Ramsay National Research Unit

Quality Assurance Framework

2026-2029

1. Introduction and Scope

Ramsay National Research Unit (NRU) is committed to support the conduct of high-quality research activities across Ramsay Health Care. The Quality Assurance (QA) Framework is designed to support quality assurance activities conducted at Ramsay facilities and contains comprehensive decision tools, guidance and supporting application documents to assist all applicants throughout the QA application process. The decision tools are designed to guide the applicants and help them determine whether their proposed activity meets the criteria for QA or research, ensuring the correct review pathway is followed.

Activities eligible for exemption from ethics review as defined in 5.1.17 in the National Statement on Ethical Conduct in Human Research (2025) such as case studies, case reports, etc are also included in this Framework.

The QA Framework applies to all Ramsay staff members, Visiting Medical Officers and external parties who are willing to conduct quality assurance activities at Ramsay Health Care facilities.

This Framework **does not cover** clinical audits undertaken under the Ramsay Clinical Auditing Program (CAP) for mandatory accreditation purposes and compliance with the National Safety and Quality Health Service Standards (NSQHS) and other regulatory and legislative obligations. The CAP Program is overseen by the National Clinical Governance Committee (CGC) and is implemented by the National Clinical Governance Unit (NCGU). Refer to the CAP Framework for more details and guidance.

2. Definitions

Quality Assurance (QA) activities (often also called “quality improvement’, “clinical audit”, or “evaluation”) have a primary purpose to monitor or improve the quality of service delivered by an individual or an organisation, usually by analysing routinely obtained data **to capture current practice and compare this to existing best practice standards/guidelines**. QA activities **do not involve extra interventions or clinical assessments**. These activities are usually self-initiated and voluntary, rather than mandatory. The QA applications are reviewed in accordance with the National Health and Medical Research Council (NHMRC) guideline, Ethical Considerations in Quality Assurance and Evaluation Activities (2014) .

3. National Research Unit Quality Assurance Framework

The QA framework is a suite of documents designed to Ramsay support staff, Visiting Medical Officers and external parties, by offering guidelines and decision support tools to assist in the development and submission of applications to the NRU.

The decision support tools aim to guide applicants through a structured set of questions to determine whether their proposed activity meets the criteria for QA or research, ensuring the correct review pathway is followed – either clinical governance oversight or if research – research ethics and research governance oversight.

In addition, the application form has been updated to provide further clarity regarding the QA requirements. These revisions aim to simplify the application process, reduce common errors, and ensure that all required information is

captured, supporting timely review by the NRU. The NRU Quality Assurance Framework encompasses the following documents:

- Quality Assurance Scope Checker and Application Pathway
- RHC Quality Assurance Guidelines
- RHC Quality Assurance vs Research Decision Tool
- RHC Quality Assurance Application Form
- RHC Guidance on Completing Quality Assurance Application Form

4. National Research Unit Process for QA Applications and Review Pathways

Principles of QA Determination

The NRU reviews QA applications in line with the NHMRC guideline, Ethical Considerations in Quality Assurance and Evaluation Activities (2014) . Activities eligible for exemption from ethics review as defined in 5.1.17 in the National Statement 2025 such as case studies, case reports, etc are also included in this framework. Irrespective of whether an activity is QA or research, the activity must be conducted in an ethical way, 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.

Some triggers that require ethical review include:

- 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.
- 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

QA Application Process

- The QA application process begins with the completion of the RHC QA Application Form.
- The applicant may request a complimentary consultation from the NRU, where ethics and governance representatives will meet and discuss the project proposal and provide guidance on the appropriate application pathway and requirements. During this session, the applicant is also advised if the proposed design may trigger ethics and governance review and is provided with the relevant information.
- The RHC QA Application Form must then be presented to the Site Executive for site endorsement at the relevant RHC facility where the study will be conducted. The site Executive should be providing the authority as endorsing the activity as a QA based on the project details. i.e confirming that it is QA. If there is doubt, the endorsement should state that additional review may be required by HREC etc.

- Once endorsement has been obtained, both the completed application form and endorsement correspondence must be emailed to the NRU inbox.
- Applications submitted to the NRU inbox are reviewed in order of submission. Each submission is independently reviewed by two NRU representatives in line with the QA Framework requirements, and a determination is communicated within 10 business days.
- A determination is made as to whether the project meets the criteria for HREC exemption or should be classified as Low-Risk Research requiring ethics and governance approval. If the two reviewers are unable to reach a consensus, the application is escalated to the Head of Research Impact & Enablement for deliberation and decision.
- When an application is assessed as meeting criteria for HREC exemption, the applicant is notified and issued with a HREC Exemption Letter. This communication includes the Site Safety and Quality Manager and outlines the site requirements.
- If an application is classified as Low-Risk Research, the applicant is advised to submit a Human Research Ethics Application (HREA) for review via REGGS. At this stage, applicants are also offered a complimentary consultation session and are provided with the relevant guidance materials to support the preparation of their submission.

5. References

1. National Health and Medical Research Council. **National Statement on Ethical Conduct in Human Research (2025).** Available from: https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2025
2. 1. National Health and Medical Research Council**. Ethical Considerations in Quality Assurance and Evaluation Activities (2014)**. Available from: https://www.nhmrc.gov.au/about-us/resources/ethical-considerations-quality-assurance-and-evaluation-activities
3. Australian Commission on Safety and Quality in Health Care. **National Safety and Quality Health Service Standards (NSQHS), second edition (2021).** Available from: https://www.safetyandquality.gov.au/publications-and-resources/resource-library/national-safety-and-quality-health-service-standards-second-edition