Office for Research

SOP-RTM-13

OFF-SITE ARCHIVING

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DO NOT USE THIS SOP IN PRINTED FORM WITHOUT FIRST CHECKING IT IS THE LATEST VERSION

1. PURPOSE:

This SOP describes the procedure for off-site archiving of clinical research studies.

2. BACKGROUND

All essential documents relating to a clinical trial must be archived in accordance with this SOP and the requirements of the International Conference on Harmonisation Good Clinical Practice (ICH GCP) guidelines (hereafter referred to as GCP).

The National Statement on Ethical Conduct in Human Research 2023 identifies that with respect to the retention, storage and subsequent disposal of the data and information, researchers:

a. must adhere to the ethical principle of respect for persons (e.g. with regard to culture and beliefs of the participants);
b. should maintain the confidentiality of individuals in accordance with any assurances made to them (e.g. during the consent process); and
c. should be aware of and adhere to applicable national and/or state or territory codes and legislation, as well as to relevant international guidelines and regulation.

3. SCOPE:

All clinical research studies, including clinical trials, conducted at Epworth.

4. APPLICABILITY:

This applies to all:

- Archiving of paper or other physical records
- Epworth employees, non-employed staff and Visiting Medical Officers (VMOs) and to all relevant external persons or parties engaged in the research activity at Epworth.

5. RESPONSIBILITIES:

Trial Sponsor – is responsible for informing the PI when a trial may be archived and destroyed.

The Principal Investigator (PI) is responsible for:

- Ensuring clinical research and trial archiving activities are conducted in accordance with this SOP.
- Supervising any activities described in this SOP that have been delegated to ensure they are conducted appropriately.
- Ensuring that any delegation of research or trial activities are recorded on the delegation log. The PI remains responsible for any delegated activity.
- N.B. If the PI leaves the study, the PI must delegate the responsibility of archiving to another person.

Group Manager Research Operations (GMRO) – is responsible for oversight of the archiving process.

6. DEFINITIONS

N/A

7. PROCEDURE:

Minimum timeframes for storage of research records are described in the table below:

Document/Study type	Archiving timeframes
Clinical trial data	Minimum 15 years for adult trials* Minimum 25 years for paediatric trials*
Trial participant's medical files	Minimum of 15 years and in accordance with applicable legislation
Gene therapy research data	Permanently
General Research	Minimum 7 years
Quality Assurance	Minimum 12 months

*The TGA position on document retention states: "The TGA requires records to be retained by the sponsor for 15 years following the completion of a clinical trial. However, in Australia the overriding consideration for sponsors with respect to record retention is the issue of product liability and the potential need for sponsors of products to produce records at any time during, and possibly beyond, the life of a product in the event of a claim against the sponsor as a result of an adverse outcome associated with the use of the product."

7.1 Trigger for archiving

a. The research files or Investigator Site Files (ISF) will be prepared for archiving at the end (i.e. completion or termination) of the research study or clinical trial.

b. For clinical research studies, the principal investigator will confirm that the study final report has been acknowledged by the HREC (if applicable) and Epworth Office for Research.

c. For clinical trials, the Monitor will discuss record retention requirements during the Close-Out Visit, and the PI will usually be asked to sign the Sponsor agreement regarding archiving requirements.

7.2 Preparing for archiving

a. The PI should inform the GMRO/OfR of the decision to archive in writing when:

- For research studies – The PI has confirmed the study has been completed and the trial can be archived.
- For clinical trials – the PI has received notification from the sponsor that the trial can be archived.

b. The study team should:

- Check the research files are complete and there are no missing documents.
- Request enough storage boxes for the documents from the GMRO.

c. The GMRO or delegate will arrange for the delivery of the requisite number of storage boxes to the team.

7.3 Archiving study documentation

a. Archiving is undertaken by a member(s) of the study team under the direction of the PI. The GMRO will offer all reasonable advice / assistance to ensure that the task is carried out in accordance with this SOP.

b. For each study an Archive Document Log (SOP-RTM-13 TEMPLATE-01) is required to be completed to record all documents that are archived in each box.

c. Only essential documents are to be archived. All files, folders and plastic outer protective coverings (where applicable) and paperclips should be removed before placing in the archive box. Paper coverings to separate documents within the archive box are advisable to ensure integrity of file.

d. Each study should be boxed separately i.e. documents from different trials should not be mixed.

e. For each study a copy of the completed Archive Document Log is to be sent to the GMRO/OfR for the Record Retention Master File.

f. For each study an archive label (SOP-RTM-13 TEMPLATE-02) must be completed and attached to the top and side of each box to be archived.

g. Once the PI is satisfied that all relevant documents for the study have been archived, the GMRO/OfR will record the contents/documents which are to be archived on the Record Retention Master File before delivery of the boxes to the archiving facility.

h. The PI or designee must inform the Sponsor of archiving arrangements and which documents will be stored in the appointed archive. The Sponsor must be informed if any changes are made to archiving arrangements.

7.4 Archiving for trials abandoned in start-up

a. For trials abandoned prior to ethics and Governance approval, archiving is the responsibility of the sponsor.

b. The trial team will need to liaise closely with the Sponsor on how to store these documents.

c. Where a Sponsor confirms that archiving is required at the local facility used by Epworth, the sponsor will be required to pay an archiving fee. In these cases, the study team should contact the GMRO to determine value of the archiving fee.

7.5 Retrieval and Return of Archived Items

a. Only the GMRO can authorise and arrange the retrieval of any item and/or box from the archive facility, on receipt of a written request from the PI or delegate. In the absence of the GMRO, the Group Director of Research will have delegated responsibility to authorise these requests.

b. A minimum period of 3 working days is required for the retrieval of archive boxes.

c. The PI/delegated person should forward written advise, by e-mail or letter, to the GMRO when the item(s) / box(es) are ready to be returned to the archived.

d. Trial documents should be made available for inspection by any appropriate regulatory authority.

7.6 Destruction of Archived data

a. Records must not be destroyed prior to the minimum required storage period for the study type.

b. Chief Medical Officer (CMO) or delegate approval must be obtained prior to destruction of research records.

c. For clinical trials, the Sponsor should notify the PI in writing when the trial records can be destroyed. If this does not happen routinely, the PI will contact the Sponsor to confirm destruction dates.

d. The OfR will request approval from the CMO to destroy archived records on receipt of notification of intention to destroy the records from the study PI.

e. The reasons for destruction of essential documents shall be documented by the GMRO or delegate on the Record Retention Master File.

8. DISSEMINATION AND IMPLEMENTATION

This SOP will be disseminated by the OfR. Updates will be made available with details of planned dates of implementation.

9. MONITORING COMPLIANCE AND EFFECTIVENESS

Compliance with this SOP will be monitored as part of OfR monitoring processes. Any problems or potential problems concerning the effectiveness of this SOP may be identified during OfR monitoring process or through users informing the OfR.

10. REVIEW AND UPDATING

This SOP will be reviewed every three years, or whenever there are changes to legislation or working practices that impact upon the content of this document. This SOP may be merged with another SOP if appropriate or removed entirely if it becomes redundant.

11. REFERENCES:

- Integrated Addendum to ICH E6 (R2): Guideline for Good Clinical Practice E6 (R2) https://www.tga.gov.au/publication/note-guidance-good-clinical-practice
- National Statement on Ethical Conduct in Human Research 2023 https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2023#block-views-block-file-attachments-content-block-1

12. RELATED DOCUMENTS:

12.1 Related Forms and Templates

- SOP-TM-13-TEMPLATE-01 Archive Document Log
- SOP-TM-13-TEMPLATE-02 Archive Box label

12.2 Related SOPs

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13. VERSION CONTROL:

Document History			
Version	**Date**	**Summary of Changes**	**Author**
1.0	6/5/2019	N/A - First Issue	Helen Christensen
2.0		Update header format. Update title to 'Off-site Archiving' to reflect the purpose of the SOP. Update Section 1 Purpose –	Sarah Rickard

		• Simplify and clarify is for Off-site Archiving of paper or other physical records for clinical research studies. • Move first two paragraphs of section 1. Purpose to section 7. Procedure. Add section 2. Background and 5. Responsibilities Update Section 3 Purpose – simplify and clarify the SOP applies to all clinical research studies, not just clinical trials. Update Section 4. Applicability, to include archiving of paper or other physical records. Expand purpose and scope to cover all clinical research. Section 7. Procedure, move responsibilities described to section 5. Responsibilities Add subheadings 7.1 Trigger for archiving and 7.2 Preparing for archiving Section 7.3: Addition of TEMPLATE-02 Archive Box label. Reference to staples and tape needing to be removed deleted. Section 7.6 – add requirement for CMO to approve document destruction. Add sections 8, 9, 10 for SOP document dissemination, monitoring and review. Update format of version control history table.	

14. APPENDIX

N/A