STANDARD OPERATING PROCEDURE (SOP):

TITLE: DOCUMENTATION OF QUALIFICATIONS AND TRAINING RECORDS

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TITLE: DOCUMENTATION OF QUALIFICATIONS AND TRAINING RECORDS

1. PURPOSE:

The purpose of this SOP is to describe the procedure related to the appropriate documentation of clinical research staff qualifications and training records at Epworth HealthCare.

2. SCOPE:

All clinical trials conducted at Epworth.

The principles of this SOP may also be applied to documentation of qualifications and training records for non-clinical trials.

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 PIs responsibility to ensure that the staff members who work on their trials have the necessary expertise and experience in order to successfully conduct proposed trials.

It is the responsibility of the Epworth clinical research staff to maintain and update their own training records.

5.1 General

- The training and development of staff are the on-going responsibility of the line managers. Line managers should regularly check that staff have an up-to-date training file and no mandatory training is outstanding.
- All Epworth clinical research staff must prepare a Curriculum Vitae (CV)(see *SOP-RG-04 Researcher Credentialing*). The CV should contain details of clinical research experience and relevant training and must be signed and dated. CVs should be updated as needed but at least every three years.
- All Epworth clinical trial staff involved in the conduct of clinical trials under the Clinical Trial Notification (CTN) or Clinical Trial Exemption (CTX) schemes must attend GCP training every three years (with refresher trainings as required within the three years) and attendance must be documented in SiteDocs. GCP training must be TransCelerate accredited (see *SOP-RG-04 Researcher Credentialing*).

- Study team members are required to complete internal training on relevant SOPs.
- All SOP training records will be maintained within SiteDocs for staff involved in the conduct of clinical trials under the CTN/CTX scheme.
- For staff not involved in a CTN/CTX clinical trial, a training log must be maintained and made available on request (see optional *TEMPLATE-01 Epworth Clinical Research SOP Training Log*).

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

Study team members are not required to undergo nor 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.

5.3 Creation, updating and archiving of training records

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

- The training record should be checked for completeness at least annually by the individual. Items to be checked are that CV and job description do not require updating, copies of all certificates, etc. are present.
- The line manager will review training records at least annually to ensure completeness and also to identify any future training requirements.

6. REFERENCES:

1. Integrated Addendum to ICH E6 (R1): Guideline for Good Clinical Practice E6 (R2) https://www.tga.gov.au/publication/note-guidance-good-clinical-practice

7. RELATED DOCUMENTS:

7.1 Related Forms and Templates

- SOP-QA-01-TEMPLATE-01 Epworth Clinical Research SOP Training Log

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

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/CTX) • Additional wording further clarifying protocol and supplementary document training requirements. • Minor formatting and grammatical corrections.

9. APPENDIX

N/A