STANDARD OPERATING PROCEDURE (SOP)

TITLE: RESEARCHER CREDENTIALING

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1. PURPOSE:

The purpose of the credentialing process is to ensure that all investigators and/or external contractors/students engaged in clinical research involving Epworth patients, staff and/or resources are known, adequately qualified and insured to conduct research at Epworth safely and in accordance with all necessary guidelines and legislation.

2. SCOPE:

This SOP applies to all investigators and/or external research contractors/students engaged in clinical research involving Epworth patients, staff and/or resources.

All researchers are required to be credentialed, regardless of project risk. This includes low and negligible risk studies.

Trial coordinators with an appointment at Epworth do not need to be credentialed unless they are engaged in the conduct of research at Epworth as an investigator.

Researcher credentialing **does not authorise clinical practice at Epworth**, and is in addition to any Epworth requirements for health professionals to undertake clinical practice (see Epworth Foundation By-laws[1] and Health Professional Registration Policy[2] for further details regarding appointment at Epworth).

3. APPLICABILITY:

This applies to all Epworth employees, non-employed staff and Visiting Medical Officers (VMOs) and to all relevant external persons or parties engaged in research activity at Epworth.

4. GLOSSARY OF TERMS:

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

For the purpose of clarity, an **investigator** is defined as a member of the research team who has the qualifications, training and delegated authority to conduct integral study procedures. This may include but is not limited to: Provision of an intervention; Interpretation of results/outcomes; Decision making authority with regards to treatment/intervention; Conduct of Interviews/focus groups; Protocol design and development.

An **external research contractor** is a person who wishes to conduct research at Epworth (either as an investigator or supporting role) without having an affiliation or appointment at Epworth. This may include but is not limited to: Academic; External institution researchers or research support staff; Volunteer/work experience.

An **External research student** is a person who intends to conduct a higher degree research project without having an affiliation or appointment at Epworth.

Conducting research at Epworth: For the purpose of this document conducting research at Epworth would also include Epworth patients or staff being invited to participate in research being conducted elsewhere or access to their identifiable data for research purposes.

5. PROCEDURE:

It is the Principal Investigator's (PI) responsibility to ensure all investigators and/or external contractors/students involved in the conduct of a research project have fulfilled the requirements of researcher credentialing prior to undertaking any research related activities. The PI may delegate certain tasks to individuals where appropriately qualified by education, training and experience (see also *SOP-TM-14 Delegation of Duties*). However, the PI retains overall responsibility for ensuring the delegated activities are conducted in accordance with this SOP.

5.1 Initial Submission Documentation

The Research Development and Governance Unit (RDGU) oversees researcher credentialing at Epworth.

All Submissions are to be completed online via the **researcher credentialing link** on the *Epworth Research Development and Governance Webpage*. The submission documentation required for researcher credentialing (summarised in *APPENDIX* A) is dependent on the appointment status and intended research activity at Epworth.

5.1.1 Employees

- Investigators who are employed by Epworth will be required to submit the following documentation via the online researcher credentialing link:
    - CV (signed and dated) including current Epworth appointment and professional registration number where applicable (see *TEMPLATE-04* for preferred CV template).
    - Appropriate GCP training certificate (dated within 3 years)
    - 5.1.2 VMOs
- In addition to the requirements outlined in section 5.1.1, where the investigator is a VMO and intending to conduct multi-institutional research at Epworth where any form of research agreement is to be executed by Epworth on behalf of a VMO PI, a signed VMO PI agreement (*TEMPLATE-02*) must be provided.
- The RDGU will facilitate final sign-off of the VMO PI agreement where required. This must be fully executed prior to the commencement of the intended research activity at Epworth.

5.1.3 External Research Contractors

- The information to be provided will depend on whether there is an existing overarching research agreement in place (i.e. collaboration agreement) that covers the arrangements for the researcher at Epworth.
- Where an overarching agreement is in place the RDGU must be provided with the relevant staff name, contact details, intended role/research activities, appropriate GCP training certificate, and whether the individual will be involved in the conduct of clinical trials under the TGA Clinical Trial Notification scheme at Epworth.

- If no overarching agreement is in place the external research contractors will be required to submit the following documentation:
  - CV (signed and dated) (see *TEMPLATE-04* for preferred CV template).
  - Appropriate GCP training certificate (dated within 3 years)
  - Fully executed Research Collaboration Agreement incorporating special condition outlined in *APPENDIX B* **or** *External Research Student or Contractor Agreement* (*TEMPLATE-03*) signed by both the applicant and the person who will be solely responsible for the conduct of the applicant at Epworth.

5.1.4 External Research Students

- The documentation to be provided for external research students will depend on whether there is an existing overarching agreement in place (i.e. collaboration agreement, HDR student agreement) that will cover the management of the proposed student project or not.
- The RDGU can advise if there is a relevant agreement in place.
- If an overarching student agreement is not in place and the project is to be conducted as part of the student's enrolled degree the External Research Contractor submission requirements (outlined in *Section 5.1.3*) will apply.
- If the proposed research to be conducted by the student is outside their enrolled degree, further discussion is required with the RDGU regarding the submission requirements.

5.2 Submission Processing and Follow-up

- Upon receipt of the researcher credentialing application, the RDGU will review to confirm the application is valid and that there are no concerns. Any inconsistencies/missing information will be queried prior to confirming the credentialing status.
- The RDGU will provide written confirmation of researcher credentialing authorisation upon receipt of a satisfactory submission.
- The PI must ensure evidence of researcher credentialing for all researchers on a project are maintained on file and available for review upon request.
- Researcher credentialing is valid for 3 years (or for the term of an authorised research project for external research contractors). It is the PI/applicant's responsibility to ensure all documentation (i.e. GCP training, professional indemnity) remains valid during this period.
- The RDGU must be notified where there is a change in appointment/affiliation or if the researcher no longer intends to conduct research at Epworth.

6. REFERENCES AND RELATED DOCUMENTS:

The Epworth Research Policy, handbook, SOPs and supporting forms and templates can be found on the *Epworth Resources for Researchers* webpage.

1. *Epworth Foundation By-laws*
2. Epworth, 2020. *Health Professional Registration Policy*

7.1 Related Forms and Templates

- SOP-RG-04-TEMPLATE-02 VMO PI Agreement
- SOP-RG-04-TEMPLATE-03 External Research Student or Contractor Agreement
- SOP-RG-04-TEMPLATE-04 Epworth Researcher CV

7.2 Related SOPs

- SOP-RG-02: Insurance and Indemnity
- SOP-RG-03: Developing Research Budgets and Contracts
- SOP-Glossary-of-Terms

7. VERSION CONTROL

Document History	
Version	**Summary of Changes**
1.0	N/A First Issue
2.0	Complete revision including further clarification regarding process for external research contractors and students. Appendices A, B & C included. SOP formatting and links updated.
3.0	All researchers are required to be credentialed, regardless of project risk. Appropriate GCP training certificate is required to credential all investigators and/or external research contractors/students. Removal of V2.0 Appendix A, and relabelled V2.0 Appendices B & C to A & B. Citations in the document updated.

APPENDIX A: RESEARCHER CREDENTIALING SUBMISSION DOCUMENTATION

Documentation	Employee	VMO	External Contractor	External student [d]
Researcher CV signed and dated	Y	Y	Y	Y
Appropriate GCP training certificate [b]	Y	Y	Y	Y
External Researcher Agreement or Research Collaboration Agreement incorporating special condition [c]	N/A	N/A	Y	Y
VMO PI agreement	N/A	As required	N/A	N/A

[a] Further guidance regarding professional indemnity insurance guidance for researchers at Epworth is provided in SOP *Insurance and Indemnity* (see Related Documents).

[b] Appropriate GCP training is mandatory for all investigators. GCP training must be updated every 3 years and delivered by a TransCelerate accredited GCP provider (a list of accredited providers can be found on the TransCelerate website).

[c] Required where an External Research Student or External Research Contractor is conducting activities on Epworth premises and/or are directly or indirectly interacting with or using identifiable data about patients or staff from Epworth and a HDR agreement is not in place

[d] where no existing overarching agreement in place (i.e. collaboration agreement, HDR student agreement) that will cover the management of the proposed student project

APPENDIX B: EXTERNAL CONTRACTORS SPECIAL CONDITION WORDING FOR RESEARCH AGREEMENTS

The below wording should be included in the Research Collaboration Agreement template for any project that involves an external researcher coming on site, contacting Epworth patients and/or accessing identifiable Epworth data (see also SOP-RG-03 Developing Research Budget and Contracts).

Special Condition:

The Epworth HealthCare (EPWORTH) Principal Investigator listed in Schedule XX is solely responsible for the conduct of the External Researcher (insert name and institutional affiliation) with relation to accessing Epworth premises and facilities, EPWORTH patients and staff and/or their personal information for the conduct of this research project.

The External Researcher warrants that he/she is adequately experienced and qualified to perform the duties required for this research project.

The External Researcher is not authorised to undertake any kind of clinical practice or procedure at EPWORTH other than those directly related to this research project.

The External Researcher is subject to the by-laws, rules and regulations of EPWORTH whilst on EPWORTH premises or handling EPWORTH information and must comply with all directions from EPWORTH representatives.

The External Researcher warrants that he/she will maintain adequate professional indemnity insurance, either personal or through their institution, to cover the research activities associated with this research project at EPWORTH.