**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**](http://www.nhmrc.gov.au/_files_nhmrc/publications/attachments/e111_ethical_considerations_in_quality_assurance_140326.pdf)**, March 2014**

**INSTRUCTIONS**

This form is to be used for [QA projects](https://www.bhs.org.au/sites/default/files/finder/pdf/ethics-committee/NHMRC%20National%20Statement%20NS.pdf) conducted by Ballarat Health Services staff member accessing existing BHS and Grampians Regional Health data. To be eligible for review as a QA project, the project must meet the following criteria:

* The data being collected and analysed is coincidental to standard operating procedures with standard equipment and/or protocols;
* In accordance with Privacy & Health Legislation requirements.
* The data is being collected and analysed expressly for the purpose of maintaining standards or identifying areas for improvement in the environment from which the data was obtained;
* The data being collected and analysed is not linked to individuals; and
* None of the triggers for consideration of ethical review (listed in point (e) of [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)) are present.

Projects that do not meet the criteria above require formal ethics review. Please note the following:

* If the QA **data is being sent to a third party** then this **is not a QA project**. An LNR application is required for Low risk applications
* *If the audit collects information for coursework or a thesis, or for inclusion in a research paper or ongoing project,* ***it qualifies as research and will require ethics approval.***

**To be eligible for Quality Assurance, the project MUST NOT:**

* Aim to generate new generalizable knowledge
* Involve any significant departure from the routine clinical care provided to patients
* Involve randomisation, control groups, or use of placebo
* Seek to gather information about the participant beyond that collected as part of routine care
* Involve additional testing, blood or tissue collection
* Involve the assessment of safety/efficacy of a new intervention/device
* Impose any additional burden, harm or risk, beyond those associated with routine care
* **Please proceed with a Low Risk Application if your activity involves any of the above.**

**Submitting your application** [QA Application 2018](https://www.bhs.org.au/sites/default/files/finder/doc/research/QualityAssuranceApplicationForm2018.docx) to be downloaded and submitted via <https://au.forms.ethicalreviewmanager.com/Account/Login>

Applications without all required signatures will not be processed.

**Review of application**

Applications are reviewed by the Secretary of the HREC (BHSSTJOG) prior to review and approval by the Sub Committee HREC Research. In general, applicants are emailed their approval or notification that further ethics review is required within 5 working days. **Data** **collection** **must not commence until approval is received.**

**Applicant to complete**

|  |  |
| --- | --- |
| QA ERM Reference number |  |
| Full Study Title |  |

**SECTION 1 | PROJECT TITLE AND DURATION**

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| --- | --- |
| **1.11** | **Short Project Title/Quick Reference (If different from full study title)** |
|  |  |

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| --- | --- | --- | --- | --- |
| **1.21** | **Anticipated duration of project** | | | |
|  | Start date | /       / | End date | /       / |

**SECTION 2 | CONTACT DETAILS**

|  |  |
| --- | --- |
| **2.11** | **List all people involved in this project** *[Copy this table and repeat for each person]* |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **3.11** | **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?** | | |  | | |

**SECTION 3 | PROJECT DETAILS**

|  |  |
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| **3.11** | **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. |

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| **3.21** | **What are the aims of the project?** |
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| **3.31** | **What is the problem, procedure or practice that will be assessed?** |
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| --- | --- |
| **3.41** | **What are the likely benefits of conducting this QA project?** |
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| --- | --- |
| **3.51** | **How will you collect the required information to meet the aims of the project? Include details of who will collect the data.** |
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| **3.61** | **What information will be collected? Provide details of all data fields (including demographic data) to be collected. Attach a copy of data collection tools.** |
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|  |  |
| --- | --- |
| **3.71** | **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.** |
|  |  |

|  |  |
| --- | --- |
| **3.81** | **How will the collected data be stored? If you will be collecting identifiable data, provide the following:**   1. **Justification for why this is necessary** 2. **Details of when identifying information will be removed from the dataset (ie one month after collection)** |
|  |  |

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| **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.** |
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| **3.10** | **How will the collected data be analysed? (ie statistical considerations)** |
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| **3.11** | **How long will you store the collected data? How will it be destroyed?** |
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| --- | --- |
| **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 |
|  |  |

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| **3.13** | **How do you plan on disseminating the results of the project? (include internal and external sources)** |
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**SECTION 4 | CHECKLIST**

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| **4.11** | **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 |
|  |  |

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| --- | --- |
| **4.21** | **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 |
|  |  |

|  |  |
| --- | --- |
| **4.31** | **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 Office via email [ResearchEthics@bhs.org.au](mailto:ResearchEthics@bhs.org.au) to receive written advice on what is required for further ethics review.

**SECTION 5 | SIGNATURES**

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| **5.11** | **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).](http://www.legislation.vic.gov.au/domino/web_notes/ldms/pubstatbook.nsf/f932b66241ecf1b7ca256e92000e23be/05CC92B3F8CB6A6BCA257D4700209220/$FILE/14-060aa%20authorised.pdf)  I agree to notify the [Research Office](mailto:ResearchEthics@bhs.org.au) 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 | /       / |

|  |  |  |  |  |  |  |
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| **5.21** | **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 | /       / | |

|  |  |  |  |  |  |  |
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| **5.31** | **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

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **6.11** | **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** |
|  | CV’s |  |  |  |
|  | Data Collection Form / List of data fields |  |  |  |
|  | Have you completed the  **Seeking Exemption from Ethics Approval.**  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.  Please complete this [**form**](https://www.bhs.org.au/media/mn5ff4pw/ballarat-health-services-exemption-from-ethics-review-application-and-protocol.docx) **and upload the form in the documents section of the QA ERM Application** |  |  |  |

**Please note: Projects involving access to Health Records**

A copy of the completed Health Information Services ‘[Request for Access to Medical Records](https://www.bhs.org.au/node/49)’ 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)**](https://www2.health.vic.gov.au/Api/downloadmedia/%7B50CEBBB5-79EA-421A-944D-754C4BC58281%7D) **SECTION 7 | APPROVAL**

Applicant to Complete

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

**Research Program Use Only**

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| **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](http://www.peninsulahealth.org.au/research-and-education/research-program/) on completion of the project. * Other (see below):  |  | | --- | |  | |  | |  | |  | |  | |  | |  | | | | |