Exemption from Ethics Committee Review

Application Form

Section A

The Ballarat Health Services & St John of God Hospital Human Research Human Research Ethics Committee (BHSSJOG 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 Office (REGO), with advice from the BHSSJOG HREC, where necessary.

Checklist

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

Criteria for Exemption from Ethics Committee Review (Based on the National Statement on Ethical Conduct in Human Research (2007))	**Yes/No**
Risk Level (*The answer to at least one of the following questions must be 'Yes' for the proposed project 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 *(The answer to one of the following questions must be 'yes' for the proposed project to be eligible for negligible risk and exemption from ethics committee review)*	
The proposed project: a) aims to establish new knowledge through the use of existing collections of data that contain only **non-identifiable data** about humans: • ***"Non-identifiable data** 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)* **OR** b) 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** c) 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	

Investigators *(The answer to this question must be 'yes' for the proposed project to be eligible for negligible risk and exemption from ethics committee review)*	
The proposed project is being conducted by Ballarat Health Services (BHS) 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 BHS	

Triggers for Consideration of HREC Review (Based on the NHMRC's Guidelines for Ethical Considerations in Quality Assurance and Evaluation Activities) *(If the answer is 'No' for all the following questions, the proposed research is 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	
The **data is being sent to a third party**.	
The audit collects information for a thesis, OR for inclusion in a research paper or ongoing project.	

Project Details

ERM Reference Number	
Date	
Project Title	
Principal Investigator	

Project Summary *(a layperson summary)*

☐ **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);

☐ **Publications**

The Ballarat Health Services and St John of God Hospital Ballarat Human Research Ethics Committee encourages the publication of results of the research in a discipline appropriate manner. Publications should provide evidence of the contribution that participants, researchers, funding sources and the organisations have made.

Application Documents

Please upload these forms to ERM .

- This form should added to your ERM Quality Assurance application.
- QA Application also needs to be added to the ERM Quality Assurance application form

Ballarat Health Services Principal Investigator Details

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

Ballarat Health Services Co-Investigator Details (repeat as required)

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

Declaration by Principal Investigator

As principal investigator, I recognise that a project 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 project can be conducted under the auspices of Ballarat Health Services 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 project can be conducted under the auspices of Ballarat Health Services with the resources outlined in the protocol.

Name: ……

Designation: ……

Signature:……

Date: ……

Quality Assurance Application and Protocol

BACKGROUND

An activity where the primary purpose is to monitor or improve the quality of service delivered by an individual or an organisation is a QA activity. Terms such as 'peer review', 'quality assurance', 'quality improvement', 'quality activities', 'quality studies' and 'audit' are often used interchangeably. In this document the term 'quality assurance' is used to include all of these terms.

QA commonly involve minimal risk, burden or inconvenience to participants, and, while some level of oversight is necessary, Human Research Ethics Committee (HREC) review processes are often not the optimal pathway for review of these activities.

Irrespective of whether an activity is QA, evaluation or research, the activity must be conducted in a way that is ethical.

This should include consideration of whether the people involved will be exposed to any harm as a result of the activity.

Those conducting the activity need to consider a range of issues including consent, privacy, relevant legislation, national/professional standards.

Taken from: NHMRC document Ethical Considerations in Quality Assurance and Evaluation Activities, March 2014

Submitting your application: ERM - QA Application to be and submitted via https://au.forms.ethicalreviewmanager.com/Account/Login

Applications without all required signatures will not be processed.

Review of application

Applicant to complete

QA Ref No (ERM Number)	
Full Study Title	

Research Program Use Only

Date Received		Date Approved	
Recommendation			

To place a check in the relevant box, double click on the box and change the default value from "not checked" to "checked"

SECTION 1 | PROJECT TITLE AND DURATION

1.1 Short Project Title/Quick Reference (If different from full study title)

1.2 Anticipated duration of project

Start date	/ /	End date	/ /

SECTION 2 | CONTACT DETAILS

2.1 List all people involved in this project *[Copy this table and repeat for each person]*

Title		**First Name**		**Surname**	
Mailing Address					
Suburb/City			**Postcode**		
Organisation			**Department**		
Appointment			**Qualifications**		
Phone (BH)			**Mobile**		
Email					
Is this person the project lead?			Yes ☐ No ☐		
Is this person the contact for the application?			Yes ☐ No ☐		
Is this person a student?			Yes ☐ No ☐		
Does this person require training in order to complete this project?			Yes ☐ No ☐ *(if yes, specify training required below)*		
Who will provide the training?					

PROTOCOL

SECTION 3 | PROJECT DETAILS

3.1 Have you prepared a separate project outline?

Yes ☐ No ☐

If Yes, ensure all questions below are covered in the project outline.
If No, complete questions 3.2 to 3.10.

3.2 What are the aims of the project?

3.3 What is the problem, procedure or practice that will be assessed?

3.4 What are the likely benefits of conducting this QA project?

3.5 How will you collect the required information to meet the aims of the project? Include details of who will collect the data.

3.6 What information will be collected? Provide details of all data fields (including demographic data) to be collected. Attach a copy of data collection tools.

3.7 What is the data source? (ie health records, electronic database). Include name and owner of any database to be used and ensure you have this person sign the declaration under 5.3.

3.8 How will the collected data be stored? If you will be collecting identifiable data, provide the following:

a. Justification for why this is necessary
b. Details of when identifying information will be removed from the dataset (ie one month after collection)

3.9 Where will the collected data be stored? Include the location of both electronic and hard copy data sources. Note – In accordance with the NHMRC guidelines and BHS procedures.

3.10 How will the collected data be analysed? (ie statistical considerations)

3.11 How long will you store the collected data? How will it be destroyed?

3.12 Will a permanent database of information be created and kept that may be used for further QA or research projects? *(if yes, provide details)*

Yes ☐ No ☐

3.13 How do you plan on disseminating the results of the project? (include internal and external sources)

SECTION 4 | CHECKLIST

4.1 Will the project be conducted by a person who does not normally have access to health information or other records for care or a directly related secondary purpose for the population to be studied? *(if yes, provide justification for why access should be granted)*

Yes ☐ No ☐

4.2 Will this project risk breaching the confidentiality of any individual's personal information (including staff), beyond that experienced in the provision of routine care or service? *(if yes, provide details)*

Yes ☐ No ☐

4.3 Will the project potentially infringe the rights, privacy or professional reputation of carers, health providers or institutions? *(if yes, provide details)*

Yes ☐ No ☐

If you have answered "yes" to any of the above questions, contact the Research Ethics and Governance Office via email ResearchEthics@bhs.org.au to receive written advice on what is required for further ethics review.

SECTION 5 | SIGNATURES

5.1 Project Lead to complete

I declare that the information I have provided is true and to the best of my knowledge. By accessing the data, I will abide by the BHS policies and procedures, and the procedures that have been described in this form.

I acknowledge my responsibilities for the appropriate use of this data in accordance with all applicable acts and guidelines including, but not exclusive to the Privacy Act 1988 (Cth), Privacy and Data Protection Act 2014 (Vic) and the Health Records Act 2001 (Vic).

I agree to notify the Research Office of any changes to the project which may impinge on the ethical principles that guide human research prior to implementation to determine if further ethical review is required.

I agree to submit a brief final report at the conclusion of my project and any abstracts accepted for publication or external presentation.

Name			
Signature		Date	/ /

5.2 Heads of departments to complete

I/we certify that:

- I/we are familiar with this project and endorse its undertaking;
- the resources required to undertake this project are available;

• the project team has the skill and expertise to undertake this project appropriately or will undergo appropriate training as specified in this application.					
Title		Name		Surname	
Position					
Signature			Date	/ /	

5.3 Data custodian to complete (complete for projects involving access to a database or where data collected could impact on another department)

I/we certify that: • I/we are familiar with this project and its implications; • I/we agree to provide access to data as described in this application and supporting documents; • Any special requirements linked to the use of this data are listed below					
Conditions					
Title		Name		Surname	
Position					
Signature			Date	/ /	

SECTION 6 | SUPPORTING DOCUMENTS

6.1 Provide details of all supporting documents in the table below

It is expected that the majority of applications will include the following documents:

- Protocol template should be used for the project outline for QA process (detailed below)
- Data collection form / List of data fields to be collected

(press the 'tab' button multiple times at end of table to create a new line for additional document if space provided is not sufficient)

Document Name	**Version No**	**Date** (DD/MM/YY)	**Office Use Only**
Protocol Template (if completed separately)			☐
Data Collection Form / List of data fields			☐
Exemption from Ethics Review Application form completed **Section A**			☐

Please note: Projects involving access to Health Records
A copy of the completed Health Information Services 'Request for Access to Medical Records' form must be included in your project file. It is expected that you will be able to reproduce this form on request. **Please refer to the following website for the Health Records Act 2001 (Vic)**

SECTION 7 | APPROVAL

Applicant to Complete

7.1	**QA Reference Number**	*ERM reference Number Research Office to provide*
	Full Project Title	
	Risk man please register	Riskman Reference No:

Research Program Use Only

7.2

☐ Approved. (Further ethics review not required)

☐ Not approved. (Further ethics review required) HREC ☐ LNR ☐

Signature _____ Date / /

Secretary BHS Human Research Ethics Committee

Conditions of approval

- Any changes to the project which may impinge on the ethical principles that guide human research must be reported to the Research Program prior to implementation to determine if ethical review is required.
- A brief final report and any abstracts accepted for publication or external presentation must be sent to the Research Program on completion of the project.
- Other (see below):

EXAMPLE OF AUDIT TOOL

Data Audit Tool (use this document to guide review of file entry)
Include episodes of care that are completed or that are currently active.

Data field	Data collection	Data source
URN		IBA
DOB	DDMMYYYY	IBA
Diagnosis	Post stroke (haemmorhagic or infarct); post Acquired Brain Injury; Neurological (other e.g. TIA)	Bossnet
Cognitive Impairment	Is there identified cognitive impairments as a result of ABI: Y/N If "No", cease data collection If "Yes", was cognitive assessment completed: Y/N *(such as neuropsychology assessment, NUCOG, MOCA, Rivermead Behavioural Memory Test or MMSE completed).* What cognitive impairment domains were identified in formal cognitive assessment or within the documentation (tick relevant boxes): ☐ Cognitive fatigue (e.g. mental fatigue, fatigue) ☐ Reduced attention or concentration (may include: distractible) ☐ Reduced speed of information processing ☐ Impaired memory ☐ Issues with executive function (may include: executive dysfunction, executive skills, high level thinking skills) ☐ Lack of initiation (may include: inertia, adynamia, lacking motivation, apathetic) ☐ Reduced planning ☐ Reduced organisation ☐ Concrete thinking (may include: rigid thinking) ☐ Perseveration ☐ Impulsivity ☐ Poor problem solving ☐ Reduced insight (may include: reduced awareness). ☐ Poor behaviour regulation (may include: inappropriate behaviour, poor self-control or self-regulation, lower frustration tolerance, sexualised behaviour, aggressive behaviours, verbal aggression, disinhibition, irritable, distressed) ☐ Emotional Lability (changing moods quickly, laughing or crying inappropriately to context). ☐ Impaired social communication and skills (May include: difficulty with social cues, poor self-monitoring within conversations, verbose)	Bossnet
Premorbid Vocational Role/s	Did the client work or study prior to injury: ☐ Yes ☐ No ☐ Not documented If the client was working or studying prior to their injury, what was their vocation/role (e.g. office administration worker, labourer, hairdresser, police officer)? If stated, what did this work role involve (e.g. typing on a computer, using labouring tools)?	Bossnet