STANDARD OPERATING PROCEDURE (SOP):	
TITLE: SOP CREATION, IMPLEMENTATION AND REVISION	Epworth

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Date:	26 Apr 2019

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1. PURPOSE:

The purpose of this SOP is to document the procedure for the creation and implementation of new clinical research SOPs and review of existing SOPs at Epworth HealthCare (Epworth).

2. SCOPE:

This SOP applies to any individual delegated the task of writing, reviewing, approving or distributing a clinical research SOP on behalf of Epworth. This applies in all instances when a need is identified to either create a new SOP or modify an existing one.

3. APPLICABILITY:

This SOP applies to the designated SOP Author and relevant clinical research staff at Epworth. Authors of SOPs should have experience of the area covered by the SOP and be authorised to create or modify these.

4. GLOSSARY OF TERMS:

Please refer to the Epworth SOP Glossary of Terms (see Related Documents).

5. PROCEDURE:

5.1 Initiating the creation of a new SOP or revision of an existing SOP

All Epworth employees engaged in clinical research are encouraged to:

- Identify the need for a new SOP or modification of an existing SOP.

- Notify their manager and/or the Research Quality Coordinator (RCQ) via the SOP feedback form (see Related Documents).

5.2 The Research Quality Coordinator will:

- Assign a SOP Author (can be the RQC).

- Assess and verify the identified need and, if appropriate, assign a Document ID number to the new SOP or a new version number to a modified SOP.

- Ensure that Template-01 (see Related Documents) is used for all new SOPs.

- Maintain a Document Register of approved SOPs that includes as a minimum the Document ID, version number, approval date, effective date and review before date.

- Maintain a folder containing all approved SOPs, with their original signature blocks completed.

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5.3 Preparation of a new SOP or revision of an existing SOP

The SOP author will:

- For a new SOP, prepare a draft in accordance with the standard SOP Template which includes the following sections:

    o Purpose – briefly describe relevant background and the reason a SOP exists.

    o Scope – define which areas of work or staff the SOP applies to.

    o Applicability – to whom the SOP applies.

    o Procedure – details of the procedure in a clear and concise style.

    o Related documents and references – may include templates for use with the SOP.

- Use sub-section numbering (e.g. 6.1, 6.2, 6.3 etc.) as required to keep the document clear and easy to follow.

- For a modified SOP, edit the current version of the SOP – making appropriate alterations to the version number and date in the footer.

- Distribute the draft new or modified SOP to the RQC, or other designated individuals, for review and comment.

- Incorporate relevant comments and arrange for further review, if required.

- When finalised remove the 'DRAFT' watermark from the document and provide to the RQC for arranging final authorisation by the Group Director of Research and Development.

5.4 Approval and Authorisation of the SOP

- Prior to the release of the SOP it will be reviewed and approved by the Group Director of Research and Development.

- Signature blocks must be completed on each original SOP.

5.5 Assigning 'Effective' and 'Review Before' dates to the SOP

- The SOP effective date shall usually be one calendar month from the date of authorisation. However, the lapsed time between SOP authorisation and the effective date may be reduced in special circumstances (e.g. urgent situations where procedures must be implemented immediately)

- All relevant staff shall be trained in or notified of the new/updated SOP between the authorisation and the effective date. Documentation of training must be kept for all individuals as per SOP-QA-01 (see Related Documents)

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- The SOP Author shall record the 'Effective Date' on page 1 of the SOP

- The SOP 'Review' date shall be three years from the SOP's assigned 'Effective' Date. However, earlier review dates may be implemented where necessary (e.g. changes to legislation)

- The SOP Author shall record the 'Review' date on page 1 of the SOP.

5.6 Distribution of the new or revised SOP

- Approved SOPs will be distributed electronically as a PDF document by the RQC. SOPs will be made available electronically or in hard copy format upon request.

- The master SOP (i.e. with original signatures) shall be securely stored and used only for making further controlled copies, if required.

- All relevant Epworth clinical research staff will be notified of this new SOP by the RQC.

- An assessment of any training requirements shall be made by the RQC and included in the training curriculum for the various roles at Epworth.

5.7 Superseded SOPs

- The RQC will notify all known personnel involved in clinical research at Epworth of superseded SOPs.

The superseded master SOP shall be clearly marked as superseded and be securely stored as a record of previously used SOP by the RQC.

6. REFERENCES:

N/A

7. RELATED DOCUMENTS:

7.1 Related Forms and Templates

- SOP-AD-01-Template-01: SOP Standard Template
- SOP-AD-01-Form-01: SOP Feedback Form

7.2 Related SOPs

- SOP-QA-01 Documentation of Qualifications and Training Records
- SOP-Glossary-of-Terms

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8. VERSION CONTROL

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

9. APPENDIX

N/A

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