STANDARD OPERATING PROCEDURE (SOP)

TITLE: SOURCE DOCUMENT MANAGEMENT

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Document ID:	SOP-TM-07
Version No:	2.0
Date Authorised:	Date of Approval
Effective Date:	03 Jun 2020
Review Date:	03 Jun 2023
Applicable Epworth Site/s:	All

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Date:	Jun 3, 2020

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1. PURPOSE:

The purpose of this SOP is to document the procedure for the preparation, approval and control of source documentation during the conduct of clinical research in compliance with ICH GCP guidelines[1] and relevant Epworth protocols[2,3].

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 the source documentation for a clinical trial is managed in accordance with this SOP. The PI can delegate at his/her discretion certain trial duties to individuals where appropriately qualified by education, training and experience (see also *SOP-TM-14 Delegation of Duties*). Delegation of trial activities must be recorded on the delegation log. The PI remains responsible for any delegated activity.

5.1 Preparation of Source Documents

- At Epworth, source data are collected through (but not limited to) the following methods:
    - Study specific worksheets (Template 1). These worksheets are based on the schedule of events defined in the trial protocol.
    - Scanned Medical Records (SMR) systems
    - Paper medical records
    - Clinical results from laboratory and medical imaging portals
- Study specific worksheets shall be created, as required, to capture trial specific data. A second research staff member, familiar with the trial, will perform a quality control (QC) check of the prepared worksheet to ensure that all items reflect the current protocol. This QC check will be documented by an email from the QC checker confirming the appropriateness of the worksheet.

- The study specific worksheets should be updated whenever an amendment to the protocol requires changes.
- The following items should be included in the study specific worksheets:
    - Header/footer information on each page clearly displaying the Study ID, visit date, Study participant ID, study participant initials and pagination
    - Checklist of expected assessments to be done for the visit and comment section to make notes
    - Data points to be collected for each assessment/ procedure with comments section to indicate any assessments not done or capture any variations in procedures
    - Signature and Date fields for each assessment

5.2 Collection of Source Data

- The PI is responsible for maintaining adequate and accurate source documents and trial records that include all pertinent observations on each of the Epworth trial participants.
- Where trial source data is entered into the Epworth SMR system the PI will ensure this is in accordance with the Epworth Health Information Documentation Protocol[2] and Health Information - Health Records Management Protocol[3].
- Source data in the source documents should be:
    - Attributable – it should be clear who made the entry
    - Legible – the entry must be easily read and understood
    - Contemporaneous – data should be recorded, signed, and dated at the time of trial conduct
    - Original – the entry must be the first place the information was recorded
    - Accurate – the entry must reflect what occurred
- Any changes to source data must be traceable, should not obscure the original entry and should be explained if necessary. Any change or correction to a paper CRF should be made with a single stroke through the incorrect information, dated, initialled, and explained (if necessary). Electronic source documents must have an inbuilt audit process to track changes to the data.
- Any biological samples/ specimens collected as per protocol should indicate if the test was Done/ Not Done on the study specific worksheet.

- Laboratory results should be reviewed and signed off as soon as possible by the PI as part of standard medical practice and patient care. Where the result is out-of-range the PI should indicate if this is clinically significant or not.
- Entries for timed serial evaluations/specimen collection (e.g. vital signs, pharmacokinetic studies etc.) must also note times on the study specific worksheet, if required by the protocol.
- If data are unavailable, an explanation should be written on the study specific worksheet with as much relevant detail as possible.
- Any paper CRFs, questionnaires, patient reported outcomes, diary data applicable to the study should be completed to the same standards as described above to maintain data integrity.
- Any data completed directly by the trial participants must be stored along with the study specific worksheets in the respective participant binders. It should be noted when any documents completed by the participant are sent and received, and where the information provided is incomplete or absent.

5.3 Access to Electronic Source Data

See *SOP-TM-09 Management of Remote and On-site Monitoring Visits* for further details regarding the arrangements for trial monitor access to electronic source data at Epworth.

5.4 ECGs

ECG Strips shall be reviewed and signed by the PI or suitably-qualified delegate and filed in the participant folder along with a photocopy if heat resistant paper has been used for the ECG.

5.5 Visiting Medical Officer's (VMOs) Source Data

If a participant is seen by a VMO in their private rooms for a clinical trial, the source documents created in those rooms (including medical records) must be available for review by the Sponsor's monitor or audits/inspections carried out by the ethics committee, Sponsor or regulatory agencies. These records must be maintained and archived according to the requirements in the trial protocol or contract.

5.6 Handling Personal Information

Personal Identifiable Information (PII) should be handled responsibly and should not be transmitted in a way that could cause loss of data or allow interception by unauthorised parties. For all laboratory reports, scans and other source documents which will be sent to the Sponsor, Contract Research Organisation (CRO) or other third parties, a copy should be made and any PII redacted from that copy before it is sent.

5.7 Archiving

Study source documentation should be kept in a secure location during the course of the study. On completion of the study, source documentation should be archived as per the trial protocol or contract (see also *SOP-TM-13 Trial Archiving*).

6. REFERENCES & RELATED DOCUMENTS:

The Epworth Research Policy, handbook, SOPs and supporting forms and templates can be found on the *Epworth Resources for Researchers* webpage.

1. *Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice E6(R2) - Annotated with TGA comments*
2. *Epworth, 2017. Health Information Documentation Protocol*
3. Epworth, 2012. *Health Information - Health Records Management Protocol*

6.1 Related Forms and Templates

- SOP-TM-07-TEMPLATE-01 Study Specific Source Data Worksheet

6.2 Related SOPs

- SOP-TM-09 Management of Remote and On-Site Monitoring Visits
- SOP-TM-13 Trial Archiving
- SOP-TM-14 Delegation of Duties
- SOP-Glossary-of-Terms

7. VERSION CONTROL

Document History	
Version	**Summary of Changes**
1.0	N/A First Issue
2.0	**Section 5.3** updated to include reference to SOP-TM-09 Removal Appendix A (transferred to SOP-TM-09) SOP formatting and hyperlinks updated.