

NEGLIGIBLE RISK/QA SINGLE-SITE APPLICATION 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 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, head of department)
- [Protocol](#)
- [Research Data Management Plan Checklist](#) (see [Guidelines on Research Data and Records Management Policy](#))
- Curriculum Vitae of all members of the research team

3. PREPARE SUPPLEMENTARY DOCUMENTS (IF APPLICABLE)

- [Waiver of Consent](#) (please complete the [Waiver of Consent Checklist](#) to confirm requirements)
- [Fee Payment Form](#) (if the project has funding – see [Fees webpage](#) to confirm requirements)
- [Authorship Record Form Template](#) (see [Guidelines on Collaborative Research and Authorship](#))
- Supporting Documents (surveys, questionnaires, etc.)

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.

Please note: Negligible risk projects do not require Committee review and can be submitted at any time

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