STANDARD OPERATING PROCEDURE (SOP):

TITLE: VENDOR ASSURANCE

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Document ID:	SOP-QA-04
Version No:	1.0
Date Authorised:	26 Apr 2019
Effective Date:	01 Jun 2019
Review Date:	01 Jun 2022
Applicable Epworth Site/s:	All

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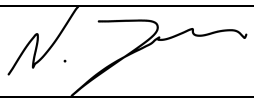
Signature:	
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1. PURPOSE:

The Principal Investigator (PI) must be able to demonstrate oversight and approval of third parties and any subcontracted duties[1]. This SOP describes the procedure for issuing and completing agreements required for such projects.

2. SCOPE:

All clinical trials conducted at Epworth HealthCare (Epworth) where a third party provider is subcontracted.

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:

The PI will obtain approval from the study Sponsor prior to engaging any third parties at the feasibility/ start-up/risk assessment stage of the trial. The PI shall also confirm whether the budget is in place, or has been applied for, to cover all third party activities.

- The PI has responsibility for ensuring all third parties are appropriately qualified/accredited and will obtain and keep copies of relevant accreditation/certification/ licenses (e.g. to manufacture/distribute MP), requesting and taking up references or remote/on-site audit.
- The PI shall ensure that all relevant documentation is provided to the third party in a timely manner i.e. research protocol, approved protocol amendments, associated documentation and copies of required approvals.
- The PI shall ensure that no activities are implemented by the third party until appropriate approval and contracts are in place.
- The PI or delegate will maintain regular contact with the third party/parties. Key correspondence and meeting minutes will be retained in the Investigator Study File (ISF).
- The PI will advise the third party of any protocol amendments that may impact the services that the third party has been engaged to provide

6. REFERENCES:

1. Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice E6(R2). Available from: 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-Glossary-of-Terms

8. VERSION CONTROL

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

9. APPENDIX

N/A