STANDARD OPERATING PROCEDURE (SOP)

TITLE: DEVELOPING CONTRACTS AND BUDGETS

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TITLE: DEVELOPING CONTRACTS AND BUDGETS

1. PURPOSE:

The purpose of this SOP is to describe the manner in which Research Agreements with external entities are to be developed, processed and accepted by the Institution and/or Principal Investigator (PI) for the purpose of conducting research at Epworth. These other entities may include, but are not limited to; industry or commercial sponsors, Contract Research Organisations (CROs), hospitals, third party providers or other research collaborators.

This SOP aims to ensure the roles, responsibilities and rights of each party involved in the conduct of a clinical trial or research project are clearly defined prior to the commencement of the project.

2. SCOPE:

Applicable to all research projects at Epworth that involve multiple parties where the roles and responsibilities must be defined.

This SOP must be read in conjunction with *SOP-RG-02: Insurance and Indemnity*.

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.

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 trained and qualified individuals. Delegation of trial activities must be recorded on the delegation log. The PI remains responsible for any delegated activity.

5.1 Budget Development

- A detailed budget must be developed for research being conducted at Epworth. It is the PI's responsibility to ensure all institutional costings have been adequately accounted for.
- The Sponsor should provide a draft budget – this must be reviewed against standard costs. The budget should be reviewed against the study protocol for completeness and to ensure all costs are adequately covered. Budget negotiations with third party providers may be handled directly by the Sponsor or PI. The service provider should provide the current list of standard costs to facilitate budget negotiation.

- For investigator initiated studies the PI is responsible for ensuring all costs are covered by an identified funding source (i.e. research grant). Budget for an investigator initiated study must be signed-off by the Clinical Institute Research lead (see suggested TEMPLATE-03) or Research Operations Manager (where no Institute Research lead).

- For internal Epworth departments or external providers where a formal service provision agreement is not in place researchers should discuss the project and the associated resource requirements with the relevant Head of Department/Manager well before project commencement and ensure written confirmation of agreement including relevant fees to provide services has been received and filed in the Investigator Site File (ISF). The Monash Partners Service Request Form can be used for this purpose.

5.2 Research Agreements – Standard and Unmodified

- APPENDIX A provides a summary of standard research agreement templates approved for use at Epworth. The type of research agreement to be used will depend on the nature of the trial and parties involved.

- For commercially sponsored clinical trials, the Sponsor will provide the research agreement to the PI for review.

- For investigator initiated projects, APPENDIX A should be used as a guide to determine an agreement acceptable to Epworth. It is the responsibility of the PI to ensure the research agreement provided by the Sponsor meets the requirements outlined in APPENDIX B where applicable.

- Where the project is to be covered under an existing overarching agreement (i.e. research collaboration agreement, overarching HDR student agreement), the PI/supervisor is responsible for ensuring the project is conducted in accordance with the agreement (including completion of any associated project and/or student declaration schedules).

- Where a proposed agreement template is not listed in APPENDIX A or the requirements listed in APPENDIX B are not met the PI must contact the RDGU in the first instance to discuss.

- The RDGU will advise if further review and approval is required and will facilitate review by Epworth legal using the approved Legal Advice Request Form.

- Standard research agreement templates completed correctly may be approved directly by the RDGU without further legal review.

- For documents requiring wet ink signing the PI must ensure at least 2 copies of the research agreement are provided to the RDGU for final sign-off by the authorised Epworth signatory.

- Electronic (digital) signatures on research related documents are acceptable however scanned and cut/paste signatures are not. Signing in counterpart is acceptable if the agreement makes reference to it.

- Where the PI is also a VMO, a fully signed VMO Clinical Interventional Research Agreement must be in place prior to Epworth signing a Clinical Trial Research Agreement on their behalf (see also *SOP-RG-04 Research Credentialing*).
- The research agreement must be signed by all parties before research governance authorisation can be granted and the project can commence.
- The RDGU will provide the fully signed research agreements to the PI for filing. It is the responsibility of the PI to ensure the Sponsor and any other party(ies) are provided with the fully signed agreement where required.
- One fully signed copy of the research agreement must be retained in the ISF.

5.3 Agreements with Special Conditions/Amendments:

- Amendments should not be made to the body of a template agreement as this will require a full legal review.
- Where an amendment is proposed to the standard agreement these should be contained within the schedule.
- All amendments must be approved in writing by Epworth RDGU or legal.
- Inclusion of special conditions previously approved by the Southern Eastern Border States (SEBS) Committee may be accepted without further legal review if satisfactory evidence of the SEBS approval is provided to Epworth RDGU and there are no concerns.
- Where satisfactory evidence of SEBS approval is not provided and/or there are concerns the agreement may require Epworth legal review prior to execution.
- To request review and approval for proposed changes to a research agreement the PI (or delegate) must submit the CTRA with all proposed changes in the schedule tracked to the RDGU.

5.4 Third Party Providers

- The requirement for a service from a third party should be identified as early as possible, ideally prior to or during the feasibility assessment for a project (see *SOP-TM-01 Clinical Trial Feasibility and Start-Up*). The PI should contact the third party and provide the necessary details to ascertain if they are able to support the research project.
- The PI should discuss the requirement for the third party service with the Sponsor and confirm there would be a budget in place to cover the associated costs.
- A service provision agreement between the external provider and Sponsor or Epworth for the conduct of any study specific procedures must be in place prior to study commencement. The

RDGU will not review the individual terms of the 3rd party agreements but will note their inclusion when recommending approval by the Group Chief Executive or delegate of Epworth.

- The PI is responsible for ensuring a service provision agreement is in place and the third party is in receipt of all necessary study documentation prior to study commencement.

6. REFERENCES & 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 Research Policy
2. Epworth Research Handbook

6.1 Related Forms and Templates

- Medicines Australia (MA) – Indemnity & Compensation Guidelines
- Medical Technologies Association Australia (MTAA) - Clinical Investigations Research Agreements
- Monash Partners Clinical Research Facilitation Toolkit
- TEMPLATE-01 Epworth Research Collaboration Agreement
- TEMPLATE-02 Epworth Material Transfer Agreement
- TEMPLATE-03 Epworth Investigator Initiated Research Budget

6.2 Related SOPs

- SOP-RG-01: Research Governance
- SOP-RG-02: Insurance and Indemnity
- SOP-RG-04: Researcher Credentialing
- SOP-QA-04: Vendor Assurance
- SOP-Glossary-of-Terms

7. VERSION CONTROL

Document History	
Version	**Summary of Changes**
1.0	N/A – First Issue
2.0	**Section 5.2 –** additional point included about meeting the requirements set-out existing overarching agreements and ensuring the relevant schedules are completed as per the terms of the agreement.

	Section 5.3 - Clarification regarding approval process for special conditions previously approved by the SEBS committee. SOP formatting and links updated.

APPENDIX A: RESEARCH AGREEMENTS & INDEMNITY APPROVED FOR USE AT EPWORTH

Sponsorship Arrangement	Agreement Source	Name of Agreement	Type of Indemnity
Clinical Trials			
Commercially sponsored or Collaborative Research Group pharmaceutical trial.	Medicines Australia (MA)[1]	CTRA	MA Standard Indemnity and HREC Review Only Indemnity (If CRG is a university or health service: no indemnity required)
		CTRA: Contract Research acting as the Local Sponsor	
		CTRA: Collaborative or CRG Studies	
		CTRA: Phase IV Clinical Trials (Medicines)	Not Required
		CTRA: Phase IV Clinical Trials (Medicines) Contract Research acting as the Local Sponsor	
Commercially sponsored studies of medical technology (i.e. device trials).	Medical Technologies Association of Australia (MTAA)[2]	MTAA Standard Clinical Investigation Research Agreement	MTAA Standard Indemnity and MTAA HREC review only Indemnity
		CTRA: Phase IV Clinical Trials (Medicines) Contract Research acting as the Local Sponsor	
Investigator Initiated, Commercially Supported trial.	Monash Partners	CTRA: Investigator-Initiated, Company Supported Studies	
Investigator Initiated, multi-centre trial.	Medicines Australia[1]	CTRA: Collaborative or CRG Studies	Not required (The terms of the indemnity will be defined in each individual agreement.
	VMIA	VMIA investigator initiated agreement	
Non clinical trials / other research projects			
Research collaboration or research with external support.	Medicines Australia[1]	CTRA: Collaborative or CRG Studies	Not required (The terms of the indemnity will be defined in each individual agreement).
	Epworth	Epworth Research Collaboration Agreement (Template 01)	
	Melbourne Academic Centre for Health (MACH)	MACH Research Collaboration Agreement	
	Monash Partners[3]	Research Collaboration Agreement	
Research requiring the transfer of bio-specimen or data (not covered in above categories).	Epworth	Material Transfer Agreement (Template 02)	Not required (The terms of the indemnity will be defined in each individual agreement.
	Monash Partners	Material Transfer Agreement	

1. https://medicinesaustralia.com.au/policy/clinical-trials/clinical-trials-research-agreements/
2. https://www.mtaa.org.au/clinical-investigations-research-agreements
3. https://monashpartners.org.au/research-facilitation/resources-and-forms/

APPENDIX B: GUIDELINES FOR COMPLETING CTRA/RESEARCH AGREEMENTS

The Sponsor or contracting party must be an Australian entity and the contract should be governed by the law for the time being in force in the State or Territory.

Make sure current version of template agreement is in use.

The sections below refer specifically to the Medicines Australia CTRA templates however the directions provided could also be applied to the relevant sections of other research agreement templates.

First Page: Details of parties:

- Epworth details (as per Table 1)
- Sponsor's name (identical to details on indemnity form and insurance certificate, must include a current ABN)
- Protocol title and number must include the Epworth project reference number (issued by the RDGU)
- A listing of the study, clinical, and legal responsibilities of Investigator site
- Date of Agreement: insert '*Date of last party to sign*'

Table 1 Epworth Details

Name	Epworth Foundation trading as Epworth HealthCare
Address	89 Bridge Rd, Richmond, Victoria Australia 3121
ABN	97 420 694 950
Contact for Notices	*<Insert PI>*
Fax for Notices	*<Insert PI fax number>*
Phone Number	*<Insert PI phone number>*

Signature Page:

- Only an authorised representative of Epworth is permitted to sign. When ready for final sign-off all agreements must be sent to the RDGU (see *SOP-RG-01: Research Governance* for further information).

Schedule 1: Key Information

- Number of study subjects required to enter and complete the study

Schedule 2: Payments:

- Payee details including terms of payment and terms for delays and termination of the study
- Who will pay whom? How much? (include breakdown – budget)
- Include ethics and governance payments, and payments to third party providers (if not covered in separate agreement.
- Include conditions on the use of funding where required.

- Include invoicing instructions

Schedule 3: Form of Indemnity

- Provided as separate document where required (see *SOP-RG-02 Indemnity and Insurance*)

Schedule 4: Insurance Arrangements

- Copy of valid certificate to be inserted (see *SOP-RG-02 Indemnity and Insurance*)

Schedule 5: Compensation for Injury

- Research related injury responsibilities including the provision and payment and/or reimbursement of necessary medical treatment for research participants when appropriate Compensation guidelines

Schedule 6: Study Protocol Identification

Schedule 7: Special Conditions

- If special conditions required please seek advice from the RDGU