Research Office Procedure
Review of Quality Assurance Activities

Purpose:

To define the type of activities that can be reviewed via Quality Assurance procedures and the procedures of the Royal Victorian Eye and Ear Hospital (Eye and Ear).

Scope:

Procedure:

To meet the following NHMRC guidance[1], the Eye and Ear has implemented a Quality Assurance review procedure as detailed below:

- participants in QA/evaluation are afforded appropriate protections and respect
- QA and/or evaluation is undertaken to generate outcomes that are used to assess and/or improve service provision
- those who undertake QA and/or evaluation adhere to relevant ethical principles and state, territory and Commonwealth legislation
- organisations provide guidance and oversight to ensure activities are conducted ethically including a pathway to address concerns.

Quality Assurance projects need to have Head of Unit/Clinic or relevant Executive Director approval. Quality Assurance projects do not need to be reviewed by the Human Research Ethics Committee. If a formal document advising review and endorsement is required for publication purposes, then the Research Office can provide a review, and can issue a letter of institutional endorsement to provide to journal editors to facilitate publication – refer to The Process section below.

If unsure of whether formal approval is required, contacting the Research Office is recommended as the HREC/Institution cannot provide approval for a project that has already been completed.

Quality Assurance Project Considerations

Privacy and data security

Project teams must ensure that data is managed (i.e. how it is collected, stored, used and destroyed) to ensure that privacy principles are adhered to and maintained in a confidential manner.

Projects that involve collection and use of data for QA

Project teams should consider the identification of risks and burdens to participants:

Risks include not only physical risks, but also psychological, spiritual and social harm or distress

(e.g. stigmatisation or discrimination) and may involve people associated with participants.

Consideration should be given as to whether the proposed QA activity poses any risks for participants beyond those routinely experienced in the environment where QA is being conducted. Burdens may include intrusiveness, discomfort, inconvenience or

embarrassment, e.g. persistent phone calls, additional hospital visits or lengthy questionnaires.

[1] *Ethical Considerations in Quality Assurance and Evaluation Activities*, NHMRC 2014

Project teams must ensure that consent from participants, where required, is adequate.

Participants in prospective projects must be provided with adequate information to provide fully informed consent. This includes the opt-out[2] recruitment approach. If there is an element of deception then ethical review is required.

Quality Assurance project requiring ethical review

The following types of Quality Assurance projects must include an ethical review either via the Low Risk Research or Greater than Low Risk pathway:

- 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

The procedure for obtaining institutional endorsement:

1. If the planned project falls within the Quality Assurance criteria and does not require ethical review, complete the Quality Assurance application form (available on the Research website). It is the responsibility of the Principal Investigator to**:**
   - ensure that the information provided on the form is accurate and detailed sufficiently to enable review;
   - approach the relevant departments for approval to access sources of information and ensure Head of Unit has signed the application form;
   - approach supporting departments for approval to provide the necessary resources (including staff, time, and facilities) and capturing agreement on a Head of Supporting Department form (available on the Research area of Eye and Ear internet site); and
   - inform all those involved in the activity of their responsibilities.
2. Email the completed form and any relevant supporting documents to ethics@eyeandear.org.au In the subject field, type “Project for Quality Assurance review” followed by the last name of the PI.

   There are no submission deadlines for Quality Assurance applications as applications are reviewed on a continuous basis.
3. When an application is received, the Research Office checks the application in order to identify

[2] The opt-out approach is a method used in the recruitment of participants into an activity where information is provided to the potential participant regarding the activity and their involvement and where their participation is presumed unless they take action to decline to participate.

any preliminary issues that might need addressing in order to facilitate thorough review. eg. failure to attach data collection pages.

4. All projects reviewed by the Research Office will be allocated a Research Office reference number. Any correspondence in relation to the project must always make reference to this project number.

5. The application is reviewed by the Research Manager. Any queries, clarification or comments will be emailed to the PI. The Research Manager can escalate the application to the Executive Director, Medical Services or the HREC Chair for additional consideration and decisions where there are additional complexities.

6. The Research Office advises the applicant, of the outcome, which can be:

   i) approval of the application; or
   ii) approval of the application subject to conditions that need to be met before approval can be granted; or
   iii) referral of the application to the HREC or the Low Risk Research Subcommittee of HREC to consider; or
   iv) declining the application.

7. Approval for Quality Assurance applications is granted for the project rather than a time frame.

8. A Final Report is required once the project is completed.

9. A record of all decisions made in relation to Quality Assurance applications reviewed by the Research Office is kept by the Research Office.

Outcomes:

Provide a procedure for ethical review of Quality Assurance activities when it is required.

References:

National Statement on Ethical Conduct in Human Research (NHMRC; 2007 and as amended)

Ethical considerations in quality assurance and evaluation activities (NHMRC; 2014)

Definitions:

Quality Assurance activities	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. Quality Assurance projects may be prospective or use data previously collected.

Legislation:

Privacy Act 1988 (Cth)

Health Records Act 2001 (Vic)

Linked Policy & Procedure:

Research Policy

Approval / Committees:

Executive Director Medical Services/Chief Medical Officer

Responsible Executive:

Executive Director Medical Services/Chief Medical Officer

Procedure Review:

Quality Assurance review processes will be reviewed every three years by the HREC Chair and Research Manager to ensure the process continues to be robust and consistent with the National Statement.

Author / Contributors:

Name	Position	Service / Program
Dr Sean Jespersen	Acting Executive Director Medical Services/Chief Medical Officer	Medical Services
Dr Marc Sarossy	Chair, Human Research Ethics Committee	Medical Services
Dr Andrea Johannessen	Research Manager	Research Office
Ms Kerryn Baker	Administrative Officer	Research Office

Policy / Procedure Details:

Details		
Policy / Procedure Number:	RS1.22	
Section:	Research	
NSQHS Standard:	1 Governance	
Legislation Section:	E – Patient's Rights F - Privacy	
Approval Date:	12/09/2019	
Review Date (s):		
Next Review Due:	29/09/2022	