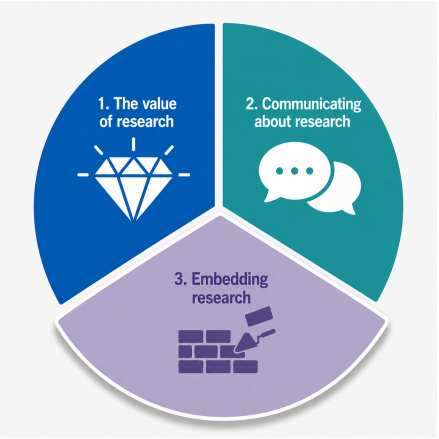
Ethics and Governance

Embedding research



This document provides information to health service leaders regarding ethics and governance, and their role in supporting staff with these processes. It is important for leaders to understand ethics and governance when supporting staff who are engaging in research to ensure projects are appropriately approved before they begin.

What are Ethics and Governance?

Ethics and governance are approval processes that help ensure research is safe, appropriate, and well-managed.

Ethics focuses on protecting the rights, wellbeing, privacy, and safety of participants involved in research.

Governance focuses on whether the health service has the capacity, resources, processes, and approvals required to safely conduct the project locally.

Both processes are important for ensuring research is conducted responsibly and in line with legal, organisational, and professional requirements.

Why are Ethics and Governance important?

Ethics and governance processes help:

- Protect patients, staff, and participant privacy and safety.
- Ensure research is scientifically and ethically appropriate.
- Reduce organisational and legal risks.
- Ensure projects align with Queensland Health and local Hospital and Health Service requirements.
- Support high-quality, trustworthy research and service improvement activities.

What is ethical approval?

Ethical approval is formal review and approval of a research project by a **Human Research Ethics Committee (HREC)**. The HREC reviews whether the project:

- Has a clear purpose and appropriate design.
- Minimises risks to participants.
- Protects participant privacy and confidentiality.
- Includes an appropriate consent process.
- Meets national ethical standards.

In Australia, research ethics processes are guided by the:

- National Statement on Ethical Conduct in Human Research (NHMRC).
- Australian Code for the Responsible Conduct of Research.

There are two main ethical review pathways in Australia:

(1) the low-risk pathway; and
(2) the greater than low risk pathway.

Local HRECs can provide advice about which pathway is most suitable for a project.

Ethics approval is generally required for projects involving:

- Patients, carers, or staff as participants.
- Access to identifiable patient information or data.
- Collection of tissue, surveys, interviews, or observations.
- Clinical interventions or changes to care being formally evaluated as research.

Even low-risk or small local projects may still require some level of ethics and/or governance review.

What is governance approval?

Governance approval is local organisational authorisation for a project to occur within a specific health service or site.

Governance review assesses whether the site can safely and appropriately support the project. This may include consideration of:

- Staffing and resource impacts.
- Funding and budget requirements.
- Data access and privacy considerations.
- Site capability and infrastructure.
- Local risks and operational impacts.
- Contracts or external partnerships.

Governance approval is usually required after ethics approval and before the project can begin at the site.

> Note: Ethics approval and governance authorisation can be sought in parallel. Final governance authorisation will be given after the ethics approval letter is submitted in the governance authorisation application.

Who seeks ethical approval for a research project?

The clinician leading the project is usually responsible for preparing the ethics application, often with support from a research mentor, supervisor, or research office.

Typical steps include:

1. Clarify the project type
   Determine whether the activity is research, quality improvement, audit, or evaluation. Local research support teams can assist with this.
2. Develop the project protocol
   Prepare a protocol outlining the project background, aims, methods, participant involvement, risks, expected outcomes and data management processes.
3. Complete ethics training if required
   Good Clinical Practice (GCP) training is mandatory when researchers are involved in clinical trials research. Some organisations require researchers to complete research integrity or ethics training before submission. Check with your local HREC to see whether this is required.
4. Submit an ethics application
   Applications in Queensland Health are commonly submitted through the Ethical Review Manager (ERM) portal.
5. Respond to HREC feedback
   The HREC may request clarification or changes before approval is granted.

How leaders can help

- Encourage early contact with local research support teams.
- Allow time for application preparation and revisions.
- Assist staff to identify mentors or collaborators.
- Discuss operational impacts, staffing, and feasibility early.
- Encourage realistic project scope and timelines.

How do we get governance approval for a research project?

Governance applications are generally submitted to the local **Research Governance Office (RGO)**.

Typical steps include:

1. Obtain ethics approval (if required)
   Most projects require ethics approval before governance authorisation can be finalised.
2. Prepare site-specific documents
   This may include:

- Site Specific Assessment (SSA) forms.
- Budget or funding details.
- Resource and staffing requirements.
- Data access approvals.
- Departmental support letters.

3. Gain local support
   Leaders or department managers may need to confirm that the project is feasible and supported within the service.
4. Submit governance application
   The Research Governance Office reviews the application and may request further information.
5. Receive site authorisation
   Research activities can only begin once governance approval is granted.

How leaders can help

- Discuss staffing, workload, and operational impacts early.
- Clarify whether resources or backfill are required.
- Assist staff to identify local approval pathways.
- Provide letters of support where appropriate.
- Help ensure projects are realistic and achievable within the clinical environment.

What is ethics exemption?

Some low-risk activities may not require full ethics review and may instead qualify for an **ethics exemption**. This commonly applies to activities such as:

- Quality improvement activities.
- Clinical audits.
- Service evaluations.
- Activities using non-identifiable, routinely collected data.

Note: Exemption decisions should never be assumed by the project team alone. A formal determination from the relevant HREC is required.

Important points for leaders

- Not all quality improvement activities are exempt from ethics review.
- Projects intended for publication may still require ethics review or exemption confirmation.
- Requirements may vary across Queensland Health services.
- Local research support teams or HRECs can advise on the appropriate pathway.

Key messages for leaders

- Ethics and governance processes protect participants, staff, and organisations.
- Early engagement with research support teams can prevent delays.
- Leaders do not need to be research experts to support staff effectively.
- Encouraging realistic, well-supported projects helps build sustainable research capability within clinical services.

Research projects should not begin before required approvals are obtained.

Find out more

Read more on **Queensland Health ethics approval and governance authorisation** via this link.

Read more on **Queensland Health research, ethics and governance processes** via this link.