

# Ramsay National Research Unit

## Quality Assurance Framework

### RHC Quality Assurance Guidelines

Quality Assurance (QA) activities are often also called ‘quality improvement’ or ‘clinical audit’. The [NHMRC: Ethical Considerations in Quality Assurance and Evaluation Activities \(2014\)](#), state that QA activities have a “primary purpose to **monitor or improve the quality of service delivered by an individual or an organisation.**” This is usually achieved by analysing routinely obtained data to capture current practice and **comparing this to existing best practice standards/guidelines.**

QA activities do not involve extra interventions or clinical assessments. Refer to Table 1 for examples of types of QA activities.

|                                                             |                                                                                                                                                                                                                                                                                                                                                                                              |
|-------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Audit                                                       | Systematic review of clinical care against benchmarks, or standards and the implementation of changes in practice if needed.                                                                                                                                                                                                                                                                 |
| Service Improvement                                         | Implementing an initiative to promote change or maintain good practice to improve quality of care.                                                                                                                                                                                                                                                                                           |
| Practice Review                                             | Systematic assessment of current practice, without comparison against a benchmark, standard, or alternative intervention. Focuses on describing or documenting current practice.                                                                                                                                                                                                             |
| Satisfaction/Knowledge Survey                               | Systematic collection of data to determine levels of satisfaction or knowledge about a service.                                                                                                                                                                                                                                                                                              |
| Program Evaluation                                          | Systematic collection and analysis of information about a specific program or intervention to allow its critical appraisal.                                                                                                                                                                                                                                                                  |
| <b>Activities eligible for exemption from ethics review</b> |                                                                                                                                                                                                                                                                                                                                                                                              |
| Case Series/Case Report                                     | A descriptive, observational, and non-experimental activity that follows a group of patients with a similar diagnosis, exposure, or treatment over time. Case series typically describe clinical observations, trends, or experiences within a limited patient group. To be considered exempt from ethics review Case Series/Case Report should involve only <b>up to five (5) patients.</b> |

Table 1: Types of QA Activities

### Quality Assurance vs Research

Quality assurance, evaluation and research can exist on a continuum. Your project might begin as one type of activity and evolve into another type of activity over time<sup>1</sup>. For this reason, the boundaries between quality assurance, evaluation and research can be fluid. Research and QA projects often use the same methods (e.g. similar design, surveys, interviews, data analysis) and the same ethical principles apply. The difference between the two is around the intent of the work:

- *Research* is to **discover** what is the right/best way of doing something
- *QA/QI* is to evaluate/assess if current practice is **meeting expected standards**

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Refer to Table 2 for more details.

| Aspect                    | Quality Assurance (QA)                                                                  | Research                                                                                                                        |
|---------------------------|-----------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------|
| Primary Purpose           | To monitor, evaluate, or improve the quality of service or care.                        | To generate new, generalisable knowledge or test hypotheses.                                                                    |
| Design                    | Often descriptive or evaluative; may include audits, surveys, and service reviews.      | Structured and hypothesis-driven; may involve experimental or observational studies.                                            |
| Comparison                | Involves comparison to established standards, guidelines, or benchmarks.                | Involves comparison to controls, or alternative interventions.                                                                  |
| Focus                     | Evaluate adherence to existing best practice.                                           | Investigates new treatments or areas where best practice is not yet established.                                                |
| Risk to Participants      | Minimal risk; no additional interventions beyond routine care.                          | May involve additional risks due to interventions or data collection beyond routine care.                                       |
| Participants              | Involves site-specific staff or departments; data relates to the specific service area. | Involves patients or participants beyond the site to ensure a representative sample can be obtained and the results generalised |
| Outcome Use               | Intended for local service improvement.                                                 | Intended for publication and contribution to generalisable scientific knowledge.                                                |
| Dissemination of Results  | Shared internally to educate and promote best practice.                                 | Shared externally through publication to inform a wider audience.                                                               |
| Ethics Review Requirement | Usually does not require HREC review, but ethical oversight is still necessary.         | Requires HREC review and approval before commencement.                                                                          |

**Table 2: Key aspects to determine QA vs Research**

Irrespective of whether an activity is QA, evaluation or research, the activity must be conducted in a way that is ethical, and 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.

## Publishing QA

QA projects are generally **internal activities** that aim to determine if a particular treatment or procedure at an institution is **meeting expected standards**. If deficiencies are detected changes might be made to clinical practice, local guidelines updated, or staff training provided.

If the primary purpose is to publish your findings, you should reconsider whether the results constitute new, generalisable knowledge, and are therefore research. *For any external publication or presentation of QAs, the site must be given the opportunity to review the final document prior to submission.*

**Note: Retrospective approval for already conducted quality assurance or research activities cannot be granted.**