF file structure by ECTU.
- Specific labelling instructions may be provided by the Sponsor but generally each box should be labelled with the Study Name, CI Name, CI Contact Number and Date of Destruction.

Once the boxes are ready and archiving has been authorised by either the Sponsor or Monitor, in the absence of which will be the Trial Manager, uplift of the data can be arranged as per Sponsor guidance. The archiving boxes should remain accessible (i.e. unsealed) for as long as possible prior to uplift so that the data can still be inspected or accessed if required. Boxes should be sealed using plastic adjustable ties as these are less able to be tampered with.

3. RELEVANT DOCUMENTS AND REFERENCES

- ACCORD SOP CR009 Study Closure and Archiving
- ACCORD SOP GS005 Archiving Essential Study Documentation
- ACCORD SOP AD001 Entering Research Information to the Electronic Patient Record
- www.accord.scot/research-access/resources-researchers/sop
- ECTU_SOP_OP_20 Requests to Lock and Unlock a Study Database