STANDARD OPERATING PROCEDURE (SOP):

TITLE: TRIAL ARCHIVING

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TITLE: TRIAL ARCHIVING

1. PURPOSE:

All essential documents relating to a clinical trial must be archived in accordance with this SOP and the requirements of ICH GCP R2.

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

The purpose of this SOP is to define the local procedure for preparing clinical trial records at Epworth HealthCare (Epworth) and their subsequent transfer to an archiving facility.

2. SCOPE:

All clinical trials conducted at Epworth.

3. APPLICABILITY:

This applies to all 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.

4. GLOSSARY OF TERMS:

Please refer to Epworth SOP Glossary of Terms (see Related Documents).

5. PROCEDURE:

The Principal Investigator (PI) is responsible for ensuring trial archiving activities are conducted in accordance with this SOP. The PI is responsible for supervising any activities described in this SOP that have been delegated to ensure they are conducted appropriately. Delegation of trial activities must be recorded on the delegation log. The PI remains responsible for any delegated activity.

- It is the responsibility of the trial Sponsor to inform the PI when a trial may be archived. It is the responsibility of the PI or appropriate delegate to ensure that all site essential study documentation is retained and archived according to ICH GCP R2 Section 8.
- The PI or designee must inform the Sponsor of archiving arrangements and which documents will be stored in the appointed archive. The Research Operations Manager (ROM) will be responsible for the archiving process at Epworth. The Sponsor must be informed if any changes are made to archiving arrangements.
- For clinical trials, data should be retained for a minimum of 15 years for adult studies or 25 years for paediatric studies.
- For areas such as gene therapy, research data must be retained permanently.
- 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."

- A clinical trial participant's medical files should be retained for a minimum of 15 years and in accordance with applicable legislation.

- Any trials that were abandoned prior to ethics and Governance approval are the responsibility of the Sponsor and the trial team will need to liaise closely with the Sponsor on how to store these documents. If the Sponsor confirms that archiving is required at the local facility, an archiving fee will apply. Any requests should be forwarded to the ROM.

  N.B. If the PI leaves the study, the PI must delegate the responsibility of archiving to another person.

5.1 Completion of the trial following close out procedures

- During the trial Close-Out Visit, the Monitor will discuss record retention requirements, and the PI will usually be asked to sign the Sponsor agreement regarding archiving requirements.

- When the PI has received the notification from the Sponsor that it is appropriate to archive the trial the ROM should be informed, by e-mail or letter, of the decision.

- The ROM will arrange for the delivery of the requisite number of storage boxes.

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

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

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

- Each trial should be boxed separately i.e. documents from different trials should not be mixed.

- For each trial a copy of the completed Archive Document Log is to be sent to the ROM for the Record Retention Master File.

- For each trial an archive label must be completed and attached within a plastic pocket to the top of each box to be archived.

- Once the PI is satisfied that all relevant documents for the trial have been archived, the ROM 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.

5.2 Retrieval and Return of Archived Items

- Only the ROM can authorise and arrange the retrieval of any item and/or box from the archive facility, on receipt of a request from the PI or delegate. A minimum period of 3 working days is required for the retrieval of archive boxes. In the absence of the ROM, the Group Director of Research and Development will have delegated responsibility to authorise these requests.
- The PI/delegated person should advise, by e-mail or letter, to the ROM when the item(s) / box(es) are ready to be re-archived.
- Trial documents should be made available for inspection by any appropriate regulatory authority.

5.3 Destruction of Archived data

- 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.
- The reasons for destruction of essential documents shall be documented by the ROM on the Record Retention Master File.

6. REFERENCES:

- Integrated Addendum to ICH E6 (R1): Guideline for Good Clinical Practice E6 (R2) https://www.tga.gov.au/publication/note-guidance-good-clinical-practice

7. RELATED DOCUMENTS:

7.1 Related Forms and Templates

- SOP-TM-13-TEMPLATE-01 Archive Document Log

7.2 Related SOPs

- SOP-Glossary-of-Terms

8. VERSION CONTROL

Document History	
Version	Summary of Changes
1.0	N/A – First Issue

9. APPENDIX

N/A