STANDARD OPERATING PROCEDURE (SOP):

TITLE: DELEGATION OF DUTIES

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STANDARD OPERATING PROCEDURE (SOP):

TITLE: DELEGATION OF DUTIES

1. PURPOSE:

The purpose of this SOP is to document the procedure for delegation of authority by the Principal Investigator (PI) to Research Personnel at Epworth HealthCare.

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 PI is responsible for the training of all Investigators and Clinical Trial staff. The PI can delegate tasks but still maintains overall responsibility for the conduct of the study at the site. Delegation of tasks by the PI allows other suitably qualified and trained clinical research staff to actively participate in the implementation and conduct of a trial at the site.

5.1 Completion of Delegation of Authority Log (DOAL)

The DOAL is completed by site staff actively involved in the study after they have received proper study training (see SOP-QA-01 Documentation of Qualifications and Training Records) and prior to taking part in any study activities. Where there is no DOAL provided by the Sponsor, FORM-01 Delegation of Authority Log can be used (see Section 7.1 Related Forms and Templates).

When completing the DOAL

- The PI and staff delegated responsibility must personally complete their name, signature and initials when completing the log.
- All Information entered in the log must be accurate, legible, contemporaneous and complete.
- The PI must acknowledge that the delegation of tasks is accurate, by initialling and dating each line entry on the log.

The log should be updated as staff are added or removed and/or study roles and responsibilities change.

If, for example, the tasks allocated to a staff member change during the course of a trial

- An "End Date" should be entered against the name of the staff member whose task allocation is changing.
- A new line is then created with the updated delegated study tasks.

No study related procedures should be performed by staff before DOAL approval by the PI.

5.2 Staff Indirectly Involved in Trial Conduct

Staff who as part of their routine practice complete a procedure (i.e. vital signs, Electrocardiography (ECG), venepuncture or imaging) on a patient who may also be participating in a clinical trial will not be considered part of the study team. As such they are not required to undertake clinical trial education, training and delegation. This may include, but is not limited to:

- Clinicians
- Specialist nurses
- Nurses
- Laboratory staff
- Ophthalmologists
- Radiologists
- Pathologists
- Pharmacists
- Technicians.

The PI is responsible for the oversight and interpretation of the results provided from the above mentioned staff and the required actions.

5.3 Departmental Responsibilities

Departments may have clinical trial related duties (i.e. intravenous investigational product administration) assigned to them by the PI. A named person will assume responsibility for the conduct of such activity on behalf of the department and as such will be delegated this task on the DOAL. The named person will be required to undertake appropriate protocol training relevant to the undertaken activity.

5.4 Change of Principal Investigator, General

If, a permanent change of PI is necessary, or if this role needs to be temporarily delegated to another Investigator (e.g. PI absence from site for an extended period), the PI should inform the

Sponsor/Clinical Research Organisation (CRO) and the Human Research Ethics Committee (HREC) of the change using the following forms (see Section 7.1 Related Forms and Templates):

- FORM-02 Notification - Change of Principal Investigator; or
- FORM-03 Notification – Temporary Delegation of Principal Investigator Responsibilities.

Any other documentation requested (e.g. Curriculum Vitae) should also be provided.

Once all necessary approvals for the change of PI are received the DOAL is updated. Any documents associated with the delegation of authority are filed in the Investigator Site File.

5.4.1 Permanent Change of Principal Investigator

For a permanent change of PI, the DOAL must be updated as follows

- An end date must be completed for the PI who is leaving. The new PI should add themselves to the delegation log as per the usual process described in section 5.1.
- If the new PI agrees with the previous delegations assigned to site staff this should be specified in the comments section of the DOAL and signed and dated.
- If a Sub-Investigator on the trial is delegated PI responsibilities, an end date should be entered on their line entry as Sub-Investigator on the DOAL, and should be initialled and dated by the PI.
- If changes are made to tasks allocated to staff, the procedure outlined in Section 5.1 should be followed.

5.4.2 Temporary Delegation of PI Responsibilities

For a temporary delegation of PI responsibilities, the DOAL should be updated as follows

- The temporarily delegated PI should start a new line entry on the DOAL listing that they are responsible for all tasks. This should be initialled and dated by the PI.
- If a Sub-Investigator on the trial is delegated PI responsibilities, an end date should be entered on their line entry as Sub-Investigator on the DOAL and should be initialled and dated by the PI.
- If changes to the DOAL occur during the delegation period these are processed as usual and initialled and dated by the delegated PI. Once delegation has ended, the changes are countersigned by the PI or a comment confirming agreement is made in the comments section which is signed and dated by the PI.
- When the delegation has ended DOAL is updated as outlined in Section 5.1.

5.5 End of Study

At the end of the study, an "end date" must be entered for all staff still actively involved in the study and initialled and dated by the PI where required. The completed DOAL must be archived with the study ISF.

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-14-FORM-01 Delegation of Authority Log (DOAL)
- SOP-TM-14-FORM-02 Notification-Change of Principal Investigator
- SOP-TM-14-FORM-03 Notification-Delegation of Principal Investigator Responsibilities

7.2 Related SOPs

- SOP-Glossary-of-Terms
- SOP-QA-01 Documentation of Qualifications and Training Records
- SOP-TM-02 Investigator Site File and Essential Documentation

8. VERSION CONTROL

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

9. APPENDIX

N/A