Quality Assurance, Quality Improvement and Evaluation Activities at ECU

ECU Research Governance have developed a range of guidelines which describe the institutional position on key ethical matters. These position statements should be used by ECU researchers and reviewers alike to ensure the ethical conduct of research at ECU is consistent with the University's position as well as other external guidelines, policies and legislation.

Background

This guideline[1] provides advice to ECU staff members and students when seeking to determine if the activity they are about to undertake constitutes research, quality assurance (QA), quality improvement (QI), or an evaluation of an ECU teaching and learning initiative (E).

What this framework does **NOT** apply to:

1. ECU's institutional monitoring and compliance activities.
2. Activities undertaken by ECU staff using **ONLY** standard ECU QA data (e.g., Tableau dashboards, ECUonQ, UTEI's). Approval for activities of this nature should be sought from the CLT Director and do not require research ethics approval.

This framework **DOES** apply if participants are potentially identifiable in activities undertaken at point 1 and 2 above.

The process of unpacking what constitutes research and what constitutes QA, QI and E is challenging because all of these activities can apply the same methodologies, and what begins as one form of activity can quickly evolve into something different.

Guideline

Rather than attempt to define activities as research or QA, QI and/or E, this guideline provides a framework enabling the identification of the set of policies relevant to the activity. Once directed to a particular set of policies, it is expected that the activity will be compliant with policy requirements.

To determine which policies an activity falls under, the following questions should be considered:

1. Will the people involved (e.g., participants, students, staff or the community) be exposed to greater than negligible risk?
2. Will the people involved (e.g., participants, students, staff or the community) be exposed to any inconvenience?
3. Does the activity potentially infringe the privacy or professional reputation of participants, providers or organisations?
4. Does the activity involve the secondary use of data (e.g., using data or analysis from QA, QI or E activities for another purpose)?
5. Does the activity involve gathering information about the participant beyond that which is collected routinely (e.g., routine collections might be Tableau dashboards, ECUonQ, UTEI's)?
6. Does the activity involve the testing of non-standard (innovative) protocols or equipment?
7. Does the activity involve the comparison of cohorts?
8. Does the activity involve randomisation?
9. Does the activity involve the use of control groups or placebos?

[1] This guideline is based on guidance provided in the NHMRC (2014) document on Quality Assurance and Evaluation Activities.

10. Does the activity involve targeted analysis of data involving Aboriginal and Torres Strait Islander Peoples, minority or vulnerable groups as defined by the National Statement whose data is to be separated out of that data collected or analysed as part of the main activity?
11. Do you plan to publish via the peer review process, or present the findings of evaluation activities at a conference?

If the answer is **YES** to **ANY** of these questions, the activity falls within the remit of the ECU Research Ethics Management System and associated policies. Therefore, the activity requires research ethics approval.

If the answer is **NO** to **ALL** of these questions, the activity falls within the remit of ECUs QA and QI policy frameworks.

Guidance for specific issues

QA/QI research activities requiring a waiver of consent.

No waiver of consent can be granted by the ECU Human Research Ethics Committee for health research where ECU is not the data custodian.

QA/QI type activities which ECU considers to be research, but the health organization considers to be exempt from ethical review.

An ECU research ethics application is required. The researcher will need to demonstrate:

1. The activity meets NHMRC QA guidelines.
2. How non-identifiable data is provided for analysis.

The researcher will need to provide:

1. A letter signed by the researcher indicating that the activity is QA and not research.
2. A letter of support from the Head of Department of the relevant health organisation.
3. Where Governance, Evidence, Knowledge and Outcome (GEKO) approval is not provided then an institutional letter of support clearly showing that the health organization is aware of all activities being undertaken which ECU classify as research (e.g., publication in journals, as part of a thesis, conference presentation etc).

Further Information

1. National Statement on Ethical Conduct in Human Research
2. NHMRC (2014) Ethical Considerations in Quality Assurance and Evaluation Activities

Contact information

For queries relating to this document please contact research.ethics@ecu.edu.au

Version History

Developed By	Date	Next Revision Due
Research Governance	*5 October 2021*	*5 October 2024*