

# 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 than 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.

## 1. Complete 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 Research Ethics Governance and Integrity Unit (REGI).

Criteria for exemption from ethics committee review (Based on the National Statement on Ethical Conduct in Human Research (2007))	Answer yes/no to each of the criteria below
<b>Risk Level</b> <i>*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</i>	
The proposed project involves no more than negligible risk: <ul style="list-style-type: none"> <li>• <i>“Research is ‘negligible risk’ where there is <b>no foreseeable risk of harm or discomfort; and any foreseeable risk is no more than inconvenience.</b> Where the risk, even if unlikely, is more than inconvenience, the research is not negligible risk.” (NS p15)</i></li> </ul>	Yes
The proposed project does not involve physical, psychological, financial, social, and information/privacy risks	Yes
<b>Data Collection</b> <i>*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</i>	
The proposed project: <ol style="list-style-type: none"> <li>aims to establish new knowledge through the use of existing collections of data that contain only <b>non-identifiable data</b> about humans:                             <ul style="list-style-type: none"> <li>• <i>“<b>Non-identifiable data</b> is 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)</i></li> </ul> </li> <li><u>or</u></li> <li>aims to establish new knowledge by use of non-sensitive, identifiable information <b>that has already been collected</b> as a routine part of practice. This includes:                             <ul style="list-style-type: none"> <li>• data collected as part of patient management via a survey/questionnaire in person or stored in medical records or databases</li> <li>• data collected as part of staff management, e.g. for training or compliance</li> </ul> </li> <li><u>or</u></li> <li>aims to establish new knowledge through the use of non-sensitive identifiable information <b>that will be collected</b> as a matter of routine business. This includes:                             <ul style="list-style-type: none"> <li>• data collected as part of patient management via a survey/questionnaire in person or stored in medical record or databases</li> <li>• data collected as part of staff management, e.g. for training or compliance</li> </ul> </li> </ol>	b) Yes

<b>Researchers</b> <i>*You must answer 'yes' to this question for the proposed research to be eligible for negligible risk and exemption from ethics committee review</i>	
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	<b>Yes</b>
<b>Triggers for consideration of HREC review</b> <u>(Based on the NHMRC's Guidelines for Ethical Considerations in Quality Assurance and Evaluation Activities)</u> <i>*You must answer 'no' to all the following for the proposed research to be eligible for negligible risk and exemption from committee review</i>	
The proposed project has the potential to infringe on the privacy or professional reputation of participants, providers, or organisations	<b>No</b>
The proposed project gathers <b>information</b> about the participant beyond that which is collected routinely (information may include bio-specimens or additional investigations): <ul style="list-style-type: none"> <li>• Testing of non-standard (innovative) protocols or equipment</li> <li>• Comparison of cohorts</li> <li>• Randomisation or the use of control groups or placebos</li> <li>• Targeted analysis of data involving minority/'vulnerable' groups</li> </ul>	<b>No</b>

#### ***How to apply for a Barwon Health reference number***

- ***Internal applicants: Apply for a reference number via the Improvement Activity Support icon on Barwon Health apps by [clicking here](#)***
- ***External applicants: Request a reference number by sending an email, noting the Principal Investigator and project title, to [regi@barwonhealth.org.au](mailto:regi@barwonhealth.org.au)***

## **2. Project details**

<b>Barwon Health Reference Number</b>	15/63
<b>Project Title</b>	The presentation and post diagnosis course of coeliac disease in the modern era
<b>Principal Investigator</b>	Dr Emma Flanagan, Gastroenterology Registrar

## **3. Project summary (a lay person summary)**

Coeliac disease (CD) is a gastrointestinal disorder whereby exposure to dietary gluten (contained in wheat, rye and barley) causes damage to the intestinal lining. This damage can result in wide-ranging symptoms and be complicated by health issues such as anaemia, weak bones (osteoporosis) and cancer. Whilst this disease was previously thought to be rare, recent evidence suggests that it affects 1-2% of the Australian population. In the past (when only a minority of cases were probably recognised) CD was thought to present early in life and primarily with gastrointestinal symptoms. Whilst it is now recognised that many cases of CD are diagnosed in adult life and present with non-gastrointestinal symptoms, there have been no detailed studies of the current modes of presentation and post diagnosis course of CD within the Australian population.

The project will involve the retrospective study of 120 cases of CD diagnosed within a single Gastroenterology practice over a 15-year period. The study will review information collected from medical records regarding the presenting symptoms and investigation results including coeliac antibody blood tests and small bowel biopsy histopathology results. The study will aim to identify whether there is a relationship between symptoms and the severity of small bowel damage, the relationship between the severity of small bowel damage at diagnosis

and complications of the disease such as osteoporosis (weak bones) as well the rate of improvement in small bowel damage after adopting a gluten free diet.

**4. Justification for exemption from HREC review (tick one)**

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- 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.

**5. Documents provided in support of this application**

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Document	Version /date
Application for Exemption of Ethics Committee review (this form)	Version 1, Date 19/5/15
Protocol	Version 1, Date 19/5/15
Waiver of Consent (if applicable)	Version 1, Date 19/5/15
Participant Information and Consent Form (if applicable)	N/A
Other ( please specify)	N/A

**6. Research team**

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**Principal Investigator**

Name (title/given name/surname)	Dr Emma Flanagan Gastroenterology Registrar
Qualifications	MBBS
Contact Phone	0418689140
Email	emmakflanagan@gmail.com

**Co-investigator (repeat as required)**

Name (title/given name/surname)	Damian Dowling Gastroenterologist
Qualifications	MBBS, FRACP
Contact Phone	5229 0443
Email	DAMIAND@BarwonHealth.org.au

### DECLARATION by Principal Researcher

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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: Emma Flanagan

Signature: 

Date: 19/5/2015

### DECLARATION by Head of Department

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I certify that I have read this application and the protocol for the above named project and;

I certify that 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: Dr Damian Dowling

Designation: Gastroenterologist. Head of Gastroenterology (Acting)

Signature: 

Date: 19/5/2015

### DECLARATION by Executive (if applicable)

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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: