STANDARD OPERATING PROCEDURE (SOP):

TITLE: TRIAL CLOSEOUT

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TITLE: TRIAL CLOSEOUT

1. PURPOSE:

The purpose of this SOP is to document the procedure to formally close a study to recruitment, put a study on hold or close-out a clinical trial.

2. SCOPE:

All clinical trials conducted at Epworth HealthCare (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 clinical trial is conducted 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 Closing a Study to Recruitment

- This section applies to when a study is closed to recruitment but is still open for patients in follow-up.
- When closing a study to recruitment, the PI needs to ensure that the following people are made aware of the changed status as soon as possible:
    - The clinical trial team, as listed on the Delegation Log
    - Pharmacy, if applicable
    - Medical imaging, if applicable
    - Research Operations Manager for applicable trials
- The Investigator Site File (ISF) should be clearly marked that the study is closed to recruitment and that no new participants should be recruited.

5.2 Premature Termination or Suspension of a Clinical Trial

- If a trial is prematurely terminated or suspended for any reason, the PI should:

- Promptly inform the trial participants and include, where appropriate, the reason for premature termination/suspension of the clinical trial
- Assure appropriate therapy and follow-up for the trial participants

- The PI needs to ensure that the following people are made aware of the changed status as soon as possible:
  - Human Research Ethics Committee (HREC)
  - Epworth Research and Development Governance Unit (RDGU)
  - The clinical trial team, as listed on the Delegation Log
  - Pharmacy, if applicable
  - Medical imaging, if applicable
  - Research Operations Manager for applicable trials
  - Epworth Clinical Trial Finance personnel
- The ISF should be clearly marked that the trial is prematurely terminated or suspended and that no new patients should be recruited.
- If the PI terminates or suspends a trial without prior agreement of the Sponsor, the PI should promptly inform the Sponsor, HREC and the RDGU and provide them with a detailed written explanation of the termination or suspension

5.3 Final Site Close-out

- The PI needs to ensure that the following people are made aware of the closure of the trial:
  - Human Research Ethics Committee (HREC)
  - RDGU
  - The clinical trial team, as listed on the Delegation Log
  - Pharmacy, if applicable
  - Medical imaging, if applicable
  - Research Operations Manager for applicable trials
  - Epworth Clinical Trial Finance personnel
- The PI should:

- Keep trial documentation and correspondence in the ISF in accordance with ICH GCP R2 Guidelines Section 8.4
- Inform the Sponsor of the completion of the trial
- Ensure appropriate final accountability and disposal of any investigational product. This may include return to the Sponsor or destruction of remaining materials
- Ensure all protocol required data has been collected
- Verify all participant folder(s) for completeness
- Ensure all final signatures and dates are obtained eg. Delegation and training logs
- Ensure participant follow-up and data queries are finalised and electronically signed, if required
- Notify the HREC and RDGU of trial close-out and provide them with a final report from the Sponsor
- Receive notification from HREC acknowledging trial closure
- Organise archiving/storage of original data and documents either offsite or within Epworth
- Attend Sponsor Close Out meeting, if required

6. REFERENCES:

7. RELATED DOCUMENTS:

- SOP-Glossary-of-Terms

8. VERSION CONTROL

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

9. APPENDIX

Not Applicable