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

## PURPOSE:

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

## BACKGROUND:

SOPs are crucial in providing instructions and guidance to researchers on various procedures required by national and international regulations in clinical trials and research projects.

## 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.

## 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.

## RESPONSIBILITIES:

All Epworth employees, non-employed staff and Visiting Medical Officers (VMOs) involved in the conduct of research and clinical trials at or under the auspices of Epworth should be aware of and comply with this procedure.

## GLOSSARY OF TERMS:

SOP – Standard Operating Procedures

GDRD – Group Director of Research and Development

OfR – Office for Research

## PROCEDURE:

All Epworth SOPs should be written with reference to the *Epworth Writing Style Guide* available on the Epworth intranet1.

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

All Epworth employees engaged in clinical research are encouraged to:

7.1.1 Identify the need for a new SOP or modification of an existing SOP.Notify their manager and/or the Office for Research (OfR) via the SOP feedback form (see [Related Documents](#_RELATED_DOCUMENTS:)).

### OfR will:

* + 1. Assign a SOP Author.
    2. 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.
    3. Ensure that Template-01 (see [Related Documents](#_RELATED_DOCUMENTS:)) is used for all new SOPs.
    4. 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.
    5. Maintain a central folder containing all approved SOPs and superseded SOPs.

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

The SOP author will:

* + 1. 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.
  + 1. Use sub-section numbering (e.g. 6.1, 6.2, 6.3 etc.) as required to keep the document clear and easy to follow.
    2. For a modified SOP, edit the current version of the SOP – making appropriate alterations to the version number and date in the footer.
    3. Distribute the draft new or modified SOP to the OfR, or other designated individuals, for review and comment.
    4. Incorporate relevant comments and arrange for further review, if required.
    5. When finalised remove the ‘DRAFT’ watermark from the document and provide to the OFR for arranging final authorisation by the Group Director of Research and Development (GDRD).

### Approval and Authorisation of the SOP

* + 1. Prior to the release of the SOP it will be reviewed and approved by the GDRD.
    2. Approval by GDRD must be in writing, and will be filed and maintained centrally with each SOP approved for audit purposes.

### Assigning ‘Effective’ and ‘Review Before’ dates to the SOP

* + 1. 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)
    2. 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](#_RELATED_DOCUMENTS:))
    3. The SOP Author shall record the 'Effective Date' on the footnote of the SOP.
    4. 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)
    5. The SOP Author shall record the 'Review' date on the footnote of the SOP.

### Distribution of the new or revised SOP

* + 1. Approved SOPs will be distributed electronically as a PDF document by the OfR. SOPs will be made available electronically or in hard copy format upon request.
    2. All relevant Epworth clinical research staff will be notified of this new SOP by the OfR.
    3. An assessment of any training requirements shall be made by the OfR and included in the training curriculum for the various roles at Epworth.

### Superseded SOPs

* + 1. The OfR will notify all known personnel involved in clinical research at Epworth of superseded SOPs.

### SOP waivers

* + 1. SOPs are mandatory for all staff involved in the activity or process to which the SOP relates.
    2. If a SOP cannot be adhered to, then prospective approval is required from the OfR and/or GDRD for a waiver using FORM-02 (see [Related Documents](#_RELATED_DOCUMENTS:)).
    3. The original waiver will be maintained in the project files and a copy held by the OfR.
    4. If a waiver is required on multiple occasions, the SOP must be reviewed.
    5. The superseded master SOP shall be clearly marked as superseded and be securely stored as a record of the previously used SOP by the OfR.

### Work Instruction creation and implementation

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

7.9.1 Work Instructions should be prepared in accordance with TEMPLATE-02 (see [Related Documents](#_RELATED_DOCUMENTS:)).

* + 1. Departmental work instructions should be sent to the OfR for review prior to approval and implementation.
    2. A final approved copy of the work instruction should be provided to the OfR for information and compliance monitoring.

### Dissemination and Implementation

This SOP will be disseminated by the OfR. Updates will be made available with details of planned dates of implementation.

### Monitoring Compliance and Effectiveness

Compliance with this SOP will be monitored as part of OfR monitoring processes. Any problems or potential problems concerning the effectiveness of this SOP may be identified during OfR monitoring process or through users informing the OfR.

### Review and Updating

This SOP will be reviewed every three years, or whenever there are changes to legislation or working practices that impact upon the content of this document. This SOP may be merged with another SOP if appropriate or removed entirely if it becomes redundant.

## REFERENCES:

1. Epworth Writing Style Guide https://intranet.epworth.org.au/BusinessServices/brand/Pages/Communications.aspx

## RELATED DOCUMENTS:

### 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

### Related SOPs

* SOP-QA-01 Documentation of Qualifications and Training Records

## VERSION CONTROL

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| **Document History** | | | |
| **Version** | **Date** | **Summary of Changes** | **Author** |
| 1.0 | 26 April 2019 | N/A First Issue | Helen Christensen |
| 2.0 | 26 Feb 2020 | 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. | Helen Christensen |
| 3.0 | 15 Feb 2024 | The main changes to this version are summarised here:  Addition of sections: background, responsibilities.  Addition of sections: 7.10, 7.11, 7.12 for procedure management.  Modified template-01 and template -02 to remove cover page with GDRD signature but retaining other information in the form of headers and footers.  To remove the need for GDRD signature of approval and written approval will be fine.  Replaced RDGU to OfR. | Sarah Rickard |

## APPENDIX

None