STANDARD OPERATING PROCEDURE (SOP):

TITLE: DOCUMENTATION OF QUALIFICATIONS AND TRAINING RECORDS

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1. PURPOSE:

The purpose of this SOP is to support Action 1.20 of the [1]National Clinical Trial Governance Framework, Clinical Performance and Effectiveness, Safety and Quality Training. The aim of Action 1.20 is to ensure that the workforce has the right qualifications, skills and supervision to provide safe, high-quality clinical trials to patients, trial participants and consumers. This SOP describes how Epworth uses its training systems to:

a. Assess the competency and training needs of the Epworth clinical trial workforce
b. Implement a mandatory training program to meet the requirements arising from the National Safety and Quality Health Service standards
c. Provide access to training to meet its safety and quality training needs
d. Monitor the workforce's participation in training.

2. SCOPE:

All activities undertaken during the conduct of Epworth research projects.

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:

It is the Principal Investigators' or delegated line managers' responsibility to ensure that the staff members who work on their research studies have the necessary expertise and experience necessary to conduct their research studies in a safe, ethical, and high quality manner.

It is the responsibility of Epworth research staff to maintain and update their own training records. This should be done concurrently with the Performance Development Plan (PDP) process including meetings with their manager.

5.1 General

- The training and development of staff is the on-going responsibility of both staff and their line manager. Line managers should regularly check that staff have an up-to-date training file and that no mandatory training is outstanding.

- All Epworth research staff must maintain an up-to-date Curriculum Vitae (CV) (see *SOP-RG-04 Researcher Credentialing*). The CV should contain details of clinical research experience and relevant training. Evidence of completed training must be retained and made available on request.

- All research staff involved in Epworth research must attend [2]GCP training every three years (with refresher trainings as required within the three years). GCP training must be TransCelerate accredited (see *SOP-RG-04 Researcher Credentialing*).

- All research staff are required to read the [3]Australian Code for the Responsible Conduct of Research and be familiar with the [4]National Statement.

- It is highly recommended that study team members meet with a Research Development and Governance Unit (RDGU) member to be familiar with Epworth governance processes.

- Study team members are required to complete internal training on relevant SOPs.

    - For staff conducting clinical trials under the Clinical Trial Notification (CTN) or Clinical Trials Approval (CTA) scheme, please request for a SiteDocs Portal account, read the SOPs assigned, and click 'Read and Understood' to complete SOP training. These training records will be maintained within SiteDocs.

    - For staff not involved in a CTN/CTA clinical trial, please refer to "Master Training Curricula" on "Resource for Researchers" Epworth website for a list of SOPs relevant to staff role. A training log of the SOPs read must be maintained and made available on request (see Appendix A of *TEMPLATE-01 Epworth Research SOP Training Plan*).

5.2 Initial Protocol Training

- Relevant trial specific training should be recorded on a training log and filed in the Investigator Site File (ISF) (see *SOP-TM-02 Investigator Site File & Essential Documentation*), in order to provide evidence of protocol specific training. The PI is responsible for ensuring all staff involved in a trial receive regular and timely protocol-specific training, updates on safety information and supervision for their participation in the trial. Once appropriately trained, duties are delegated by the PI as outlined in *SOP-TM-14 Delegation of Duties*.

5.3 Protocol Amendment Training

- The PI is responsible for identifying and implementing required training on amendments to the protocol in a timely manner. Once ethical and governance approval is obtained training should be completed to ensure relevant changes are implemented.

- The PI or delegate will provide the study team with training materials (i.e. training slides, summary of changes or tracked changes of approved amendment) via email. Upon receipt, study team members will be required to reply to confirm they have read and understood the

changes. This must be filed in the Investigator Site File (see *SOP-TM-02 Investigator Site File & Essential Documentation*).

5.4 Supplementary Trial Documents Training Requirements

The PI is required to undergo and document training on the following supplementary trial documents:

- Investigator Brochure (IB). The IB is a reference document which informs the protocol. Updated versions of the IB are acknowledged by the PI and documented on IB signature page (if provided by sponsor).
- Urgent safety data, SAE reporting including dear investigator letters and aggregated reports. The PI will disseminate urgent safety data to the study team.
- PICF training is covered in the content of the protocol. Initial and amended training on the main and additional PICFs will not be documented.
- Only imaging/radiology manuals informing above standard of care imaging techniques will require training by a radiology delegate.

5.5 Clinical Trial Staff training

- Investigators and research support staff involved in clinical trials studies should complete either the "Trial Essentials for Investigators" or "Trials Essentials for Research Support Team" comprehensive course packages developed by [5]Australian Clinical Trials Education Centre (ACTEC) respectively.
- Refresher of some of the individual courses embedded within the comprehensive course packages are highly recommended and should be discussed with line managers during PDP meetings.

5.6 Laboratory Operations training

- Investigators and research support staff who are involved in laboratory operations must have the following prior to starting any laboratory work:
    - [6]International Air Transport Association (IATA) approved Civil Aviation Safety Authority (CASA) Certified Dangerous Goods Packing and Shipping certificate, which needs to be renewed every two years. The cost will be covered by RDGU.
        - Please refer to *SOP-TM-05 Handling and Shipping*
    - To undergo local lab induction. Please contact the Laboratory Manager via email (ER-MOCI@epworth.org.au).
- Investigators and research support staff must be trained and familiar with the equipment or laboratory procedures prior to working independently in the laboratory. Such trainings must be documented containing the name of procedures/equipment, training date and trainer's name.

5.7 Data management and privacy training

- All investigators and research support staff handling Epworth patient data need to complete the following:
    - E-learning on Privacy developed by [7]Office of the Australian Information Commissioner (OAIC)
    - To read and be familiar with Chapter 3 of [8]NHMRC Management of Data and Information in Research, Chapter 9 of [9]OAIC Guide to Health Privacy, and Best Practices of De-identifying data by [10]Australian Research Data Commons (ARDC).

5.8 Creation, updating and archiving of training records

The following process will be used for the creation, updating and archiving of training records:

- All new research staff members must complete a *SOP-QA-01 Clinical Research Training Plan* within 6 months (or an agreed timeframe with their line manager for part-time staff) of the commencement of their employment at Epworth.
- All research staff training plans must be:
    - Regularly reviewed, updated, and agreed by both the staff member and their manager
    - Discussed and updated as part of the annual staff PDP process
- The line manager will review training records along with PDP to ensure completeness and also to identify any future training requirements.
- It is highly recommended that line managers use the ACTEC Competency Framework that contains additional annotations by Epworth RDGU. These annotations highlight relevant internal SOPs and online course pertaining to a particular skill, which research staff may require to repeat to achieve satisfactory performance. RDGU can provide this document to the line managers upon request.
- It is the responsibility of the line managers and staff to each keep a written copy of the training records, and for the staff member to retain evidence and dates of completion. These must be available upon request by RDGU.

6. REFERENCES:

1. National Clinical Trials Governance Framework (NCTGF) https://www.safetyandquality.gov.au/publications-and-resources/resource-library/national-clinical-trials-governance-framework-and-user-guide
2. Integrated Addendum to ICH E6 (R1): Guideline for Good Clinical Practice E6 (R2) https://www.tga.gov.au/publication/note-guidance-good-clinical-practice

3. Australian Code for the Responsible Conduct of Research https://www.nhmrc.gov.au/about-us/publications/australian-code-responsible-conduct-research-2018
4. NHMRC National Statement https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018
5. Australian Clinical Trials Education Centre (ACTEC) https://actec.myopenlms.net/
6. International Air Transport Association (IATA) approved Civil Aviation Safety Authority (CASA) Certified Dangerous Goods Packing and Shipping certificate https://www.caaa.com.au/safe-transport-of-infectious-substances/
7. Office of the Australian Information Commissioner e-learning on privacy https://education.oaic.gov.au/elearning/privacy-in-practice/welcome.html#top
8. NHMRC Management of Data and Information in Research https://www.nhmrc.gov.au/sites/default/files/documents/attachments/Management-of-Data-and-Information-in-Research.pdf
9. OAIC guide to Health Privacy https://www.oaic.gov.au/privacy/privacy-guidance-for-organisations-and-government-agencies/health-service-providers/guide-to-health-privacy
10. Australian Research Data Commons (ARDC) Resource on Identifiable Data https://ardc.edu.au/resource/identifiable-data/

7. RELATED DOCUMENTS:

7.1 Related Forms and Templates

- SOP-QA-01-TEMPLATE-01 Epworth Clinical Research Training Plan
- ACTEC Competency Framework with RDGU annotations (upon request)

7.2 Related SOPs

- SOP-Glossary-of-Terms
- SOP-RG-04 Researcher Credentialing
- SOP-TM-02 Investigator Site File & Essential Documentation
- SOP-TM-14 Delegation of Duties
- SOP-TM-05 Handling and Shipping

8. VERSION CONTROL

Document History

Version	Summary of Changes
1.0	N/A First Issue
2.0	• SOP Scope broadened to include all clinical trials (not just CTN/CTA) • Additional wording further clarifying protocol and supplementary document training requirements. • Minor formatting and grammatical corrections.
3.0	• Provided further details and resource for training requirements • Major update SOP-QA-01 TEMPLATE-01 to include specific training requirements

9. APPENDIX

N/A