Ethical considerations for quality improvement and clinical audit activities

Guideline authorisation

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Medical Services

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Purpose

This guideline aims to provide an ethical framework which supports staff to apply sound ethical considerations when undertaking quality improvement and clinical audit activities that impact on patients, staff and/ or the organisation.

Quality improvement and audit activities are recognised as an essential part of improving health services. Basic ethical principles for healthcare are applied to this decision-making process. These principles are outlined by many organisations including the National Health and Medical Research Council:

- Respect for basic human life;
- Justice and equity regardless of background;
- Autonomy;
- Acting with integrity.

Scope/ site specifics

This guideline applies to all Sunshine Coast Hospital and Health Service (SCHHS) employees who are conducting quality improvement, clinical audit and redesign activities that possibly include elements of research. Trigger questions apply to both clinical and non-clinical activities to ascertain whether there are ethical considerations. Ethical determinations are not limited to clinical research.

Guideline

Identifying ethical implications of an activity (quality improvement or clinical audit) - apply the Trigger questionnaire (Appendix 1).

Questionnaire result

Responses to the questionnaire will result in 2 possible outcomes:

1. All statements are false

The activity is a quality/ audit activity that does not require any further ethical consideration. The activity can commence after consideration and approval by the relevant line manager, service group manager or group lead, eg. Chair of the Falls Action Group.

If the quality/ audit activity is intended for publication in journals or presented in open/ external forums (eg. poster at a professional conference) approval should be sought from the relevant line manager, service group manager or group lead prior to submitting an abstract, letter, manuscript or poster for consideration for publication or presentation.

2. At least one statement is true

The activity requires further ethical consideration by a Human Research and Ethics committee (HREC).

- Submissions for an ethical opinion from either The Prince Charles Hospital or Royal Brisbane and Women's Hospital HRECs are lodged using the Ethical Review Manager.
- Once logged into the ERM, create a new project and select 'Queensland Health' and 'LNR Form'.
- Complete the PRE LNR QUESTIONS and click 'Yes' to Question 5 which asks, 'Is the study a clinical audit or quality assurance activity?'
- A brief project plan and cover letter are required as part of the ERM submission for an ethical opinion. This opinion will determine whether the activity is either quality improvement or research.
- The outcome is typically provided in writing within 1-2 weeks from submission and may be progressed by the HREC out of session.
- Activities determined to be research must follow SCHHS procedure Research application and approval. Refer to Appendix 2 - Ethical consideration for quality improvement and clinical audit activity flowchart.
- Note: further detailed information can be found in the NHMRC paper Ethical Consideration in Quality Assurance and Evaluation Activities, March 2014.

Contact

Staff and line managers who are unsure of the ethical requirements of an activity should contact:

SCHHS Research Governance and Development
Phone 5202 2991
email SC-Research-Support@health.qld.gov.au

OR

SCHHS Quality Improvement Team
Safety Quality and Innovation Unit
Phone 5202 7774
email sc-safety-ready@health.qld.gov.au.

For all quality improvement and audit activity, ongoing feedback of the progress and outcomes of the activity are to be coordinated as part of the initial activity plan and reported accordingly.

All quality improvement activities are to be recorded in the SCHHS Quality Improvement Register.

Definition of key terms

Term	Description
Quality improvement (QI)	"An organised process that assesses and evaluates health services to improve practice or quality of care". Quality improvement includes terms such as 'quality assurance', 'quality activities', 'quality studies', and 'audit' (in medical, surgical, clinical, and non-clinical areas). Quality improvement activities are generally conducted with the purpose of determining health service performance in relation to a standard, procedure or other pre-determined guideline; or seek to identify patient satisfaction with service. Where a standard does not exist, and the quality activity aims to identify best practice care, an ethical opinion should be sought.
Clinical audit	"The provision of any summary of clinical performance over a specified period of time. The summary may include data on processes of care (e.g. number of diagnostic tests ordered), clinical endpoints (e.g. blood pressure readings), and clinical practice recommendations (proportion of patients managed in line with a recommendation)." Clinical audits are generally activities which aim to identify the "status quo" in health service performance or functioning. Where a clinical audit aims to answer a question (for example, what is the relationship between a particular treatment and hospital re-admission), an ethical opinion should be sought.
Research	Research projects are activities which aim to identify new information and knowledge (for example, what is the best way to treat a patient group; what long-term outcomes do patients experience following clinical care). Research projects are generally developed on the basis of a specific question, with aims and/or hypotheses that inform the conduct and outcomes of the study. Research can be conducted with or without the direct involvement of patients (for example, a retrospective chart review).
Trigger questions	In this context, the considerations are applied when screening for any ethical impact of an activity on the patients, staff and/or the organisation. These trigger questions are based upon the NHMRC Ethical Considerations in Quality Assurance and Evaluation Activities document.

References and further reading

Australian and New Zealand College of Anaesthetists (2018). *Guidelines on Quality Assurance and Quality Improvement in Anaesthesia*. http://www.anzca.edu.au/documents/ps58-2012-guidelines-on-quality-assurance-in-anaes.pdf

Australian Commission on Safety and Quality in Health Care (2017), *National Safety and Quality Health Service Standards; 2nd Ed*. ACSQHC; Sydney.

Australian Council on Healthcare Standards (2013), *Risk Management and Quality Improvement Handbook. Sydney Australia; ACHS.*

Carr, E.C.J. (1999). Talking on the telephone with people who have experienced pain in hospital: clinical audit or research? *Journal of Advanced Nursing, 29*(1), pp.194-200.

Jamtvedt, G., Young, J.M., Kristoffersen, D.T., O'Brien, M.A., Oxman, A.D. (2006) Audit and feedback: effects on professional practice and health care outcomes. *Cochrane Database of Systematic Reviews* 2006(2):CD000259.

National Health and Medical Research Council (2018). *Australian Code for the Responsible Conduct of Research.*

National Health and Medical Research Council (2014), Ethical Consideration in Quality Assurance and Evaluation Activities,

National Health and Medical Research Council, Australian Research Council & Universities Australia (2018). *National Statement on Ethical Conduct in Human Research*. NHMRC; Canberra.

Primary legislation, policy, standards or other authority

Hospital and Health Boards Act 2011

Metro North Hospital and Health Service Research

National Safety and Quality Health Service Standards 2nd ed – Clinical governance

Other related or supporting documents

SCHHS procedure 000879 - Research application and approval

SC QHEPS Safety, Quality and Innovation Unit intranet site

SC QHEPS Quality improvement and redesign services intranet site

SCHHS procedure 000132 - Health record access for research and clinical audit

Consultation

Director Safety, Quality and Innovation
Chief Operating Officer
Executive Director of Allied Health
Executive Director of Medical Services
Medical Lead, Safety Quality and Innovation Unit
Research Operations Group
Director, Project Management Office
Safety Improvement Support Officer, Women's and Family Services
A/ Manager, Library Services
Principal Advisor, Quality Improvement
Director, Research
General Manager Medical Services
General Manager Surgical Services
Executive Director Nursing and Midwifery Services
Director, Strategy and Performance, MHAS
Quality Improvement Facilitator
Quality Improvement Advisor
Safety Improvement Support Officer, Community Integrated and Sub-Acute Services
Principal Engagement Officer, SQIU

Compliance

Annual review of the quality improvement register and clinical audit register:

- % of quality improvement activities and clinical audits with ethics questionnaire completed.
- % of quality improvement activities provided a further ethical opinion.

Document approval

Version	Prepared by	Endorsed by	Authorised by	Review due
4.0	Principal Advisor, Quality Improvement	Director, Safety Quality and Innovation Unit	Executive Director Medical Services	02/04/2022

Appendix 1 - Trigger questionnaire

Identifying if ethical considerations apply (True or false)

1. Does the activity potentially infringe the privacy or professional reputation of participants, providers or organisation, *e.g. is the patient's information required beyond that which is needed for routine care?*

   True/ false

2. Does the activity involve secondary use of data - use of data or analysis for another purpose, *e.g. using the data from one project for a different project or purpose?*

   True/ false

3. Will you be gathering information about the participant beyond that which is collected routinely? Information may include bio-specimens or additional investigations, *e.g. the patient is asked to provide extra blood specimens beyond what is routinely collected.*

   True/ false

4. Does the activity require testing of non-standard (innovative) protocols or equipment, *e.g. is a new device or type of service delivery being trialled and compared with standard care?*

   True/ false

5. Does the activity involve a comparison of cohorts*, e.g. patient groups (such as age groups) are selected out of the original sample for comparisons?*

   True/ false

6. Does the activity involve randomisation or the use of control groups or placebos, *e.g. one group of patients is selected for routine care while another group are provided the new care?*

   True/ false

7. Targeted analysis of data involving vulnerable populations whose data is to be separated out of that data collected or analysed as part of the main QA/evaluation activity, *e.g. Aboriginal and Torres Strait Islander people/s, vulnerable populations?*

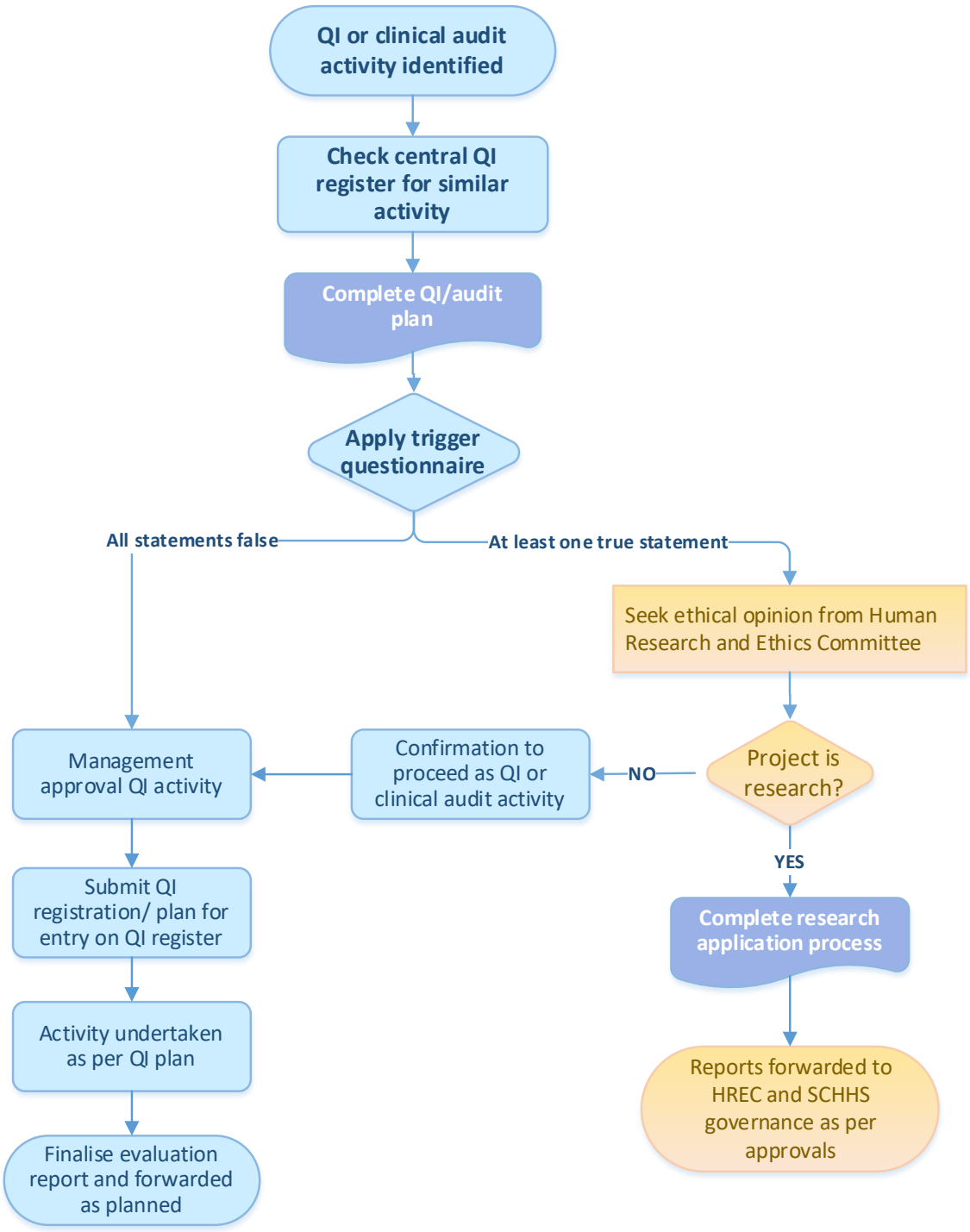
   True/ false

All statements false – No further ethical considerations required. Prepare the QI/ clinical audit activity plan for manager approval.

At least one statement true - Seek ethical opinion from HREC. Refer to Appendix 2 - Ethical Consideration for Quality Improvement and Clinical Audit Activity flowchart.

Appendix 2 – Flowchart

Ethical consideration for quality improvement and clinical audit activity



For further information, contact:

Quality Improvement Team, 5202 7774/
sc-safety-ready@health.qld.gov.au

Research Governance and Development Unit, 5202 2991/
sc-research-support@health.qld.gov.au

Ref. SCHHS procedure Ethical considerations for quality improvement and clinical audit activities (Doc ID 000018)