STANDARD OPERATING PROCEDURE (SOP)

TITLE: NON-HREC REVIEW PROCESS FOR RESEARCH INVOLVING NO MORE THAN LOW-RISK

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1. PURPOSE:

Chapter 5 of the National Health and Medical Research Council (NHMRC) National Statement on ethical conduct in Human Research 2007 (updated 2018)[1] (the National Statement) permits institutions to establish levels of ethical review other than by a Human Research Ethics Committee (HREC) for projects deemed to be no more than low risk. The purpose of this SOP is to outline the process for non-HREC level of ethical review of projects at Epworth.

2. SCOPE:

This SOP applies to any project that can be considered by non-HREC review pathways as defined by the National Statement. Examples of such projects are listed in *Appendix A.*

Chapter 5 of the National Statement also acknowledges that there are instances where a research project may be exempt from ethical review. If an investigator can justify that their project meets the conditions outlined in section 5.1.22 of the National Statement a submission to the Research Development and Governance Unit (RDGU) is not necessary. If you require an acknowledgement letter for publication purposes, processes set out in this SOP must be followed.

Where there is any uncertainty about whether a proposed project meets the criteria for non-HREC review an independent assessment by an external HREC will be required.

Quality Assurance/Improvement projects are **not** considered under this SOP. Refer to the Quality page on the Epworth *intranet* for guidance on the registration of Quality and Improvement Projects. However if you require an acknowledgement letter for publication purposes, processes set out in this SOP must be followed.

3. APPLICABILITY:

This SOP applies to all Epworth employees, non-employed staff and Visiting Medical Officers (VMOs) wishing to obtain institutional ethical approval for a research project.

4. GLOSSARY OF TERMS:

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

5. PROCEDURE:

The Research Development and Governance Unit (RDGU) oversees the review of Low and Negligible Risk projects deemed suitable for ethical consideration via the non-HREC review pathway. The internal RDGU work instruction for processing such applications in accordance with the National Statement is available on request.

It is the Principal Investigator's (PI) responsibility to ensure that ethical approval and governance authorisation for a project is obtained prior to commencement.

It is the PI's responsibility to ensure that each investigator/author involved in a project reviewed and approved in accordance with this SOP have undergone researcher credentialing where applicable (see *Related Documents*).

5.1 Initial Submission

- The PI or delegate must complete the request for non-HREC review using *FORM 01* or *FORM 02* (as appropriate) and submit along with any supporting documentation to *research@epworth.org.au*.
- Any documents accompanying the submission must include a version number and date within the document.
- 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).
- For multi-site projects the *Ethics Review Manager* (ERM) Quality Assurance & Negligible Risk Form will be accepted on the proviso that the Epworth specific details are provided. Individual institutional consideration regarding ethical review exemption is still a requirement.
- Upon receipt of the application, the RDGU will assign an Epworth identification number. The application will be reviewed to determine if it meets the criteria for non-HREC review or whether it requires ethical review by an external HREC.
- If the project meets the criteria for non-HREC review all ethical and governance considerations will be addressed as part of the review.
- Any inconsistencies or missing information will be queried with the project team.
- The RDGU will provide written confirmation of ethical approval and governance authorisation upon receipt of a satisfactory submission.

5.2 Post-governance authorisation

- The PI must ensure evidence of ethical approval and governance authorisation for a project is kept on file and is available for review upon request.
- The PI must ensure that any amendments or changes to the project are approved by the RDGU prior to implementation.
- It is the PI's responsibility to ensure progress reports for low risk projects are provided to the Epworth RDGU at least annually.

- It is the PI's responsibility to provide a comprehensive final report at the completion of the project.

5.3 non-HREC review and approval for non-Epworth research conducted by VMOs

- The RDGU can provide external review and approval for research projects for Epworth VMOs on request. Where this is requested the steps outlined in section 5.1 and section 5.2 must be followed.

6. REFERENCES:

1. National Statement on Ethical Conduct in Human Research (2007) – updated 2018, section 5.1.18 to 5.1.21. *https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018*

7. RELATED DOCUMENTS:

7.1 Related Forms and Templates

- SOP-RG-01-FORM-03 Research Support Form
- SOP-RG-08-FORM-1 Non-HREC level ethical review request
- SOP-RG-08-FORM-2 Case Study Notification
- SOP-RG-08-TEMPLATE-01 Case Study Consent

7.2 Related SOPs

- SOP-RG-04 Researcher Credentialing
- SOP-Glossary-of-Terms

8. VERSION CONTROL

Document History	
Version	**Summary of Changes**
1.0	N/A original
2.0	Clarification processes set out in this SOP must be followed if requiring review of QA/QI projects for publication purposes.

Appendix A: Essential elements of projects potentially suitable for non-HREC review

Review required	Projects that involve:
Exempt from ethical review (no submission required)	• no more than negligible risk to participants and involves the use of existing collections of data or records that contain only non-identifiable data • data being collected and analysed expressly for the purpose of identifying areas for improvement in the environment from which the data were obtained • the use of research data where the extended consent provided by the participant covers the secondary use of the data.
Epworth Non-HREC level of ethical Review	• that pose no more than low or negligible risk to participants as defined by the national statement; • research that involves comparison of two or more health interventions conducted under routine clinical practice conditions (i.e. comparative effectiveness research) • data collected that potentially infringes on the privacy or professional reputation of participants, providers or organisations. • secondary use of data consistent with the primary purpose of collection. • information collected beyond that which is collected routinely. • the use of identifiable clinical data for education or research purposes where the patient has provided explicit consent • projects using surveys or basic short interviews.