STANDARD OPERATING PROCEDURE (SOP):

TITLE: INVESTIGATOR SITE FILE AND ESSENTIAL DOCUMENTATION

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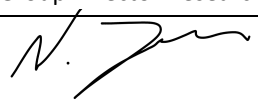
Signature:	
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1. PURPOSE:

The purpose of this SOP is to describe the procedures related to the maintenance of the Investigator Site File (ISF) and associated essential documents for clinical trials at Epworth HealthCare (Epworth).

2. SCOPE:

Applicable to 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 maintenance of the ISF and associated essential documents is in accordance with this SOP. The PI can delegate at his/her discretion certain trial duties to suitably qualified individuals. Delegation of trial activities must be recorded on the delegation log. The PI remains responsible for any delegated activity.

5.1 The Investigator Site File and Essential Documents

The PI and/or delegate must:

- File essential documents in the ISF at the site in a timely manner. All site-related documents should be made available for review, by auditors or regulatory authority(ies) and the sponsor's representatives for all sponsored trials (the ISF can be maintained electronically in SiteDocs or as a hard copy version).
- Keep a minimum list of essential documents (as applicable to the research project) from the following stages of the trial (as per ICH GCP R2 Section 8 [1]).
    - Before the clinical phase of the trial
    - During the clinical conduct of the trial
    - After completion or termination of the trial
- Ensure trial documentation is maintained and archived as per SOP-TM-13: Trial Archiving.

5.2 Documentation of Investigational Site Qualifications and Training Records

The PI and clinical trial staff must:

- Maintain an up-to-date *Curriculum vitae* (CV) (as per SOP-QA-01: Documentation of Qualifications and Training Records) and ensure this is filed in the ISF prior to the commencement of the trial.
- Be qualified by education, training, and experience to assume responsibility for the proper conduct of the research. This should be evidenced in the CV and other training documents and certificates (see also SOP-RG-04: Researcher Credentialing).
- Meet all the qualifications required for the type of research to be undertaken and as specified by the applicable regulatory requirement(s) or sponsors for sponsored clinical trials (as applicable).
- Maintain a list of appropriately qualified persons to whom the PI has delegated significant trial-related duties. The list is in the form of a Delegation Log and delegated duties should be captured and signed and dated by the PI on a per person basis before they start any trial-related activities. A delegation log is usually provided by the Sponsor for Commercially Sponsored clinical trials.

5.3 The Investigator Site File

- The site file should contain all the applicable essential documentation referred to in ICH-GCP R2 section 8.
- For commercially sponsored studies, sponsoring companies will normally provide the ISF complete with tab separators for ease and consistency of filing.
- For trials conducted on behalf of smaller companies, which may not provide the ISF structure, and for investigator initiated trials, the ISF should be structured in accordance with the Drug Information Association (DIA) TMF reference model.
- Agreements (collaborative, funding, loan equipment, Clinical Trial Research Agreement etc.) and financial information (budgets, invoicing etc.) may be filed in a separate location to the ISF.
- For trials involving investigational products or other medicines, the site pharmacy will usually keep investigational product shipping, receipt and accountability documents in the Pharmacy Site File (PSF). Researchers at the site itself do not have to replicate these documents. However, the records must be made available to Sponsors monitors and auditors.
- The ISF and PSF can be consolidated into one at the end of the study.

6. REFERENCES:

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

- Drug Information Association (DIA) TMF reference model https://tmfrefmodel.com/

7. RELATED DOCUMENTS:

7.1 Related Forms and Templates

7.2 Related SOPs

- SOP-QA-01 Documentation of Qualifications and Training Records
- SOP-RG-04 Researcher Credentialing
- SOP-TM-13 Trial Archiving
- SOP-Glossary-of-Terms

8. VERSION CONTROL

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

9. APPENDIX

N/A