STANDARD OPERATING PROCEDURE (SOP):

TITLE: CLINICAL RESEARCH INSURANCE AND INDEMNITY

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

Document ID:	SOP-RG-02
Version No:	1.1
Date Authorised:	Mar 16, 2023
Effective Date:	Apr 16, 2023
Review Date:	Apr 16, 2026
Applicable Epworth Site/s:	All

Author:	Jane Loke Research Development and Quality Officer
Approved by:	Professor Ingrid Winship Group Director Research and Development, Chief Research Officer
Signature:	Ingrid Winship Ingrid Winship (Mar 16, 2023 16:14 GMT+11)
Date:	Mar 16, 2023

STANDARD OPERATING PROCEDURE (SOP):

TITLE: CLINICAL RESEARCH INSURANCE AND INDEMNITY

1. PURPOSE:

Epworth must ensure that all clinical research is covered by appropriate insurance and indemnification where necessary. For clinical trials, in particular those that are externally sponsored and/or involve unapproved therapeutics, specific insurance must be in place to cover any possible claims arising from harms to participants.

The purpose of this SOP is to:

- Delineate the scope of cover of Epworth's clinical research insurance; and
- Set-out the requirements for insurance and indemnity for clinical research conducted at Epworth HealthCare (Epworth).

2. SCOPE:

This SOP applies to all clinical research at Epworth, including sponsored clinical trials, investigator initiated clinical research, collaborative group research and student clinical research.

Where the research project involves multiple parties, this SOP should be read in conjunction with SOP-RG-03: Developing Contracts and Budgets.

3. APPLICABILITY:

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

- at Epworth; or
- for the benefit of Epworth, or on behalf of Epworth.

4. GLOSSARY OF TERMS:

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

5. PROCEDURE:

The Principal Investigator (PI) is responsible for the research project to be conducted at Epworth and therefore must be familiar with all regulatory and institutional requirements as per the Research Policy[1] and Research Handbook[2]. The PI can delegate at his/her discretion certain trial duties to suitably qualified individuals. Delegation of trial activities must be recorded on the delegation log. The PI remains responsible for any delegated activity.

5.1 Epworth Insurance Policies

Epworth has Public Liability and Medical Indemnity Insurance. The certificates of currency for these may be found here. Details of the actual policies are available on request from the Research Development and Governance Unit (RDGU). All employed clinicians are covered under Epworth's Medical Indemnity Insurance policy for claims arising from acts, omissions or breaches of

professional duty in the course of employment where the employee is acting within their scope of clinical practice.

Epworth has taken out separate insurance to cover activities related to clinical research, and in particular clinical trials. The Epworth clinical trial insurance policy provides coverage in relation to Epworth's liabilities as a research site. Under this policy coverage extends to:

(1). All employees conducting research, in accordance with the research protocol, and *for the benefit of or on behalf of Epworth**.

(2). Non-employed principal investigators (i.e. sub-contractors) involved in Epworth Initiated trials – i.e. *for the benefit of or on behalf of Epworth**.

**This includes commercially sponsored trials conducted by Epworth, trials initiated by Epworth and VMO initiated trials where Epworth provides the trial coordination services to the VMO.*

Please note, although insurance coverage is possible for investigator initiated trials, Epworth will NOT currently act as a sponsor for investigator initiated trials conducted under the Clinical Trial Notification (CTN) scheme (see section 3.1).

Insurance cover under Epworth's policy does not automatically extend to research involving:

- Patients aged 5 and below.
- Pregnancy studies.
- Overseas (non-Australian) studies.

Where any proposed research at Epworth, involves one or more of the above exceptions the PI must make appropriate arrangements to obtain insurance cover. Researchers should speak with the RDGU if they wish to obtain assistance with this.

Epworth's clinical trial insurance policy does not cover claims where there is a deviation from the research protocol or where written, informed consent has not been obtained from the research participant.

Non-employed researchers including Visiting Medical Officers (VMOs), external research contractors and external students involved in the conduct of research at Epworth, but which is not *for the benefit of or on behalf of Epworth* are NOT covered by Epworth's insurance policy and must ensure adequate research related professional indemnity insurance is in place prior to commencing any research related activities (see SOP-RG-04: Researcher Credentialing).

5.2 Commercially Sponsored Research

In order to manage the risk associated with legal liability that may arise from the conduct of commercially sponsored research, Epworth enters into Research Agreements with the Australian local sponsor of the intended research (see SOP-RG-03: Developing Contracts and Budgets).

In addition to the Agreement, the following standard form of indemnity is required to ensure adequate indemnity arrangements are in place for commercially sponsored clinical trial research:

- The Medicines Australia (MA) form (for pharmaceutical trials).
- The Medicine Technology Association of Australia (MTAA) form (for device trials).

- The PI should obtain the Standard Form of Indemnity and Insurance Certificate from the Sponsor as soon as it is agreed that the site will participate in the research project.
- The PI must ensure the standard form of indemnity and insurance certificate for a clinical trial meets the criteria set-out in Appendix A.
- A copy (or at least 2 if they are submitted in hard copy) of standard form of indemnity signed by the Sponsor must be provided to the RDGU as part of the Research Governance Authorisation Request Pack (see SOP-RG-01: Research Governance). The RDGU will then seek final sign-off by the authorised Epworth signatory. One fully signed copy of the indemnity form must be retained in the Investigator Site File.
- Where there are any alterations to the requirements outlined in Appendix A, evidence of Epworth legal review and approval must be in place before the indemnity will be signed on behalf of Epworth.
- Commercial insurance certificates typically expire every 12 months. The PI must ensure an up to date Insurance certificate is kept on file throughout the duration of an approved project, and a copy is forwarded on to RDGU

5.3 Collaborative Group Research

- The Collaborative Group Research Agreement (and Research Agreements in general) states that each party is liable for its acts and omissions in relation to the conduct of the research and each party must maintain insurance to provide indemnity to it in relation to any liability which it may incur (see SOP-RG-03: Developing Contracts and Budgets).
- Some Collaborative Research Groups (CRG)s are registered as business entities and will provide a standard form of indemnity and evidence of insurance in the same manner as a commercial sponsor. Where this is the case the requirements listed in Appendix A must be followed.
- Universities acting as CRGs will generally not provide a standard form of indemnity but should provide evidence that their insurance covers clinical trial activity.
- Some CRGs may be entitled to indemnity under an insurance or indemnity scheme arranged by a State or Territory of the Commonwealth of Australia. Evidence of insurance is not required.
- The nature of the CRG must be clear in any application to conduct research at Epworth. The RDGU can provide further advice where required.

5.4 Investigator Initiated Research

- The agreement for investigator initiated multi-centre research states that each party is liable for its acts and omissions in relation to the conduct of the research and each party must maintain insurance to provide indemnity to it in relation to any liability which it may incur.
- Investigator Initiated clinical trials to be conducted under the TGA CTN scheme, where the PI is an Epworth employee, must be sponsored by an appropriate external entity (i.e. an affiliated academic institution or Contract Research Organisation (CRO)). ***Epworth will not take on the responsibility of Sponsor for this category of research under any circumstances.***
- Where the Sponsor is a non-commercial entity it must hold insurance in place with regards to the management and design of the clinical trial. Indemnity for the conduct of Epworth employees will be covered by Epworth Clinical Trial Insurance (subject to previously stated exceptions section 4.1). Investigators who are not employees must ensure they hold adequate professional indemnity insurance to cover the research related activity.
- Where an employee is undertaking original research, not conducted under a CTN, not commercially funded nor undertaken as a student project, indemnity for the management, design and conduct of the research project will be provided through Epworth's Clinical Trial Insurance Policy.

5.5 Student Research

- Where an Epworth employee is undertaking a student project, the management, design and conduct of the research is covered under Epworth Clinical Trial Insurance Policy. For non-employees the research will fall under the academic institutions indemnity scheme. For the latter, evidence of the relevant policy/certificate must be in place prior to submitting the project for research governance authorisation (see SOP-RG-01: Research Governance).
- If an employee is involved in student activities outside of normal work hours or outside of the scope of their employment professional indemnity or university insurance may be required.

6. REFERENCES:

1. Epworth Research Policy
2. Epworth Research Handbook

7. RELATED DOCUMENTS:

7.1 Related Forms and Templates:

- Medicines Australia (MA) – Indemnity & Compensation Guidelines. https://medicinesaustralia.com.au/policy/clinical-trials/indemity-and-compensation-guidelines/

- Medical Technologies Association Australia (MTAA). https://www.mtaa.org.au/clinical-investigation-research-agreements

7.2 Related SOPs:

- SOP-RG-01: Research Governance
- SOP-RG-03: Developing Contracts and Budgets
- SOP-RG-04: Researcher Credentialing
- SOP-Glossary-of-Terms

8. VERSION CONTROL

Document History	
Version	Summary of Changes
1.0	N/A – First Issue
1.1	Fixed hyperlinks that did not work. Clarified that only one standard form of indemnity is required if it is not a hard copy submission. Minor correction of SOP reference number on footnote.

APPENDIX A: INSURANCE AND INDEMNITY REQUIREMENTS

Standard Form of Indemnity Requirements:

- The Sponsor is an Australian entity (All commercially sponsored clinical trials conducted under the TGA CTN scheme must be indemnified and insured by an Australian Sponsor).
- Bears the declaration signature of the Sponsor and the Chief Executive or duly authorised representative of the organisation
- Is provided by the commercial Sponsor in a form no less favourable than the current version of the MA Form of Indemnity or the MTAA Indemnity Form.
- Has the full legal name (identical to that on the insurance certificate), address and ABN (all Australian) of the Sponsor organisation
- Paragraph 1 clearly identifies sites and PIs conducting the research.
- Displays the correct and full details for Epworth HealthCare as the indemnified party (Table1)

Table 1

Name	Epworth Foundation trading as Epworth HealthCare
Address	89 Bridge Rd Richmond Victoria Australia 3121
ABN	97 420 694 950

Insurance Certificate Requirements:

- The class of insurance should be for Public and Product Liability or equivalent such as General Liability or Clinical Trials.
- The full legal name of the Australian Sponsor (as stated in the CTN) is documented.
- The full legal name of the sponsor organisation is identical to that on the Indemnity Form.
- If the certificate is specific for the trial then the title and protocol number should be correct.
- Australia is included as a territory.
- The cover per claim is at least $10M.
- The expiry dates and trial period dates are stated and current.