

## PROCEDURE: GUIDELINES AUDIT AND QUALITY ASSURANCE APPLICATION

### Defining Audit and Quality Assurance (QA)

The NHMRC document titled Ethical Considerations in Quality Assurance and Evaluation Activities [Ref 1] explains quality assurance or audit as follows:

*“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.”*

*“Irrespective of whether an activity is called research or QA or evaluation, those conducting the activity must consider whether the people involved (e.g. participants, staff or the community) will be exposed to any risk, burden, inconvenience or possible breach of their privacy”*

The NHMRC document uses the term “evaluation” to encompass the activities which fall under the umbrella of quality assurance and audit and acknowledges that “QA, evaluation and research exist on a continuum of activity, and work that begins as one form of activity can evolve into another over time”.

Nevertheless, it is important to attempt to categorise the activities into research, audit and quality assurance because different levels of review are required for each type of activity. The NHMRC document [Ref 1] suggests that the following are activities which do not require ethical review”

- *“The data being collected and analysed is coincidental to standard operating procedures with standard equipment and/or protocols;*
- *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... are present.”*

The NHMRC document defines the “triggers for ethical review” as:

- *“Where the activity potentially infringes the privacy or professional reputation of participants, providers or organisations.*
- *Secondary use of data - using data or analysis from QA or evaluation activities for another purpose.*
- *Gathering information about the participant beyond that which is collected routinely. Information may include biospecimens 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 whose data is to be separated out of that data collected or analysed as part of the main QA/evaluation activity.”*

Other aspects which would suggest that the activity might need further review include:

- The purpose is not principally to review or improve the quality of a service.
- Where contact with patients identified through a data searching process is required.
- Where consent from patients, volunteers or other health professionals is required.
- The completion of questionnaires which are not part of standard care
- The use of data which is not available within the researcher’s own domain.
- Collection of highly sensitive information.
- The comparison of performance of individual health care professionals, departments or institutions.
- Where the research may possibly infringe Australian Privacy Principles [Ref 2] [Ref 3]
- Where publication or presentation may directly or indirectly identify an individual.

The NHMRC National Statement on Ethical Conduct in Human Research [Ref 4] and the document Ethical Considerations in Quality Assurance and Evaluation Activities [Ref 1] suggest “oversight of the activity is required, but ethical review is not necessary”. The latter document provides guidance about identifying risks of burdens. However, unless it is very clear that the activity is clearly quality

assurance, it is highly recommended that a determination on the nature of the activity be made through application to the Research Office. This determination will be made out of session by the Chairman or delegate and written confirmation of this decision will be provided.

The following sections describe the submission documents<sup>1</sup> which are appropriate for consideration of an activity as quality assurance or evaluation. If the activity is subsequently deemed to be research other documents may be required.

## **Cover Letter – Investigator Statement**

Each submission requires a brief cover letter or email from the investigator which provides a rationale for the proposed activity.

## **Study Plan**

A study plan provides a narrative by which the Chairman can understand the purpose and the conduct of the evaluation activity. It also provides the definitive document of procedures and principles. It should accurately describe all the procedures and discuss any ethical issues associated with the study. Possible headings for a quality assurance or audit activity include:

1. **Title**
2. **Investigator Details and Qualifications**
3. **Purpose Of Activity**
4. **Existing Guidelines or Standard of Care**
5. **Participants** (Types of patient, date range, health care professional etc.)
6. **Existing Data Sources** (for example OACIS, Departmental Records, etc)
7. **Data Collection** (for example patient surveys about their care)
8. **Data Security and Confidentiality Issues**
9. **Ethical Considerations.** (Issues which may need special consideration).

## **Participant Consent**

Where consent to involvement in the activity is required the activity is more appropriately considered as low and negligible risk research. The exception to this may be where a patient is asked about their perceptions of the quality of their care or a health care professional is being asked about their attitudes to a type of treatment. In these instances, unless sensitive information is being sought, completion of the questionnaire is of negligible risk and completion may be taken as consent to use the data gathered. A statement to this effect should be included on the questionnaire wherever possible. If this is not possible then an accompanying document may provide this information.

## **Other documents**

Other documents which may be required and must be submitted include:

- Questionnaires – both paper-based and electronic, eg SurveyMonkey questionnaires.
- Data collection spreadsheets

## **Signatures and approvals**

Confirmation that the study has been discussed and approved by the department in which you work and the Royal Adelaide Hospital or CALHN is primarily a Research Governance responsibility. However, it would be expected that the ethics submission has been discussed with senior people with delegated authority to approve the conduct of the research. These may be heads of Department, Clinical or Nursing Directors or Allied Health Directors. Ethics approval may require a letter or email to confirm that the research has been discussed and agreed by these people.

## **Submission Process**

If you have not submitted a study for ethical review previously it is highly recommended that you consult with the CALHN Researcher Support Officer prior to submission. This can save much time

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<sup>1</sup> All submitted documents should be in MS-Word or searchable PDF format. Scanned PDF documents are undesirable. Each document should be clearly labelled and given a version number and revision date. The version number, revision date, page number and total number of pages of each document should be included in the document footer.

and effort. The Researcher Support Officer may help you decide whether the submission will be considered audit, quality assurance or LNR research. Contact details are listed below.

The Chairman of the committee will make the final decision as to whether the submission requires ethical review. The initial review will occur within 5 working days [Ref 6]. If it is judged to fit within the scope of quality assurance, audit or evaluation a signed emailed letter to this effect will be provided. This letter will state that the activity is considered "exempt from ethical review at the Royal Adelaide Hospital" and should suffice to meet the needs of journal editors should publication be considered. In the response the Ethics Officer will indicate whether a governance review of the activity is likely to be required.

## **Governance Review**

Quality assurance activities are considered part of good clinical practice and provided that the data sources fall solely within the province of the investigator's department or usual clinical practice, governance review is not usually considered necessary. If the activity requires access to other data sources an Access Request Form will be required. For further information about this process contact the Researcher Support Officer on 8222-3337.

## **Scope of Approval**

Activities considered as quality assurance audit and evaluation at the Royal Adelaide Hospital and The Queen Elizabeth Hospital may not be considered so at other institutions and if you wish the ethical review to be recognised across institutions within SA Health you should submit the application as Low and Negligible Risk Research. Mutual acceptance interstate is not possible because the NHMRC National Mutual Acceptance process applies only to clinical trials.

## **CALHN Research Office**

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## References

- 1 Ethical Considerations in Quality Assurance and Evaluation Activities NHMRC 2014 available at [http://www.nhmrc.gov.au/files\\_nhmrc/publications/attachments/e111\\_ethical\\_considerations\\_in\\_quality\\_assurance\\_140326.pdf](http://www.nhmrc.gov.au/files_nhmrc/publications/attachments/e111_ethical_considerations_in_quality_assurance_140326.pdf)
- 2 Australian Privacy Principles, Privacy fact sheet 17. Australian Government January 2014. Available at <http://www.oaic.gov.au/privacy/privacy-resources/privacy-fact-sheets/other/privacy-fact-sheet-17-australian-privacy-principles>
- 3 Guidelines approved under Section 95A of the Privacy Act 1988, NHMRC 2014 available at <https://www.nhmrc.gov.au/guidelines/publications/e43>
- 4 National Statement on Ethical Conduct in Human Research. NHMRC 2007 available at <https://www.nhmrc.gov.au/guidelines/publications/e72>
- 5 RAH HREC – Review and Decision Timelines available at [http://www.rah.sa.gov.au/rec/downloads/REC\\_Review\\_and\\_Decision\\_Timelines.pdf](http://www.rah.sa.gov.au/rec/downloads/REC_Review_and_Decision_Timelines.pdf)
- 6 RAH HREC – Procedure: Guidelines for an Ethics Application – Low and Negligible Risk

## Revision history

Version 1.0 A Thornton 5 October 2014  
Version 2.0 B Swart 10 October 2015