STANDARD OPERATING PROCEDURE (SOP)

TITLE: SOP CREATION, IMPLEMENTATION AND REVISION

DO NOT USE THIS SOP IN PRINTED FORM WITHOUT FIRST CHECKING IT IS THE LATEST VERSION

Document ID:	SOP-AD-01
Version No:	2.0
Date Authorised:	Date of Approval
Effective Date:	26 Mar 2020
Review Date:	26 Mar 2023
Applicable Epworth Site/s:	All

Author:	Helen Christensen Research Quality Coordinator
Approved by:	Prof Nik Zeps Group Director Research and Development
Signature:	Nikolajs Zeps (Feb 26, 2020)
Date:	Feb 26, 2020

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.

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:

All Epworth SOPs should be written with reference to the *Epworth Writing Style Guide* available on the Epworth intranet[1].

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- Maintain a central folder containing all approved SOPs and superseded SOPs.

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:
    - Purpose – briefly describe relevant background and the reason a SOP exists.
    - Scope – define which areas of work or staff the SOP applies to.
    - Applicability – to whom the SOP applies.
    - Procedure – details of the procedure in a clear and concise style.
    - 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 (GDRD).

5.4 Approval and Authorisation of the SOP

- Prior to the release of the SOP it will be reviewed and approved by the GDRD.
- SOPs will be signed electronically using Adobe Sign. An audit report generated by Adobe Sign will be filed and maintained centrally with each SOP approved for audit purposes.

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)

- 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.
- 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.

5.8 SOP waivers

- SOPs are mandatory for all staff involved in the activity or process to which the SOP relates.
- If a SOP cannot be adhered to, then prospective approval is required from the RQC and/or GDRD for a waiver using FORM-02 (see Related Documents).
- The original waiver will be maintained in the project files and a copy held by the RQC.
- If a waiver is required on multiple occasions, the SOP must be reviewed.

The superseded master SOP shall be clearly marked as superseded and be securely stored as a record of the previously used SOP by the RQC.

5.9 Work Instruction creation and implementation

Work instructions (WIs) are documents that underpin SOPs and set-out in more detail what should be done.

- Work Instructions should be prepared in accordance with TEMPLATE-02 (see Related Documents).
- Departmental work instructions should be sent to the RQC for review prior to approval and implementation.

- A final approved copy of the work instruction should be provided to the RQC for information and compliance monitoring.

6. REFERENCES:

1. Epworth Writing Style Guide
https://intranet.epworth.org.au/BusinessServices/brand/SitePages/Brand%20resources.aspx

7. RELATED DOCUMENTS:

7.1 Related Forms and Templates

- SOP-AD-01-FORM-01 SOP Feedback Form
- SOP-AD-01-FORM-02 SOP Waiver Request
- SOP-AD-01-TEMPLATE-01 SOP Standard Template
- SOP-AD-01-TEMPLATE-02 Work Instruction Template

7.2 Related SOPs

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

8. VERSION CONTROL

Document History	
Version	**Summary of Changes**
1.0	N/A First issue
2.0	Section 5.4: Updated to reflect electronic signature approval process. Inclusion of Section 5.8: SOP waiver process. Inclusion of Section 5.9: Work instruction creation and implementation. Minor formatting and inclusion of new templates and Epworth reference guide.