

NEGLIGIBLE RISK/QA MULTI-SITE GOVERNANCE SUBMISSION GUIDE

DEFINITION OF NEGLIGIBLE RISK RESEARCH

Where there is no foreseeable risk of harm or discomfort; and any foreseeable risk is no more than inconvenience. Where the risk even if unlikely, is more than inconvenience, the research is not negligible risk.

Before you begin your application, please review the [National Statement on Ethical Conduct in Human Research](#) and the [Australian Code for the Responsible Conduct of Research](#).

1. GENERATE A LOCAL BARWON HEALTH REFERENCE NUMBER

Generate a reference number via the [Barwon Health Research Reference Number Generator](#).

Please note: All projects must have a Barwon Health representative

2. PREPARE MANDATORY APPLICATION DOCUMENTS

- [Quality Assurance \(QA\) VIC – complete via ERM](#) (required to be signed by the principal investigator, associate investigators, department head)
- HREC Approval Letter
- All documents listed within the HREC Approval Letter

3. PREPARE SUPPLEMENTARY DOCUMENTS (IF APPLICABLE)

- HREC Approval of Amendment Letter(s) (if any) and all documents listed within the HREC Approval of Amendment Letter(s)
- [Fee Payment Form](#) (if the project has funding – see [Fees webpage](#) to confirm requirements)
- Agreements/Insurance Certificate/Indemnity

4. SUBMIT YOUR APPLICATION

- Please refer to our [document naming guidelines](#) before submitting your application
- Submit your complete application (containing all supporting documents and signatures) via [Ethics Review Manager](#) (ERM) by clicking the 'Submit' button

5. REVIEW OF YOUR APPLICATION

Once submitted, your application will be reviewed in office. Feedback and approval letters will be provided within ERM.

If you require assistance, please contact the Research Ethics, Governance & Integrity (REGI) Unit by emailing regi@barwonhealth.org.au.