STANDARD OPERATING PROCEDURE FOR ARCHIVING CLINICAL STUDIES

SOP NUMBER:	TASC SOP013 v12
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1. PURPOSE

To define the procedure for archiving Essential Documents (including electronic media) for Clinical Trials of Investigational Medicinal Products (CTIMPs) sponsored by NHS Tayside (NHST) and/or the University of Dundee (UoD).

2. SCOPE

This Standard Operating Procedure (SOP) applies to all researchers and Sponsor staff participating in CTIMPs sponsored or co-sponsored by UoD and/or NHST, for hosted projects where local archiving has been agreed at study start up, and to offer guidance to researchers of non-CTIMPs. This may also include any studies identified by Sponsor at initial Sponsor review.

3. RESPONSIBILITIES

Sponsor:

- To ensure archiving facilities are available.
- To ensure a named Good Clinical Practice (GCP) Archivist is identified.
- To assess archive storage facilities considering size, location, environmental conditions/pests, confidentiality, and security.
- To ensure that where a third-party archive facility is used, a contractual agreement is in place. Any changes to the arrangements shall be agreed by the named GCP Archivist.
- To put in place regular audits of any third-party archive to ensure the archive continues to meet the Sponsor and regulatory requirements.
- To archive the Sponsor File appropriately.

Named GCP Archivist:

- To review and approve where appropriate, requests to archive.
- To ensure CTIMP data is stored securely, retrieved, and destroyed with all activities recorded appropriately.
- To control and restrict access to CTIMP data, ensuring approval from Sponsor before permitting any retrieval.
- To contact Chief Investigator (CI)/Delegate prior to end of archiving period to agree destruction or retention of records as appropriate. If unable to contact an appropriate individual, to liaise with Sponsor to determine destruction or otherwise.
- To co-ordinate secure destruction of documents.

***Chief Investigator*:**

- To ensure archiving costs are agreed before CTIMP start-up, including the provision of archive boxes i.e. from tay.crc@dundee.ac.uk.
- To include an archiving plan within the study Protocol.
- To ensure research data is archived in a way that permits accurate reconstruction of the research and is not destroyed before the agreed date.
- To inform the Sponsor in writing if the CI is leaving and ensure archiving arrangements and contact person is in place prior to this.
- To seek agreement from the Sponsor, if an extension to the retention period of the archived material is required.
- To contact named GCP Archivist on TASCArchiving@dundee.ac.uk to arrange for archiving to take place.
- To ensure that study data is collated and prepared for archive.
- To instruct all sites to archive as detailed in Agreement/Protocol.
- To ensure the anonymity of any electronic data in accordance with General Data Protection Regulation (GDPR) e.g. images.
- It is the CI's responsibility that arrangements are made to ensure that patient medical records including those belonging to deceased patients, and the source data held within, are retained.
- It is the CI's responsibility that patient medical records carry a "Do Not Destroy until [date]" label, marked clearly as Research on the front of the record that reflects the retention requirement.
- To ensure the confidentiality of records which could identify subjects shall be protected in accordance with the requirements of the GDPR and Data Protection Act (2018).

Clinical Research Centre (CRC):

- To co-ordinate the logging of archive boxes and arrange transport to/from secure facility.
- To order archiving boxes/supplies as appropriate.

4. PROCEDURE

4.1 Preparation

4.1.1 Order and collect archive boxes/supplies as agreed at funding stage.

4.1.2 Ensure essential documents are boxed in a fashion as to easily enable reconstruction of the trial.

4.1.3 Essential Documents - Trial Master File (TMF)

All component parts of the TMF must be archived once the trial is completed. Essential Documents Include:

- Sponsor File
- Trial Master File (held by the CI)
- Pharmacy Site File (held by the Clinical Trial Pharmacist at sites)
- Investigator Site File (held by the Principal Investigator (PI) at sites)
- Laboratory information if any laboratory analysis takes place.

Individual teams may archive completed sections of the TMF once an activity is complete.

4.1.4 Essential Documents may be generated in electronic and/or paper form and recorded on the plan. The Sponsor/GCP Archivist must be made aware of the location (file path/URL) of electronic data.
4.1.5 Electronic data required for the recreation of the study (including metadata) shall be held on a UoD or NHST designated secure server using a validated system.
4.1.6 Data files shall be held in a format such that they cannot be altered or deleted. Access shall be restricted to those authorised only.
4.1.7 Records of e-archived media must be retained, and any migration of data must be validated.
4.1.8 Boxes must not to be over filled or they will be rejected.

4.2 Archiving

4.2.1 Complete an Archiving Record Form (Doc Ref 122) and forward for review to TASCArchiving@dundee.ac.uk.
4.2.2 Once authorised by the archivist the CI/Delegate should liaise with CRC on tay.crc@nhs.scot for transfer of archive boxes to CRC.
4.2.3 The Archiving Record Form should accompany the archive boxes.
4.2.4 The Archiving Record Form will be allocated a box identifier for each box by CRC (e.g. box 998, 999 etc.).
4.2.5 Each form will be signed and scanned by the CRC and a copy of each form placed in the relevant box.
4.2.6 The CI/Delegate will receive a scanned copy of the form.
4.2.7 CRC will seal and label each box. The scanned copy will be retained by CRC and be available for audit and inspection.
4.2.8 CRC will arrange transfer of archive boxes to approved storage facility.
4.2.9 CRC will log the archiving/box details onto their archiving spreadsheet as appropriate.
4.2.10 For the TMF (or any part therein) to be considered to have been archived, they must come under the control of the GCP Archivist.

4.3 Retention period

4.3.1 All CTIMPs will be archived for 25 years from the end of trial date, unless subject to any other third-party obligations e.g., funding terms and conditions or are subject to legal requirements (i.e. Legal Hold).

4.4 Recall/Retrieval from Archive

4.4.1 Recall and access to archived studies will be restricted and requires approval by the Sponsor, as delegated to the GCP Archivist and/or R&D Director, to ensure legitimate reason for request. Recall of archived material should only take place under exceptional circumstances.
4.4.2 Recall by the regulatory authorities must be readily available.
4.4.3 Recall requests must be made using the Archive Recall Form (Doc Ref 120) for specified archive box(es) in a given study and sent to TASCArchiving@dundee.ac.uk for approval. Retrieval from a third-party archive facility may incur additional costs for the researcher.
4.4.4 CI or Delegate to liaise with CRC to arrange retrieval of approved study boxes.
4.4.5 The GCP archivist will approve a loan period of no longer than 4 weeks.
4.4.6 Any changes to the contents of the archive boxes must be documented on the relevant Archiving Recall Form (Doc Ref 120).

4.5 Destruction/Minimum Retention Period for Archiving

4.5.1 The GCP Archivist will contact CI, Delegate or Sponsor at the end of archiving period to agree destruction or retention of records as appropriate. The GCP Archivist will coordinate destruction with an approved agent.

4.5.2 If the GCP Archivist, or Delegate, are unable to contact or obtain a response from the CI, or Sponsor for hosted studies, within 10 working days, they will review the archiving record form. If no valid reason can be identified for retaining beyond the allocated archiving period, it will be securely destroyed.

4.6 Archiving for Non-CTIMPS

4.6.1 Unless otherwise advised by Sponsor at initial Sponsorship review, non-CTIMP studies do not fall under the remit of the GCP Archivist.

4.6.2 Physical documentation should be archived securely and locally by the study team. This can be in a secure location e.g. locked room, cupboard, cabinet with limited access.

4.6.3 A record of what documentation is kept where should be provided for the Sponsor for their records (TASCGovernance@dundee.ac.uk).

4.6.4 Any electronic data or documentation must be stored on NHS Tayside/University of Dundee servers/cloud facilities.

4.6.5 The location of electronic data and documentation should be provided for Sponsor, the URL/File path to the location of this data should be given.

4.6.6 Destruction following archiving - all documents should be destroyed at the end of the archive period once Sponsor approval for destruction is in place. Ensure any participant identifiable data is disposed of as confidential waste.

4.7 Guidance and Considerations

4.7.1 The study documentation must be in a manner which makes it easy to read and reconstruct the trial activity.

4.7.2 Consider keeping the documents within their ring binders, allowing staples and dividers to remain in as it is important for the regulatory authorities to be able to inspect the TMF as it should be for ease of inspection. Loose paper is not recommended.

4.7.3 Consider removing plastic pockets as these are not generally secure and can degrade over time.

4.7.4 Consider removing bright coloured paper/card as these degrade over time and can imprint onto important documentation.

4.7.5 Boxes should not be overfull; the boxes need to remain structurally sound and able to endure the possibility of being recalled and archived again.

4.7.6 The weight of boxes for safe handling should be considered.

4.7.7 Each box must only contain the content for a single study, sharing boxes for multiple studies is not appropriate.

5 ABBREVIATIONS & DEFINITIONS

CI	Chief Investigator
CRC	Clinical Research Centre
CTIMP	Clinical Trial of an Investigational Medicinal Product
GCP	Good Clinical Practice
GDPR	General Data Protection Regulation

NHST	NHS Tayside (Tayside Health Board)
PI	Principal Investigator
SOP	Standard Operating Procedure
TASC	Tayside Medical Science Centre
TMF	Trial Master File
UoD	University of Dundee

6 ASSOCIATED DOCUMENTS & REFERENCES

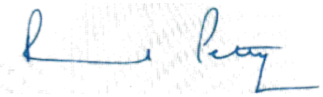
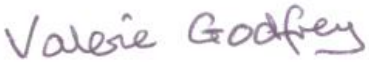
Doc Ref 120: Recall from Archive Request Form
Doc Ref 122: Clinical Research Archive Approval Form

Data Protection Act (2018)
General Data Protection Regulation (2018)

7 DOCUMENT HISTORY

Version Number:	Reviewed By (Job Title):	Effective Date:	Details of editions made:
9	Patricia Burns (Senior Research Governance Manager)	01/04/2020	SOP simplified and rewritten for CTIMPs with input from Lorna Talbot, named GCP Archivist.
10	Tracy Petrie Quality Assurance Support Officer	24/09/2020	Updated NHS email addresses and new website on footer.
11	Patricia Burns (Senior Research Governance Manager) & Billal Elahi (Clinical Research Governance Co-ordinator)	24/09/2022	Scheduled review no changes required.
12	Billal Elahi (Clinical Research Governance Coordinator)	08/03/2023	Updated SOP to current practice. Updated the associated documents Doc Ref 120 and Doc Ref 122. Removal of Doc Ref 111 (Guidance: Preparing Clinical Research Studies for Archive) and Doc Ref 121 (Archiving plan).

8. APPROVALS

Sign		Date
APPROVED BY: *Signature*	Professor Russell Petty, R&D Director, NHS Tayside 	2nd March 2023
APPROVED BY: *Signature*	Dr Valerie Godfrey, TASC QA Manager, Chair of Clinical Research Guidelines Committee 	01 Mar 2023