ARCHIVING ESSENTIAL DOCUMENTS

Research and Development

Standard Operating Procedure for Archiving of Clinical Trial Data and Essential Documentation in clinical research trials

SOP Number : SOP-17-05	**Effective Date:** October 2021
Version Number: v05	**Review Date:** 2-3 years

1.0 BACKGROUND

This document sets out the procedures to be followed by all West Hertfordshire Hospitals Trust (WHHT) staff who are involved in the archiving of research study documentation.

It provides clear guidance on the archiving of all essential documents related to research studies carried out at WHHT.

2.0 PURPOSE

This document describes procedures for the archiving of essential clinical trial documentation. It covers Clinical Trials of an Investigational Medicinal Product (CTIMPs) sponsored and hosted by the WHHT and sponsored non-interventional trials. For externally sponsored multi-centre trials, archiving requirements should be outlined in the contract.

Medical notes will be archived in accordance with standard care guidance and are not covered by this SOP.

The Trust, as Sponsor, is required to have a named archivist at each site to comply with the legal requirements.

3.0 APPLICABLE TO

Any Trust employee involved with clinical research sponsored or hosted by WHHT including, but not limited to, Unit Heads, Chief Investigators (CI), Principal Investigators (PI), Consultants, Co-investigators, Clinical Trial Pharmacists, Research Managers, Statisticians, Research nurses, Allied Health Professionals, Trial Coordinators, R&D Department, the Research & Development Steering Group (RDSG) & Data Managers.

4.0 RESPONSIBILITIES

4.1 Named Archivists

The named archivist for WHHT is the Associate Director of R&D.

All essential documents relating to the clinical study must be archived in accordance with this SOP and the requirements of the UK regulations. The Sponsor has responsibility for archiving the trial documentation.

4.2 Retention times of essential documents

For trials that are not intended to support Marketing Authorisation applications (or variations) to the Competent Authority, the Sponsor and the CI shall ensure that the documents contained, or which have been contained, in the Trial Master File (TMF) are retained for 5 years after the conclusion of the trial. In addition, the Sponsor and the CI shall ensure that the medical files of trial participants are retained for at least 5 years after the conclusion of the trial.

For trials intended to support Marketing Authorisation applications (or variations) to the Competent Authority, the Marketing Authorisation Holders must arrange for essential clinical trial documents (including Case Report Forms (CRFs)) other than participant's medical files, to be kept by the owners of the data:

- for at least 15 years after completion or discontinuation of the trial,
- or for at least 2 years after the granting of the last marketing authorisation
- or for at least 2 years after formal discontinuation of clinical development of the investigational product

4.3 For CTIMPs sponsored by the Trust

The responsibility for archiving is held with the CI or delegated individual (DI) and agreed with the Trust Archivist and clearly documented.

4.4 For Hosted CTIMP trials conducted at WHHT

The Sponsor's requirements for retention of materials, their retention periods and location should be defined by the Sponsor prior to trial start and formally documented in the contract. The PI/DI is responsible for archiving research documentation locally. The Sponsor should inform the investigator site in writing when trial materials are no longer required to be retained.

The relevant documentation from CTIMPs must be archived for at least 5 years after conclusion of the trial under the Regulations and during this period must be: -

a) readily available to the licensing authority on request; and

b) complete and legible

4.5 Sponsored non-interventional trials

Relevant documentation should be archived in accordance with the information submitted for ethical approval.

5.0 PROCEDURE

5.1 General

All essential documents will be archived either on site or off site using an external archiving company with whom the Trust has a service level agreement. The company meets all essential criteria to store confidential information safely and securely.

Prior to archiving documents, please refer to study protocol and related contracts/agreements to ensure that the documents are archived in accordance with Sponsor requirements.

5.2 Documents to be archived

All essential documents retained within the TMF and/or Investigational Site File (ISF) should be archived alongside the CRFs and the Pharmacy Clinical Study Files. Any essential trial documentation that has been kept somewhere other than the TMF or the ISF during the study should be returned to the CI/DI after the study is finished so that all documents can be archived together. Where there are different arrangements, these should be clearly documented.

5.3 The Archiving Process

The designated person in the clinical units prepares the study documents for archiving as follows and as per the archiving process map (See section 5.7).

1. Pack the TMF, ISF, if applicable, the CRFs and Pharmacy Study Files in the standard archiving boxes with lids.
2. Complete the Archiving Details Form, retaining a completed copy within the archiving box and a completed copy on the outside of the box. (See appendix 2).
3. A copy of the completed Archiving Details Form should be returned to the R&D Department marked ‘for attention of archivist’.
4. When archiving is complete and the boxes are ready to be collected liaise with the named archivist to arrange delivery to a secure room pending collection from the external storage company. The named archivist will ensure that the archiving database is updated.
5. Retain copy of signed Archiving Details Form in the R&D Office.

5.4 Retrieval of Archived Boxes

Materials that have been archived may, on occasion, need to be retrieved, e.g. for regulatory inspection. The CI, DI or R&D Director/Associate Director should complete an Archiving Retrieval Form (see appendix 3) and send it to the named archivist. A copy of this form should be sent to the R&D Department. The required boxes will be identified by the named archivist and return requested. Once returned to the named archivist they will be stored in a secure room pending collection by the requestor who will need to provide identification.

5.5 Return of archived boxes to storage

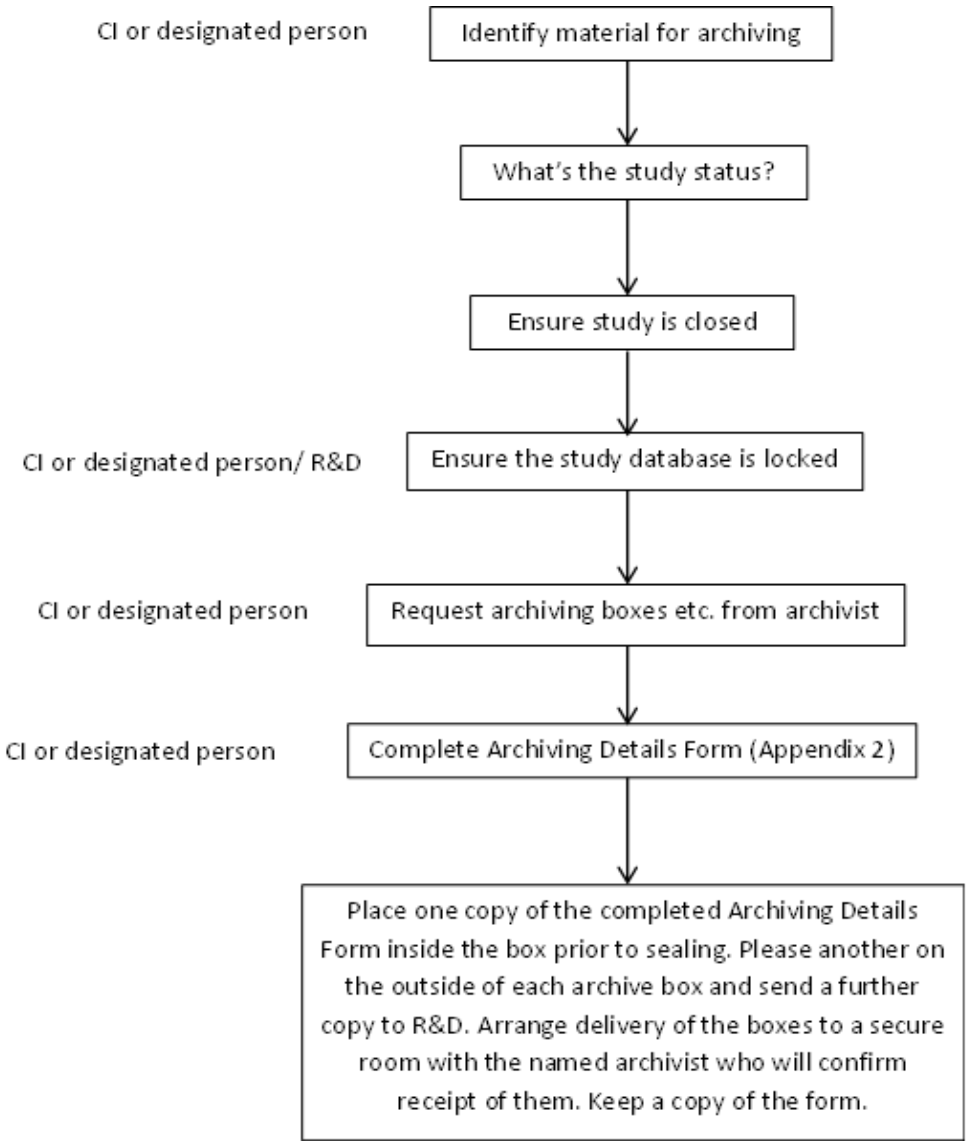
Following the withdrawal of the archived documents, each archive box represented to the offsite archiving company will be treated as a new consignment and therefore must be clearly labelled showing any additional or removed documentation. The box(es) will then be returned as per section 5.4.

5.6 Destruction of archived study documents

Archived documentation can only be destroyed once written permission has been obtained from the following, in accordance with the study protocol requirements and Sponsor SOPs.

- Sponsor or CRO
- Investigator or Host Institution

5.7 Archiving process map



6.0 RELATED DOCUMENTS

- SOP-21- Trial Closure

7.0 APPENDICES

Appendix 1 - Definitions
Appendix 2 - Archiving Process Map
Appendix 3 - Archiving Retrieval Form

8.0 VERSION HISTORY

Revision Chronology:		
Version Number	**Effective Date**	**Reason for Change**
SOP-17-05	October 2021	1. Change from general Standard Operating Procedures (gSOP) to SOP 2. Removal of the '10.0 Agreement' from the template - all agreement signatures will be collated on a new 'SOP Signature Sheet Document'
gSOP-17-04	October 2017	Minor amendments following review
gSOP-17-03	not known	Minor amendments following review
gSOP-17-02	22/05/2014	Minor amendments following review
gSOP-17-01		Minor amendments following review

9.0 AUTHORSHIP & APPROVAL

Author

Signature  **Date** 28/10/2021

R&D Steering Group Approval

Signature  **Date** 28/10/2021

Appendix 1: Definitions

Archive
The material storage area, including its operation, necessary for the secure retention and maintenance of material

Archive Details Form
Document which must be completed for each clinical study archived. The form contains study details, investigators details, box contents and the destruction date. A copy should be in each box archived, one sent to the R&D Department and a copy, signed as received by the named archivist, with the research team.

Case Report Form (CRF)
A printed, optical, or electronic document designed to record all of the protocol required information to be reported to the sponsor on each trial subject.

Chief Investigator (CI)
The investigator with overall responsibility for the research. In a multi-site study, the CI has co-ordinating responsibility for research at all sites. All applications for ethical review should be submitted by the CI.

Clinical Trial
A clinical study in which participants are assigned to receive one or more interventions (or no intervention) so that researchers can evaluate the effects of the interventions on biomedical or health-related outcomes. The assignments are determined by the study protocol. Participants may receive diagnostic, therapeutic, or other types of interventions. A Study Type.

Clinical Trial of Investigational Medicinal Product (CTIMP)
A clinical trial that is within the scope of the UK Medicines for Human Use (Clinical Trials) Regulations 2004. An investigation in human subjects, other than a non-interventional trial, intended: a) to discover or verify the clinical, pharmacological and/or other pharmacodynamic effects of one or more medicinal products, b) to identify any adverse reactions, or c) to study absorption, distribution, metabolism and excretion, with the object of ascertaining the safety and/or efficacy of those products.

Essential Documents
Essential documents are those documents which individually and collectively permit evaluation of the conduct of the trial and the quality of the data produced. Essential documents include the Trial Master File (TMF), source documents, Case Report Forms (CRFs) and the pharmacy documentation relating to the trial which should have all accountability and destruction records for the study drugs.

Investigational Medicinal Products (IMP)
A pharmaceutical form of an active substance or placebo being tested, or to be tested, or used, or to be used, as a reference in a Clinical Trial, and includes a medicinal product which has a marketing authorisation but is, for the purposes of the trial - a) used or assembled (formulated or packaged) in a way different from the form of the product authorised under the authorisation, b) used for an indication not included in the summary of product characteristics under the authorisation for that product, or c) used to gain further information about the form of that product as authorised under the authorisation.

Named Archivist
Person responsible for ensuring archiving requirements are met as required in the regulations.

Principal Investigator (PI)
The investigator responsible for the research site. There should be one PI for each research site. In the case of a single-site study, the chief investigator and the PI will normally be the same person.

Site File
Site Files are held by the PI at sites and contain copies of the essential documents, local approvals, signed consent forms and completed data forms.

Source Documents
Original documents, data, and records (e.g., hospital records, clinical and office charts, laboratory notes, memoranda, subjects' diaries or evaluation checklists, pharmacy dispensing records, recorded data from automated instruments, copies or transcriptions certified after verification as being accurate copies, microfiches, photographic negatives, microfilm or magnetic media, x-rays, subject files, and records kept at the pharmacy, at the laboratories and at medico-technical departments involved in the clinical trial).

The Medicines & Healthcare products Regulatory Agency (MHRA)
The MHRA is the competent authority for the UK in relation to the Directive 2001/20/EC and the Clinical Trials Regulations, and for Medical Devices, the competent authority in relation to the Medical Devices Regulations 2002.

The Regulations
Medicines for Human Use (Clinical Trial) Regulations 2004 transposed the EU Clinical Trials Directive into UK legislation, as Statutory Instrument 2004 no 1031. This became effective on the 1st May 2004. An amendment to implement Directive 2005/28/EC was made to the Regulations as Statutory Instrument 2006 no 1928.

Trial Master File
The Trial Master File contains all essential documents held by the sponsor/Chief Investigator which individually and collectively permits the evaluation of the conduct of a trial and the quality of the data produced.

Appendix 2: Archiving Details Form

DEPARTMENT NAME:	
PRINCIPLE INVESTIGATOR:	**PROTOCOL NO:** **R&D NO:**
DATE OF ARCHIVING:	**BOX NO: (OF)**
BOX CONTENTS: **Archive until:** **(Do not destroy without Investigator authorisation)**	
SIGNATURE ……..……..……. **(CI, designated person or R&D Director/Associate Director)** **NAME (PRINT): ……..…….**	

Please place one copy of this form in the box prior to sealing, another on the outside of the box and return a further copy to R&D Office.

Retain a copy of this form once receipt is acknowledged.

Acknowledgement of receipt of sealed archive box:-

Signed:……..

Name:……

Date: …../……../……

Appendix 3: Archiving Retrieval Form

DEPARTMENT NAME:	
PRINCIPLE INVESTIGATOR:	**PROTOCOL NO:** **R&D NO:**
DATE OF REQUEST	
BOXES NOs REQUESTED:	**TIME FRAME:** **I need access to this data by:**
SIGNATURE: ……..…….. **(CI, designated person or R&D Director/Associate Director)** **NAME (PRINT):……..….**	

Please complete and forward to the named archivist and send a copy of this form to the R&D Office