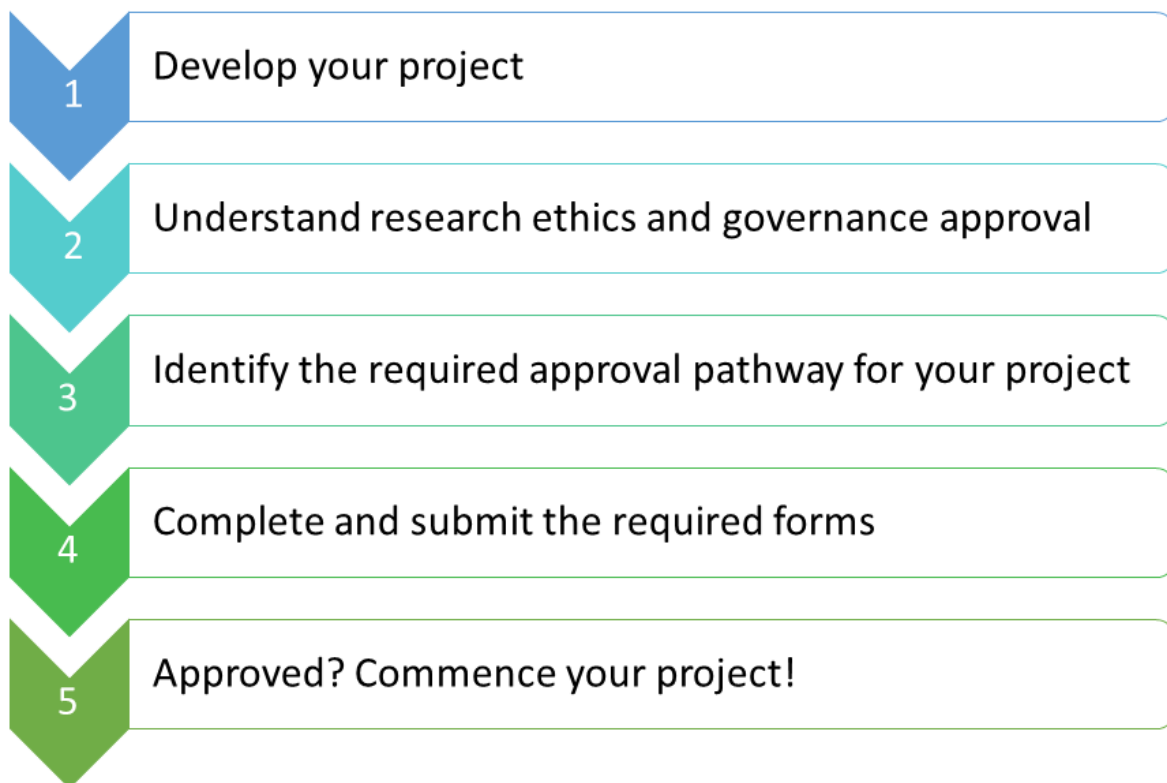


A Simple Guide to Approvals for Research Projects at Northern Health

All research activities at Northern Health require appropriate approvals. This Guide will assist you to understand the most appropriate pathway for approval of the project you have planned. However, we **strongly encourage** you to meet with the Research Development and Governance Unit (RDGU) (ResearchDGU@nh.org.au) early in your project planning process, especially if you are new to Northern Health and/or research. *Engaging with the RDGU early supports timely approval and project commencement.*



Step 1: Develop your project

In order for your project to be ready for ethics and governance review, the following key project development tasks need to be undertaken:

1. Clearly describe the aims, objectives and hypothesis(es) of your project.
2. Evaluate the feasibility of your project
3. Discuss the project in detail with an experienced research supervisor (if appropriate)
4. Decide on the appropriate approval pathway

More information on these steps can be found [below](#).

Step 2: Understand Research Ethics and Governance Approval

Research Ethics

The relationship between researchers and research participants should be one of trust, mutual responsibility and ethical equality. [The National Statement on Ethical Conduct in Human Research 2023](#) (National Statement) sets out the values upon which this relationship should be shaped. These values include *respect for human beings, research merit and integrity, justice, and beneficence*. To ensure research is conducted in alignment with these values, most research projects (especially those that are greater than low risk) will require review by a Human Research Ethics Committee (HREC). The HREC will use the guidance provided by the National Statement to assess whether a research project meets ethical standards and guidelines, and where necessary, advise on adjustments to the research protocol required to achieve this. While Northern Health does not have an in-house HREC, the required approval can be granted by a HREC from another institution ([see below](#)).

Research Governance

Prior to commencing a research project, researchers require both ethics and governance approval. Research Governance refers to the processes that are followed to ensure that the project aligns with strategic intent, is feasible, and satisfies all of the regulatory requirements, including ethical compliance. Approval is managed by the Northern Health RDGU. It is separate to ethics approval, and is commonly referred to as Site Specific Assessment (SSA). The documentation required includes sign-off by relevant persons/departments at Northern Health to confirm that each participating department has the resources, expertise and facilities to conduct the project.

Step 3: Identify the required approval pathway for your project

The level of risk to both participants and organisations that is associated with your planned project determines the approval pathway it will need to follow before your project can commence at Northern Health.

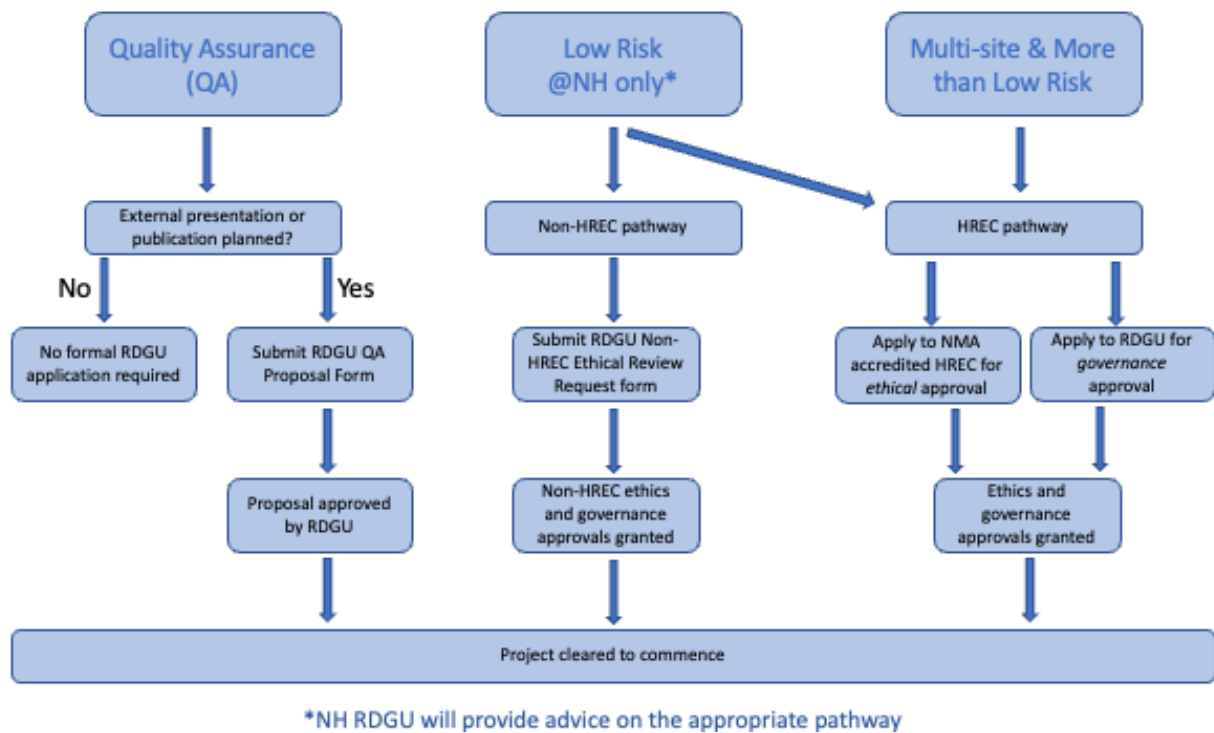
The following table and flowchart aim to assist you to identify and understand the appropriate pathway for your project. Please contact RDGU if unsure.

| | Approval Pathway | | |
|-------------------------------------|--|--|--|
| | Quality Assurance ¹ | Non-HREC | HREC |
| Primary purpose | Assessment of current standard of care to compare against established benchmarks or evaluate an established aspect of care. Does not include prospective evaluation of a quality improvement activity or change in standard of care. | Any other quality improvement (QI) or research activity | Any other quality improvement (QI) or research activity. |
| Collection of data | Only data already collected as part of clinical care or hospital processes may be included | Any other data, including surveys and investigations additional to routine clinical care collected prospectively | Any other data, including surveys and investigations additional to routine clinical care collected prospectively |
| Number of centres | Northern Health only | Northern Health only | Northern Health only where activity is more than low risk; Multicentre studies where data is shared across sites |
| Need to discuss with NH RDGU | Yes, if findings from the QA project are planned for dissemination, either via a conference presentation or publication, outside of Northern Health [#] | Yes | Yes |
| Investigator Team | NH staff with usual access to the required data | Must be led and/or supervised by experienced NH Researcher | Must be led and/or supervised by experienced NH Researcher |
| Risk | No risk to participants or organisation | Low* risk to participants or organisation | Low or More than low risk to participants or organisation |
| Approval method | QA Proposal Form if findings planned for dissemination, either via conference presentation or publication, outside of Northern Health | Non-HREC Pathway | HREC Pathway |
| Examples | <ul style="list-style-type: none"> Clinical morbidity and mortality audits Retrospective data collection to evaluate prescribing patterns or clinical investigations Evaluation of a change that has already been implemented in service delivery | <ul style="list-style-type: none"> Projects/Audits where: <ul style="list-style-type: none"> a standard is not known the purpose is quality improvement the generation of new knowledge is required NH Patient surveys | <ul style="list-style-type: none"> Projects requiring consent or waiver of consent Multi-site surveys and other data collections outside routine care Clinical Trials Biobanks Genomics |
| Exemplars | <i>Coming soon</i> | <i>Coming soon</i> | <i>Coming soon</i> |

* The term 'negligible' risk has not been used, in line with upcoming changes to the National Statement (2023).

[#] Northern Health Research Week is considered an external event requiring approval for presentation of QA Projects.

¹ Further information about Quality Assurance, Quality Improvement, and Research Projects can be found [below](#).



The following research activities are exceptions to the above pathways:

1. Narrative or systematic reviews: no approval required from NH RDGU
2. Case reports or series: patient consent required as per **NH RDGU Patient Case Report Consent Form**.

Step 4: Complete and submit the required forms

The RDGU can provide guidance on the completion of submissions required for your project. *Getting it right the first time will mean a shorter time to approval.*

Remember that the RDGU does *NOT* write your ethics and governance applications for you.

Quality Assurance

- **NH RDGU QA Review Request Form**

Low Risk, single site, Non-HREC pathway

- **NH RDGU Non-HREC Ethical Review Request Form** (concurrently provides governance review)

HREC pathway

Ethics

Applications for Ethics Approval should be submitted externally to a HREC certified by the NHMRC. Each HREC may have slightly differing application processes, but all applications are submitted through a central system (ERM). We recommend contacting your selected HREC early for advice and assistance.

Certified HRECs in Victoria commonly used by NH researchers (as at March 2023):

- [Austin Health HREC](#)
- [Royal Melbourne Hospital HREC](#)
- [Monash Health HREC A & B](#)

Other Victorian certified HRECS:

- [Alfred Health HREC](#)
- [Peter MacCallum Ethics Committee](#)
- [Royal Children's Hospital HREC](#)
- [St Vincent's Hospital HREC D](#)

Note that these HRECs are also part of the National Mutual Acceptance Scheme and their reviews are accepted across Australia by members of this scheme. Revisions to this scheme are underway and therefore we advise researchers to check with us about accepting HREC approvals from other HRECs not listed here.

Governance

Application to NH RDGU for governance approval is submitted via the same central system (EMR) used for HREC submissions. The site-specific assessment (SSA) governance form can be submitted at the same time as the ethics approval application. Although governance approval can only be granted following HREC approval, submission of the SSA concurrently with the ethics application means that NH can begin the process of governance approval while the ethical approval process is undertaken. Please contact NH RDGU for advice and assistance with completing the SSA.

Step 5: Commence your project

Once you have received ethical (if required) and governance approvals, you can commence your project. Congratulations! We look forward to keeping track of your progress and sharing the outcomes of your research with the NH research community.

Supporting Information

Quality Assurance

Although Quality Assurance (QA) projects have often been associated with research activities strictly they are not research. Rather, QA refers to a suite of processes aimed at ensuring that specific standards are met. To qualify as a QA project, specific criteria must be satisfied. If findings from QA projects are planned for internal Northern Health use only and there is no plan for dissemination of findings outside Northern Health, no formal application to the Research Development and Governance Office (RDGU) is required. If findings from a QA project are planned for dissemination, either via a conference presentation or external publication, a formal QA Proposal Form must be completed and submitted to the RDGU (ResearchDGU@nh.org.au) to obtain a QA project reference number. If in doubt about future external dissemination plans, we recommend obtaining a QA reference number.

The following criteria must be satisfied for a project to be classified as QA:

- Evaluation of data collected as part of routine clinical care or service delivery
- Retrospective or prospective collection of data already recorded in the medical record to assess the quality or effectiveness of an investigation or intervention against a known standard
- No prospective recruitment or randomisation of participants
- No risk to participants or organisation or breach of confidentiality
- Project restricted to Northern Health
- Participants records (medical records, databases, data/tissue banks) used for these activities may only be accessed by those with usual access (through routine clinical care or professional practice) or by those with a directly related secondary purpose.

Note - By definition, any requirement for either a patient or a staff member to collect new data or undertake any additional non-standard activity means it is not a QA activity.

The following are examples of QA projects:

- Clinical morbidity and mortality audits
- Retrospective data collection to evaluate prescribing patterns or clinical investigations
- Evaluation of a change that has already been implemented in service delivery

Research Activities, including Quality Improvement

Both Quality Improvement (QI) and research activities collect new information to test hypotheses, and, therefore, have no meaningful distinction. The level of ethical approval required for activities is determined by the *level of risk* that the project poses for participants and/or the organisation. Essentially, approval by a Human Research Ethics Committee (HREC) is required for all quality improvement and research activities that involve more than low risk to participants or the organisation. However, Northern Health has established a non-HREC pathway for a number of project types that are deemed to be low risk, and will be conducted only at Northern Health.

Mandatory steps in development of your project

1. Clearly describe the aims, objectives and hypothesis(es) of your project. Envisage what the conclusion to your findings may look like, and how it may influence clinical care, established knowledge, or future studies. A background literature review is often necessary to establish gaps in knowledge and help to shape your QA activity or research project. The [Northern Health Library Service](#) provides a number of support services to assist in reviewing the literature. Remember that it may be inappropriate to embark upon a project as a 'fishing' exercise.
2. Evaluate the feasibility of your project by calculating the sample size (if appropriate), data collection tools, time required, resources and personnel required. Embarking on a project that is unlikely to be finished may be an inappropriate use of resources and unethical.
3. Discuss the project in detail with an experienced research supervisor (if appropriate), as the principal investigator takes primary responsibility for the progress and completion of the project.
4. Decide on the appropriate approval or reporting pathway. We encourage you to discuss your project with the RDGU (ResearchDGU@nh.org.au). Remember that the RDGU does *NOT* write your protocol or application for you.