STANDARD OPERATING PROCEDURE (SOP):

TITLE: HOSTING AN AUDIT OR INSPECTION

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1. PURPOSE:

The purpose of this SOP is to document the procedures at Epworth HealthCare (Epworth) prior to, during and after an external audit or an inspection is performed.

2. SCOPE:

All research conducted at Epworth; all documents (trial related and administrative) and SOPs currently effective may be subject to the audit/ inspection.

3. APPLICABILITY:

This applies to all Epworth employees, non-employed staff and Visiting Medical Officers (VMOs) and to all relevant external persons and 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:

5.1 PRIOR TO THE AUDIT/ INSPECTION

5.1.1 Any Epworth clinical research employee who receives notification of a possible or confirmed forthcoming inspection/audit should immediately inform their line manager and the Research Development and Quality Officer (RDQO).

5.1.2 The Group Director of Research and Development and Research Operations Manager are to be immediately advised by the RDQO of the possible or confirmed forthcoming inspection/audit.

5.1.3 The Sponsor should also be informed of any inspection or audit which is not Sponsor-driven (e.g. by a Human Research Ethics Committee - HREC audit or regulatory inspection).

5.1.4 A person responsible for coordinating actions during the audit/inspection will be appointed by senior management.

5.1.5 The trial team should organise an internal meeting with all stakeholders and any third party vendors (e.g. pharmacy, imaging) to prepare for the audit/inspection.

5.1.6 The trial team should be aware of the purpose and scope of the audit/inspection, when the audit/inspection is scheduled, who should be present, and/or be available. Generally, the auditor/inspector will send a notification of the upcoming audit/inspection including the scope and agenda of the audit. If this information is available, the person responsible for coordinating the audit should make sure that all stakeholders have a copy of this document.

Any correspondence from the auditor/inspector regarding the audit/inspection should be forwarded to Research Development and Governance Unit (RDGU).

5.1.7 The trial team should check that all documents and correspondence pertaining to the study audit are available, easily accessible, and updated.

5.1.8 The trial team should ensure that the list of study personnel/delegation of responsibilities log is current, accurately reflects all personnel who have been involved in the study, and that the activities they performed in the trial match the activities delegated to them.

5.1.9 The trial team should check that current curriculum vitae, updated Good Clinical Practice (GCP) certification (within 3 years), relevant training certifications evidencing qualifications of investigators, and medical licenses (if applicable) are in the Investigator Study File (ISF).

5.1.10 The trial team should ensure the ISF is aligned with ICH GCP, well organised and complete with all versions of all documents available.

5.1.11 The trial team should check that all training logs for trial staff are current and complete.

5.1.12 The trial team should ensure that source data in the source document are attributable, legible, contemporaneous, original, and accurate (ALCOA). Please refer to SOP-TM-07 Source Document Management.

5.1.13 A designated audit/inspection room should be booked on the Epworth email system.

5.1.14 On arrival, the auditor/inspector must not be given further access to the facility or be allowed to commence any activity until the Epworth person responsible for coordinating the audit/inspection has been notified and confirmed the auditors/inspectors' details.

5.2 DURING THE AUDIT/ INSPECTION

5.2.1 The PI and trial team should be present during the start and end of the audit/inspection.

5.2.2 All the appropriate trial staff should make themselves available in person (or phone, in exceptional circumstances) to answer any questions during the audit/inspection.

5.2.3 The auditor/inspector must be accompanied at all times when outside of the designated audit/inspection room.

5.2.4 During an inspection it is advisable to have a note taker present to record interviews.

5.2.5 Any comments or observations made by the auditor/inspector should be recorded in writing and reviewed by the trial team at the end of each day.

5.2.6 Original documents may be provided to the auditor/inspector but may not be retained by them. The auditor/inspector may be given copies of documents to retain if the documents have been de-identified and stamped as an exact copy. A list of all copied documents provided to the auditor/inspector should be maintained.

5.2.7 The taking of photographs, the use of tape recorders or other electronic equipment, access to databases and the review of internal audit reports by the auditors/inspectors will not be permitted without legal review or written approval.

5.2.8 The auditor/inspector may request a facility tour to view the laboratory, clinic rooms, testing equipment and investigational product storage area. If this was specified in the agenda, ensure that the relevant stakeholders (for instance, laboratory staff and ward nurses etc.) know about this tour and are prepared to answer any questions from the auditor/inspector.

5.3 AFTER THE AUDIT/ INSPECTION

5.3.1 At the end of the audit/inspection, the auditor/inspector will usually hold a close-out meeting with the PI(s) and trial team to discuss general observations and findings during the audit/inspection, and to inform the site of the next steps in the audit/inspection process.

5.3.2 The close-out meeting is an opportunity to clarify or discuss any findings.

5.3.3 In case there are any observations or findings that cannot be resolved immediately, the trial team can request additional time to provide evidence to the auditor/inspector at a later date.

5.3.4 In accordance with their own guidelines, the auditor/inspector may issue a formal report of the audit/inspection findings (if any) and the timelines to action and close each item at a later date. Some Sponsors do not issue audit reports to sites but will follow up with specifics site to action any findings.

5.3.5 For all critical findings or serious breaches of GCP and/or regulatory requirements identified in the audit/inspection, the Epworth trial team should implement a corrective and preventive action plan (CAPA). Please refer to SOP-QA-02 Management of Serious Breaches and CAPA Process'.

5.3.6 Following the audit/inspection, the trial team should conduct an internal meeting to de-brief, evaluate the audit/inspection and communicate any required actions to the unit. The trial team should ensure that relevant staff members have been delegated tasks that were raised during the audit/inspection and ensure that the required actions in response to the finding(s) are completed within the appropriate timeframe.

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

7. RELATED DOCUMENTS:

7.1 Related Forms and Templates

N/A

7.2 Related SOPs

- SOP-QA-02 Management of Serious Breaches and CAPA Process
- SOP-TM-07 Source Document Management
- SOP-Glossary-of-Terms

8. VERSION CONTROL

Document History	
Version	Summary of Changes
1.0	N/A First Issue
1.1	• To broaden the scope to include all research. • To include notification to RDGU for any correspondence of audit/inspection. • To emphasise having relevant training certificates, and proper source document management in ISF • Minor corrections on formatting.

9. APPENDIX

N/A