**STANDARD OPERATING PROCEDURE (SOP):**

**TITLE: SOURCE DOCUMENT MANAGEMENT**

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

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| Signature:         | ![Signature]       |

| Date:              | 26 Apr 2019        |
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 at Epworth HealthCare (Epworth).

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 suitably qualified individuals. 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.
  - Electronic Medical Records (EMR) 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:
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.

- 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 Electronic Source Data

For data from EMRs, two options are available to allow Monitors from the Sponsor to review the data in the EMR:

1. Secure, restricted, direct access to the EMR (see Appendix A). The Monitor should only be able to view the EMRs of participants in the trial.

2. If direct access to the EMR is not possible, the CTC should print all of the EMR and certify them as a true copy. These copies of the EMRs will be filed in the participant folder before each monitoring visit.

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.

6. REFERENCES:

1. Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice E6(R2)

   6.1 Relevant Epworth Policies
   - Privacy of Health Information Policy
   - ICT - Acceptable Use of Resources Policy
   - Password Security Policy

7. RELATED DOCUMENTS:

   7.1 Related Forms and Templates
   - SOP-TM-07-TEMPLATE-01 Study Specific Source Data Worksheet

   7.2 Related SOPs
   - SOP-Glossary-of-Terms

8. VERSION CONTROL

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<tr>
<td>1.0</td>
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9. **APPENDIX A: Setting-Up Trial Monitor Access to BOSSnet**

Access to EMR at Epworth HealthCare is strictly controlled to ensure confidentiality of patients’ medical and personal information. Clinical Trial Monitors are regarded as “non-staff” and do not have the same level of access to medical records as Epworth employees. If Source Data Verification involves reference to electronic records a temporary account must be created by IT. This temporary account provides restricted access to only those patients identified as participating in the trial to be monitored.

For IT purposes there are two types of non-staff accounts:

- Monitors who **have never had** IT access before and need to have an account created
- Monitors who **have had** IT access before and need to **have their account re-activated prior to any monitoring visit** (e.g. their previous password may have expired between visits).

### 9.1 PROCEDURE

The PI or delegate is responsible for requesting IT access for Clinical Trial Monitors. **Remember to allow at least 5 business days for the account to be created or re-activated by IT.**

**For monitors who have NEVER monitored at Epworth before:**

- This person will need to have a new account **enabled**.
- Go to the IT website *Non-Staff IT Access Request form:*  
  [https://legacyintranet.epworth.org.au/forms/iscomputeraccess/NonStaffReq.asp](https://legacyintranet.epworth.org.au/forms/iscomputeraccess/NonStaffReq.asp)
- In the “staff member’s manager” provide Trial Co-ordinator details.
- Cost centre is “Research, Clinical Trials, and Governance”. Please pick your division as appropriate for the External Contractor.
- When you click BOSSnet a small text box appears. It asks for you to identify the name of another person who does the same role as the monitor. For this request put your name in this box (see below)
In the last text box on the form you need to indicate:

a. Write a specific request for IT to action: “Please enable/re-enable non-staff user access to Windows and BOSSnet for John Smith”

b. Enter start and stop dates for access to IT services like BOSSnet

c. List the patients’ names and UR numbers. Separate each patient with a semicolon (;) to make it easier for IT to read (see below)

Requests can take up to 5 business days to be processed.

Once processed IT Department will provide an email directly to the Trial Monitor containing the appropriate Log-in details.
For monitors who have PREVIOUSLY monitored at Epworth before:

- This monitor will need to have their existing account **re-enabled**. There is a possibility the account has been disabled due to inactivity or mandatory requirement for a password change.

- Current clinical trials staff members now have authorised access to email IT directly (rather than use the form as indicated in section 5.1 for monitors who have never worked here).

- Send an email to the IT helpdesk - ServiceDesk@epworth.org.au

- Put something relevant in the Subject heading, e.g. *Please enable/re-enable non-staff user access to Windows and BOSSnet for John Smith*.

- Provide a start date and a stop date. This is so IT can provide the correct level of restricted access to coincide with the monitor’s visit

- List the patients and their UR numbers in the email (see example below)