**APPLICATION FOR EXEMPTION OF ETHICS COMMITTEE REVIEW (For negligible risk, quality assurance, and audit projects)**

The Barwon Health Human Research Ethics Committee (BH HREC) acknowledges that some projects may involve no more that negligible risk (including some quality assurance, quality improvement, audits and service redesign projects). The decision about whether or not your project requires HREC review is made initially by the Research Ethics, Governance & Integrity (REGI) Unit, with advice from the BH HREC, where necessary.

Generate a Barwon Health Reference Number Prior to Submitting Your Application

Generate a reference number via the [Barwon Health Research Reference Number Generator](https://redcap.barwonhealth.org.au/redcap/surveys/?s=MTWRTLKHXX) (please open with Google Chrome).

\*Please note: All projects must have a Barwon Health representative\*

Checklist

Use the following checklist to determine whether you can apply for an exemption from BH HREC review. If in doubt, seek advice from the REGI Unit.

|  |  |
| --- | --- |
| **Criteria for Exemption from Ethics Committee Review**([Based on the National Statement on Ethical Conduct in Human Research (2007)](http://www.nhmrc.gov.au/guidelines/publications/e72)) | **Yes/No** |
| **Risk Level** (*You must answer ‘Yes’ to at least one of the following for the proposed research to be eligible for negligible risk and exemption from ethics committee review)* |
| The proposed project involves no more than negligible risk: *“Research is ‘****negligible risk’*** *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.” (NS p15)* |  |
| The proposed project does not involve physical, psychological, financial, social, and information/privacy risks |  |
| **Data Collection***(You must answer ‘Yes’ to at least one of the following for the proposed research to be eligible for negligible risk and exemption from ethics committee review)* |
| The proposed project:1. aims to establish new knowledge through the use of existing collections of data that contain only **non-identifiable data** about humans:
* ***“Non-identifiable data i****s data that has never been labelled with individual identifiers or from which identifiers have been permanently removed, and by means of which no specific individual can be identified. A sub-set of non-identifiable data are those that can be linked with other data so it can be known they are about the same data subject, although the person’s identity remains unknown.” (NS p27)*

**or**1. aims to establish new knowledge by use of non-sensitive, identifiable information **that has already been collected** as a routine part of practice. This includes:
* data collected as part of patient management via a survey/questionnaire in person or stored in medical records or databases
* data collected as part of staff management, e.g. for training or compliance

**or** 1. aims to establish new knowledge through the use of non-sensitive identifiable information **that will be collected** as a matter of routine business. This includes:
* data collected as part of patient management via a survey/questionnaire in person or stored in medical record or databases
* data collected as part of staff management, e.g. for training or compliance
 |  |
| **Researchers***(You must answer ‘yes’ to this question for the proposed research to be eligible for negligible risk and exemption from ethics committee review)* |
| The proposed project is being conducted by Barwon Health staff or students or affiliates under the supervision of senior BH staff and is not instigated by an external person who is not affiliated with BH |  |
| **Triggers for Consideration of HREC Review**[(Based on the NHMRC’s Guidelines for Ethical Considerations in Quality Assurance and Evaluation Activities)](http://www.nhmrc.gov.au/_files_nhmrc/publications/attachments/e111_ethical_considerations_in_quality_assurance_140326.pdf)*(You must answer ‘No’ to all the following for the proposed research to be eligible for negligible risk and exemption from committee review)* | **Yes/No** |
| The proposed project has the potential to infringe on the privacy or professional reputation of participants, providers, or organisations |  |
| The proposed project gathers **information** about the participant beyond that which is collected routinely (information may include bio-specimens or additional investigations):* Testing of non-standard (innovative) protocols or equipment
* Comparison of cohorts
* Randomisation or the use of control groups or placebos
* Targeted analysis of data involving minority/’vulnerable’ groups
 |  |

Project Details

|  |  |
| --- | --- |
| **Barwon Health Reference Number**  |  |
| **Project Title**  |  |
| **Principal Investigator**  |  |

Project Summary (a lay person summary)

**Justification for Exemption from HREC Review (tick one)**

**[ ]**  **My project involves use of existing data or records** that contain only non-identifiable data about human beings;

**[ ]**  **My project involves only ‘negligible risk’** (as defined in the National Statement on Ethical Conduct in Human Research, Chapter 2.1, Paragraph 2.1.7, i.e. there is no foreseeable risk of ‘harm’ or ‘discomfort’ to participants and any foreseeable risk involves no more than ‘inconvenience’ to participants);

**[ ]  My project has prior approval** from a NHMRC accredited HREC.

Application Documents

Please refer to the [Negligible Risk/QA Single-Site Application Guide](http://www.barwonhealth.org.au/audits-qa-and-negligible-risk-applications) for documentation requirements.

Barwon Health Principal Investigator Details

|  |  |
| --- | --- |
| Name (title/given name/surname) |  |
| Qualifications |  |
| Contact Phone |  |
| Email |  |

Barwon Health Co-Investigator Details (repeat as required)

|  |  |
| --- | --- |
| Name (title/given name/surname) |  |
| Qualifications |  |
| Contact Phone |  |
| Email |  |

 **Declaration by Principal Researcher**

As principal researcher, I recognise that a research activity that is exempted from ethics committee review must comply with the *National Statement on Ethical Conduct in Human Research* and *The Australia Code for Responsible Conduct of Research*. I confirm that to the best of my knowledge, and based on the answers I have provided in this form, this project qualifies for exemption from ethics committee review.

Name:

Signature:

Date:

**Declaration by Head of Department**

I certify that

* I have read this application and the protocol for the above named project and;
* This research can be conducted under the auspices of Barwon Health utilising the resources outlined in the protocol

**AND/OR** - (Executive Officer’s approval is at the discretion of Head of Department)

🞏 This application must be approved by the executive director of my department.

Name:

Designation:

Signature:

Date:

**Declaration by Executive *(if applicable)***

I certify that

* I have read this application and the protocol for the above named project
* This research project can be conducted under the auspices of Barwon Health with the resources outlined in the protocol.

Name:

Designation:

Signature:

Date: