STANDARD OPERATING PROCEDURE (SOP)

TITLE: RESEARCH GOVERNANCE

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TITLE: RESEARCH GOVERNANCE

1. PURPOSE:

The purpose of this SOP is to provide guidance on preparing and submitting documentation to demonstrate compliance with the governance requirements for research projects being conducted at Epworth.

2. SCOPE:

This SOP applies to all clinical research at Epworth (i.e. involving Epworth staff, patients and/or resources) with the exception of projects deemed eligible for the non-HREC review pathway at Epworth. In these instances *SOP-RG-08 Non-HREC review process for research involving no more than low-risk* should be referred to.

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:

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 *Epworth Research Handbook*[2]. The PI can delegate at his/her discretion certain trial duties to individuals where appropriately qualified by education, training and experience (see also *SOP-TM-14 Delegation of Duties*). Delegation of trial activities must be recorded on the delegation log. The PI remains responsible for any delegated activity.

See *APPENDIX A* for an illustration of the steps involved for obtaining research governance authorisation at Epworth.

5.1 Project Registration with Epworth Research Development and Governance Unit (RDGU)

- All new research studies to be conducted at Epworth must be registered with the RDGU.
- For clinical trials, registration with the RDGU should take place following completion of the feasibility and site selection process and all relevant departments have confirmed their support (see *SOP-TM-01 Clinical Trial Feasibility and Start-Up*).
- For non-clinical trial research the RDGU advises investigators to have discussed feasibility and strategic fit with all relevant Epworth stakeholders prior to registration. The RDGU can advise on this on request.
- Refer to *APPENDIX B* for the minimum information required by the RDGU to register a project.

- At registration, the RDGU can advise the PI of the minimum requirements for governance approval as per the *Epworth Research Handbook Appendix A*.
- Issuing of governance registration does not imply project authorisation.

5.4 Epworth Research Governance requirements

The following topics should be addressed to obtain governance approval, noting that the documentation required will depend on the nature of the study. The RDGU can provide advice regarding what is required as a minimum at the time of registration.

5.4.1 HREC Review and Approval

- It is the PI's responsibility to ensure that the appropriate ethical approval is obtained in accordance with the Epworth Research Policy
- The PI or delegate should confirm the submission requirements of the reviewing HREC or sub-committee prior to submitting the research project for review.
- The PI must ensure the Epworth Participant Information and Consent Form (PICF) wording requirements (see *FORM-01 PICF Content Checklist*) are reviewed and approved by the HREC.
- A Memorandum of Understanding (MoU)/External Entity Agreement (EEA) is required by most HRECs prior to reviewing a submission from Epworth. The RDGU will facilitate review and implementation of a MoU/EEA with the reviewing HREC where required.
- The ethics approval letter must include written confirmation 'Epworth HealthCare' is an approved site.
- All ethically approved documents and correspondence required for the conduct of a clinical trial must be filed in the Investigator Site File (ISF) (see *SOP-TM-02 Investigator Site File and Essential Documents*). All ethically approved documents and correspondence required for the conduct of any other research must be located in a study site folder (either in an electronic or hard copy file) and available for auditing purposes.

5.4.2 Site Specific PICF

- The PI is responsible for ensuring the Participant Informed Consent Form (PICF) and other site specific documents are based upon the current HREC approved Master documents and appropriately amended to include the site specific information (see *FORM-01*).
- Tracked and clean versions of the site specific documents must be filed in the ISF, for clinical trials (see *SOP-TM-01 Feasibilities and Trial Start-Up*), or the study site folder for all other projects, prior to commencement of the trial.

5.4.3 Researcher Credentialing

- It is the PI's responsibility to ensure that they, and all researchers involved in the project are suitably qualified and experienced and are authorised to conduct research at Epworth according to the *Researcher Credentialing SOP-RG-04*.

5.4.4 Budget and Research Agreements

- The RDGU is not responsible for reviewing and approving budgets. PIs must ensure, in conjunction with all relevant departments and 3rd parties, that they have sufficient resources to conduct the study to completion.

- If relevant, the CTA Study Start-Up team (for applicable clinical trials) and/or the PI will be responsible for negotiating budget and contract arrangements with sponsors (see SOP-RG-03: Developing Contracts and Budgets).

- Evidence of support with third party service providers must be established in accordance with *SOP-RG-03 Developing Contracts and Budgets* and *SOP-QA-04 Vendor Assurance*.

- PIs will be required to sign an affirmation that they have sufficient funding to conduct their study.

5.4.5 Resource Support and service provisions

- As per the Epworth Research Handbook where a project requires resources to be allocated from departments or providers outside of the researcher's area of direct reporting. The PI must ensure written support is obtained from the affected party/ies (see optional *FORM-03 Research Support Form*).

5.4.6 Insurance and Indemnity

- All research projects and/or researchers must have adequate indemnity and insurance arrangements in place. This must be confirmed prior to research authorisation being granted and maintained throughout the life of the project (see *SOP-RG-02 Clinical Research Insurance and Indemnity*).

5.4.7 Ionising Radiation

- Where the research project involves exposure to ionising radiation the guidance outlined in *SOP-RG-05 Conducting Research with Ionising Radiation* must be followed.

5.4.8 Clinical Trials Notification (CTN)

- The Sponsor is responsible for submitting the CTN.

- The Epworth HealthCare site must be listed on the CTN where trial procedures are to be conducted.

- The PI or delegate is responsible for providing the site details (outlined in *APPENDIX C*) for inclusion in the CTN and ensuring the details are correct prior to the CTN draft being submitted to the TGA.

- The PI must ensure the Sponsor has provided a copy of the CTN acknowledgement prior to the commencement of the trial at Epworth. As per the *Epworth Research Handbook*, Epworth will not be the Sponsor for a clinical trial.
- Where the CTN is not in place at the time of governance authorisation, the PI should be able to provide evidence of the draft CTN that will be submitted by the Sponsor to the TGA once governance authorisation is received.
- The Sponsor's insurance does not take effect until the TGA acknowledgement is issued.
- The PI is responsible for ensuring evidence of the CTN acknowledgement listing Epworth as a site is filed in the ISF prior to trial commencement.

5.4.9 Clinical Trial Registration

- It is the responsibility of the PI to ensure clinical trials are registered on a publicly accessible site prior to the commencement of the trial at Epworth (see *Epworth Research Handbook*). Registration is usually completed by the Sponsor.
- Evidence of registration should be filed in the ISF prior to commencement of the trial.

5.5 RDGU Governance Authorisation

- The PI, or delegate must submit the required documentation as detailed in 5.4 as relevant to the RDGU for governance authorisation.
- The *Researcher Declaration Form* (see *Related Documents*) must be used as a guide to ensure all governance requirements are met prior to submitting the final documents for Research Governance Authorisation.
- Although evidence of support from relevant departments/divisions is not required as part of the submission pack it must be available and provided to the RDGU upon request.
- The RDGU will then seek final governance authorisation and sign-off on all applicable documentation by the Epworth Group Chief Executive or delegate.
- The RDGU will provide written confirmation of Governance Authorisation to the PI upon receipt of required documents and sign-off by the Group Chief Executive or delegate.
- The PI must ensure all conditions of Governance Authorisation are met prior to commencement of the trial (i.e. CTN and Clinical Trial Registration are in place if not already)

5.6 Once a project has commenced

APPENDIX D includes examples of types of post-authorisation submissions.

The PI must:

- Report to the RDGU any serious breaches of GCP or the protocol relating to Epworth that have been confirmed by the Sponsor (as per *SOP-QA-02 Management of Serious Breaches and CAPA*).
- Comply with the safety reporting requirements as per *SOP-TM-06 Management and Reporting of Safety Events* and adhere with the requirements of the approving HREC.
- Submit to the RDGU any amended or updated documents that may have any financial, logistical, legal and/or risk implications. This must be accompanied with a summary of the changes and all relevant supporting documentation to facilitate review.
- Notify the RDGU by email of any changes to study personnel and ensure all new researchers are credentialed (as per the *Researcher Credentialing SOP-RG-04*) prior to commencing study related activities. This email notification should include:
    - new investigator details,
    - appointment at Epworth,
    - Researcher credentialing date or credentialing documentation, and
    - project number and role in the project.
- Ensure that any changes to resourcing requirements are discussed and agreed to in writing by the affected party/ies (see optional *FORM-03 Research Support Form*).
- Confer with The RDGU to seek confirmation of ongoing governance authorisation and sign-off on all applicable documentation by the Epworth Group Chief Executive or delegate.
- Where an amendment does not meet the requirements for submission to the RDGU the PI must acknowledge the variation in writing (see optional *FORM-04 PI Amendment Acknowledgment*). The date of PI acknowledgement is considered the governance authorisation date in this instance.
- Ensure all documentation associated with amendments (tracked and clean), audits, deviations, breaches, general correspondence, safety and progress reports are filed in the ISF/ study site folder.
- In addition to any HREC requirements, provide a written summary of the trial status to the RDGU on an annual basis until the end of the project this may be in alignment with the HREC reporting timeframes or on the anniversary of research governance authorisation.
- Inform the RDGU in a timely manner when a trial is open to recruitment, closed to recruitment and/or placed on-hold for any reason.
- Provide a final report to the RDGU upon project completion.

The RDGU conducts auditing activities of research at Epworth (see *SOP-QA-05 Clinical Trial Internal Quality Assurance*). The PI must accommodate these activities and allow time to meet with the auditor, where required.

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 Research Policy*
2. *Epworth Research Handbook*

6.1 Related Forms and Templates

- SOP-RG-01-FORM-01 PICF Content Checklist
- SOP-RG-01-FORM-02 Researcher Declaration
- SOP-RG-01-FORM-03 Research Support Form
- SOP-RG-01-FORM-04 PI Amendment Acknowledgement

6.2 Related SOPs

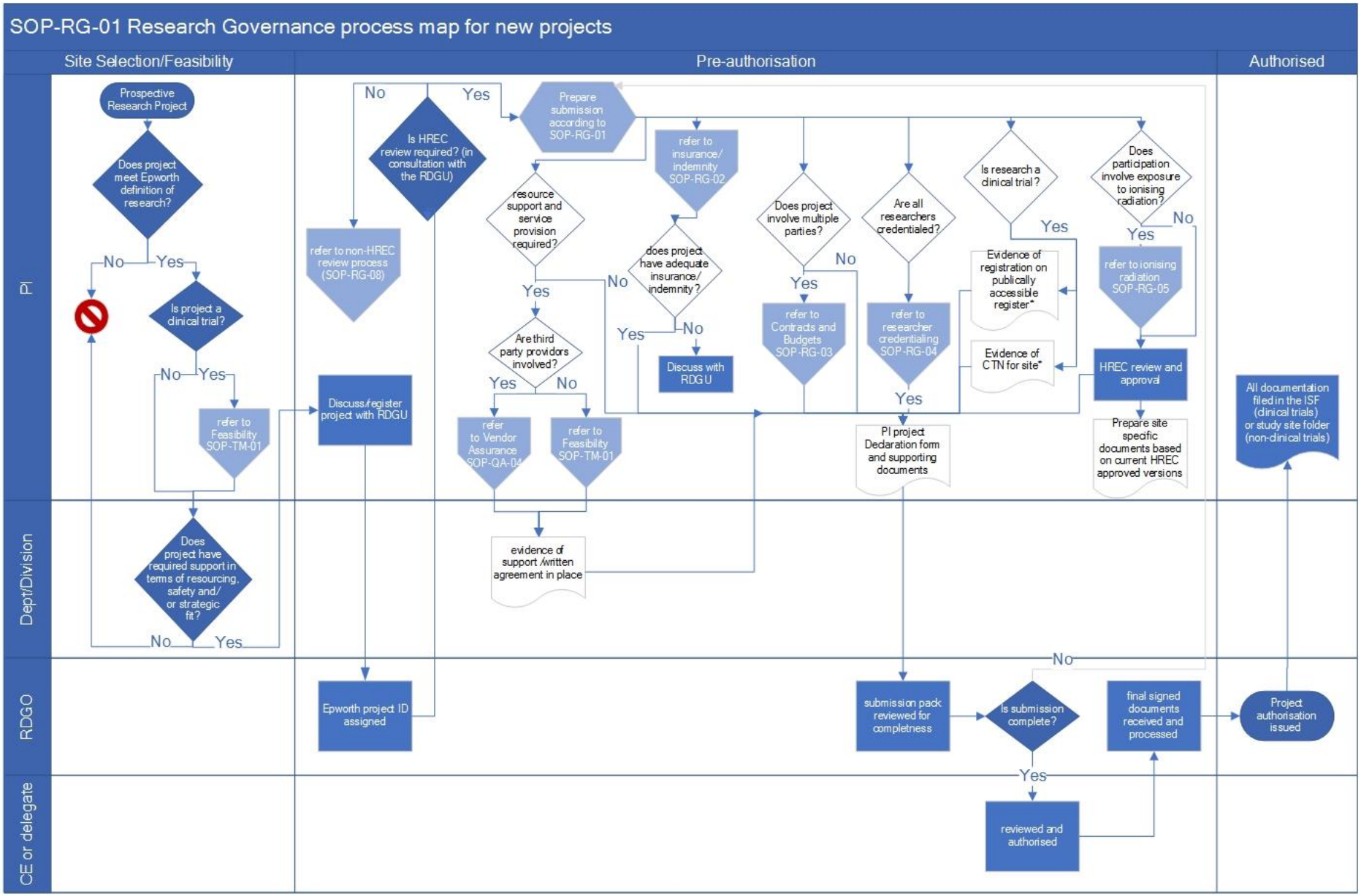
- SOP-QA-02 Management of Serious Breaches and CAPA
- SOP-QA-04 Vendor Assurance
- SOP-QA-05 Clinical Trial Internal Quality Assurance
- SOP-RG-02 Clinical Research Insurance and Indemnity
- SOP-RG-03 Developing Contracts and Budgets
- SOP-RG-08 Non-HREC review process for research involving no more than low-risk
- SOP-RG-05 Conducting Research with Ionising Radiation
- SOP-TM-01 Feasibilities and Trial Start-Up
- SOP-TM-02 Investigator Site File and Essential Documents
- SOP-TM-06 Management and Reporting of Safety Events
- SOP-TM-14 Delegation of Duties
- SOP-Glossary-of-Terms

7. VERSION CONTROL

Document History	
Version	**Summary of Changes**
1.0	N/A First issue
2.0	**Section 5.1** - inclusion of specific reference to Epworth Research Handbook Appendix A: Epworth Research Governance Approval Hierarchy. **Section 5.4.5** - this is a new section. Added to provide further guidance on seeking written confirmation from relevant departments. **Section 5.6** - inclusion of further guidance regarding processing of post approval amendments.

	Hyperlinks to referenced documents updated.
3.0	**Section 5.4.1** - reference to online HREC MoU list removed (RDGU will facilitate implementation where required). **Section 5.4.7** - section replaced with reference to SOP-RG-05 Conducting Research with Ionising Radiation**.** SOP formatting updated.
4.0	**Section 2.0** - clarification projects to be reviewed by non-HREC review pathway are outside the scope of this SOP. **Section 5.0/Appendix A**- research governance process map inserted. **Section 5.4.2/Appendix A**- Epworth complaints contact details removed from Appendix A (and added to FORM-01 PICF Content Checklist). **Section 5.4.8** - further clarification added regarding CTN requirements. **Section 5.6** - further clarification regarding post-authorisation notification requirements**.** **Appendix D –** included to provide examples of the types of post authorisation submissions. Hyperlinks to referenced documents updated.
4.1	**Appendix 3 –** Epworth site contact details to be included in the CTN updated

APPENDIX A: RESEARCH GOVERNANCE PROCESS FLOWCHART FOR NEW PROJECTS



APPENDIX B: MINIMUM INFORMATION REQUIRED FOR PROJECT REGISTERATION

Study Title:

Epworth Principal Investigator:

Sponsor:

Study Coordinator:

Epworth Site(s):

The most recent version of the project protocol must accompany the registration request.

APPENDIX C: EPWORTH SITE CONTACT DETAILS TO BE INCLUDED IN THE CTN

Name of Approving Authority	Epworth Foundation trading as Epworth HealthCare
Approving Authority Contact Officer	Gary Layton
Position	Group Manager – Research Operations
Contact Phone	03 9426 8630
Contact Email	*research@epworth.org.au*

APPENDIX D: POST-AUTHORISATION SUBMISSIONS

The below table includes examples of submissions that are authorised or acknowledged by the RDGU. Note this is not an all inclusive list.

Authorised / Acknowledged	Examples
Acknowledged by RDGU	Updates with no financial/logistic/legal/risk profile impact: • Annual reports • Final reports • Recruitment updates not related to Significant Safety Issues (SSI) • DSMC outcome notifications (if no financial/logistic/legal/risk implications) • Addition of Investigators
Acknowledged by RDGU with notification to ED - A&M or ED - Clinical Services and Nursing Officer and GDRD	Updates with risk profile impact: • Suspected Unexpected Serious Adverse Event (SUSAR) impacting Epworth • Serious Safety Issue (SSI) impacting Epworth • Urgent Safety Measure (USM) impacting Epworth • Serious GCP breaches
Authorised by ED, A&M or ED, Clinical Services and Nursing Officer	Updates that impact the project financially/logistically/legally/risk profile: • Contract Addendums • Addition of Hospital Site(s) • Significant Protocol Amendments
Authorised by ED - A&M, ED - Clinical Services and Nursing Officer, GDRD or ROM	Updates that minimally impact the project financially/logistically/legally/risk profile: • Standard Indemnity Addendums • MOU Addendums • Change of Principal Investigator