



Government of **Western Australia**  
Department of **Health**

# Research Projects in NMHS MH

What we expect the researcher and the service to adhere to



better health • better care • better value

# What constitutes research?

There is no generally agreed definition of research. But research can be described as:

- A systematic approach that is used to describe, explain, predict, and in some cases influence processes and behaviours
  - Invention and generation of new ideas

**Applied research:** Research that seeks to answer a question in the real world

**Basic research:** Research that fills in gaps in our knowledge— not always applicable or useful immediately

# Research Vs QI

**Research on human subjects** – conducted with/about people, their data, or tissue and is designed to answer a specific set of research question;

- may have elements of risk
- may not always benefit the participants directly.

**Quality Improvement (QI)** – are designed to assess or improve a process, program or system, or improve activity performance;

- does not increase participants' risk
- aimed to directly benefit the organisation or participants

# How to differentiate between Research and QI

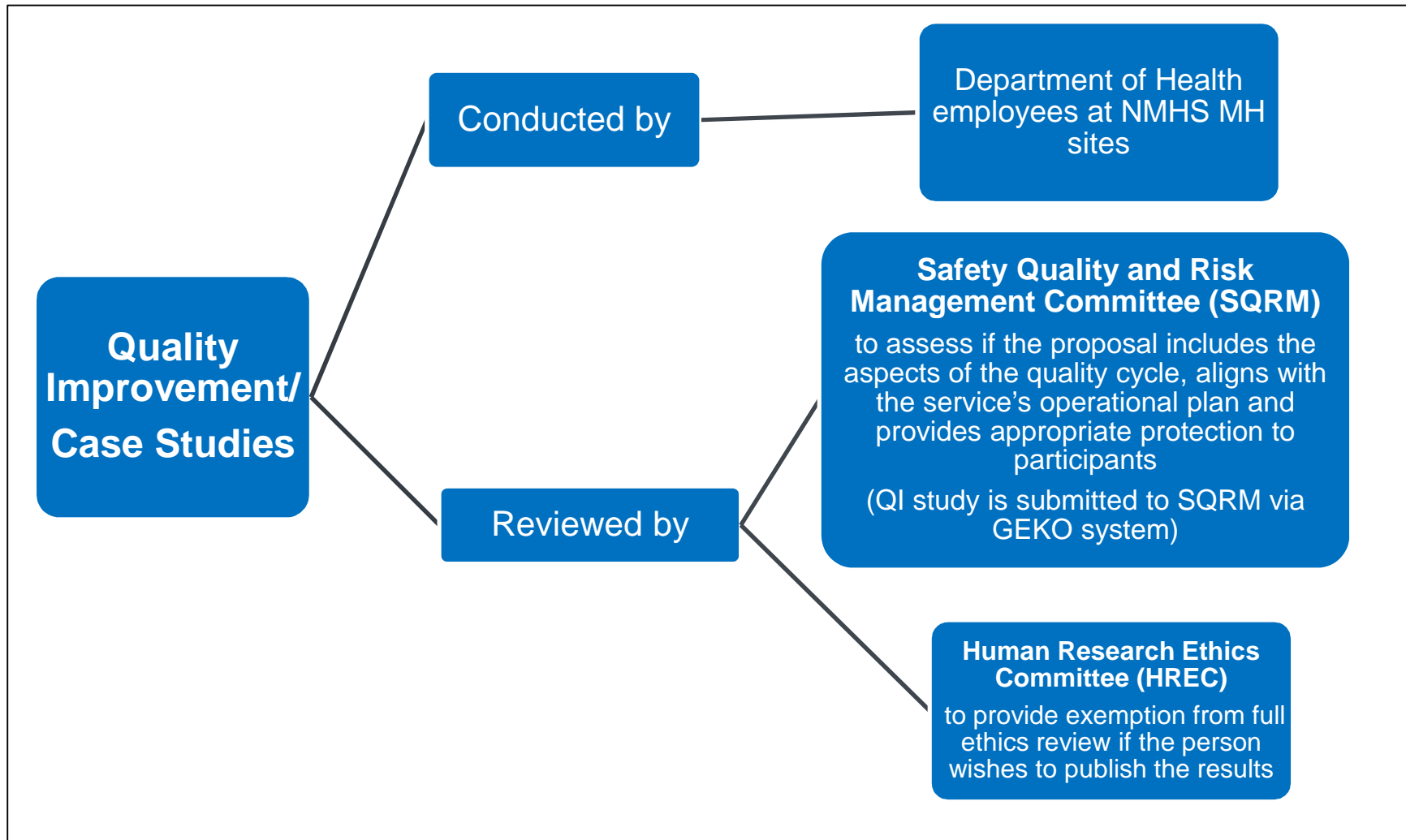
**If the answer to any of the first 9 questions about your study is NO, then this is a QI study**

1. Will the participants' personal information be used for a purpose other than the purpose for which it was collected?
2. Does the proposed QI activity pose any risks for patients beyond those of their routine care?
3. Does the proposed QI activity impose a burden on patients beyond that experienced in their routine care?
4. Is the proposed QI activity to be conducted by a person who does not normally have access to the patient's records for clinical care or a directly related secondary purpose?
5. Does the proposed QI activity risk breaching the confidentiality of any individual's personal information, beyond that experienced in the provision of routine care?
6. Does the proposed QI activity involve any clinically significant departure from the routine clinical care provided to the patients?
7. Does the proposed QI activity involve randomisation or the use of a control group or a placebo?
8. Does the proposed QI activity seek to gather information about the patient beyond that collected in routine clinical care?
9. Does the proposed QI activity potentially infringe the rights, privacy or professional reputation of carers, health care providers or institutions?

**If you answered YES to question 10, you need to apply to the HREC for ethics review exemption in order to be able to publish your findings**

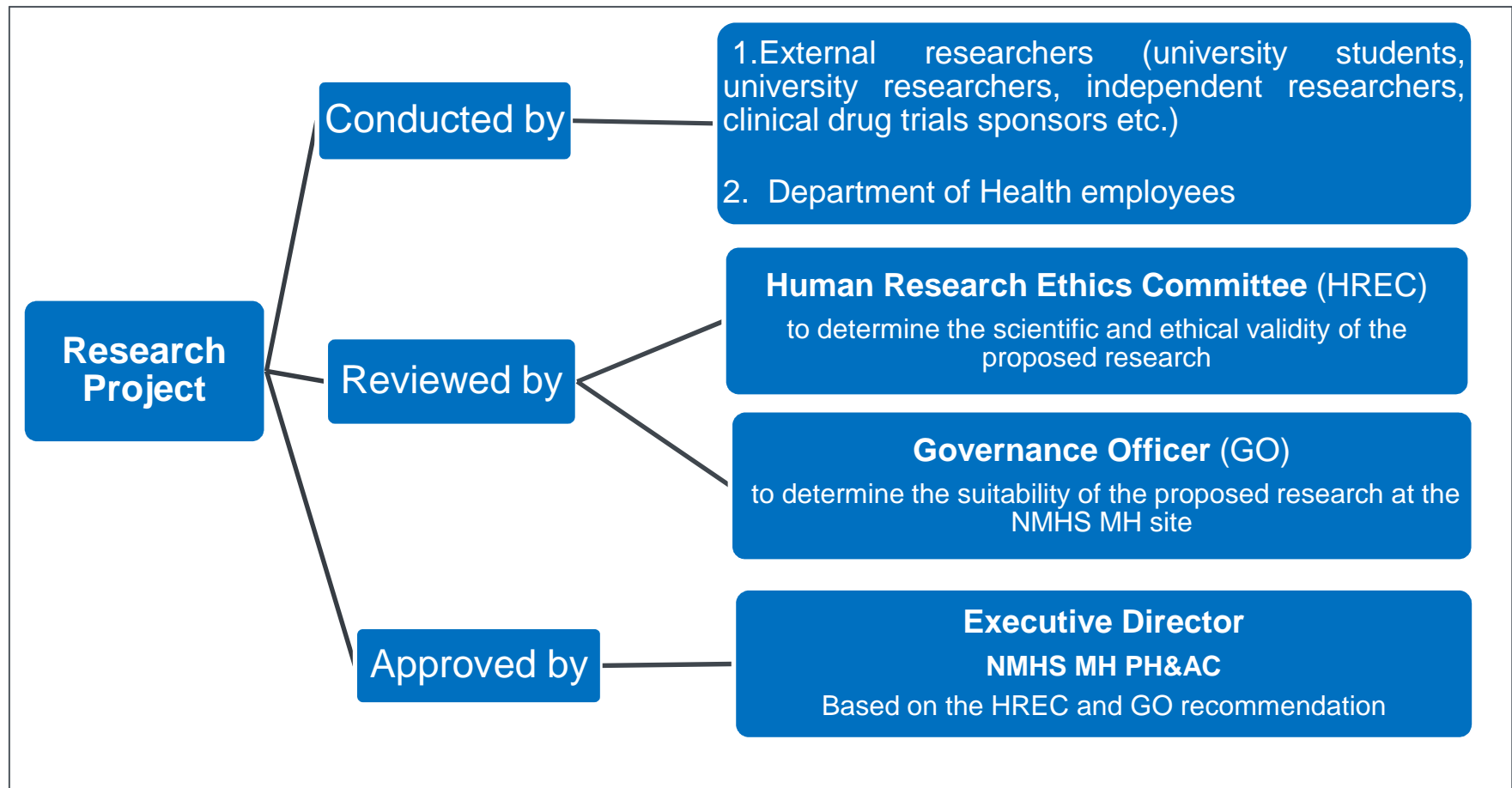
10. Is it intended that the results of the proposed QI activity will be published?

# Approval process for QI projects



# Approval process for research projects

A project must have HREC and Governance (institutional) approval in order to be conducted in NMHS MH.



# Research Governance Service (RGS)

## What Is It?

- It is a centralised IT system that supports the research governance framework for all human research conducted within WA Health or accessing WA Health participants, their tissue or data.

## Who is it for?

- RGS is for all those involved in conducting and approving/monitoring human research projects in WA Health: investigators, sponsors, site administrators (i.e. Service Managers/Program Directors), HRECs and Governance Offices.
- The RGS must be used to process all ethics and governance applications involving WA public health organisations.

# Research Governance Service (RGS)

## How does it work?

- **All users** must create an RGS account in order to be able to access RGS. <https://rgs.health.wa.gov.au/Pages/Home.aspx>
- **The Researcher** completes the Ethics Form, Site Specific Assessment Form and the Budget Form in the RGS and attaches relevant project documents as PDFs.
- **The Researcher** submits the Ethics Form & Project documentation to HREC for ethics review and approval.
- **The Researcher** submits the Budget Form to the Service Manager/Program Director for approval and submits the SSA and the Budget Form (once approved) to the Governance Officer for governance review.
- **The Service Manager/Program Director** receives an email from RGS informing that a new task was created in RGS for them.
- **The Service Manager/Program Director** reviews the SSA and Budget Form and signs the Budget Form
- **The Governance Officer** recommends the project for approval/rejection to the Executive Director.
- **The Executive Director** approves or rejects the project based on the HREC and Governance Officer's recommendation



# What is the researcher required to do?

- **Contact and obtain** confirmation from the Service Director/Program Manager that the project is supported at the site
- **Create** account in RGS
- **Submit** the project for review and approval to the Research Ethics and Governance Office (REGO) via RGS (i.e. submit the Ethics Form, Project Protocol, Information Sheet and Consent Form, Flyers, Questionnaires, Tests, Site Specific Assessment Form and Budget Form)
- **Conduct** the project in a ethical manner once approved
- **Comply** with all the approval requirements

## What is the NMHS MH Service Manager/Program Director required to do?

- **Meet/discuss** the project with the researcher
- **Understand** what the service is required to do in order to support the project (e.g. infrastructure, staff time, other support)
- **Speak** with the teams regarding whether the service can support the project
- **Create** account in RGS
- **Review** the project documentation via RGS
- **Authorise** the project at the site: review the Site Specific Authorisation Form and sign the Budget Form via RGS
- **Check** that the project has HREC / institutional (governance) approvals before it starts at the service
- **Provide support** once the project is approved

# What is the institution required to do?

- **Provide Support** to researchers before submission to REGO and during the life of the project (HREC Chair, Executive Officer, Governance Officer)
- **Review** all research projects to ensure scientific and ethical merit, and compliance with NHMRC and NMHS MH policies (HREC, Executive Officer, Governance Officer)
- **Approve** all research projects based on the HREC recommendation and GO recommendation (Executive Director or Delegate)
- **Review and approve amendments** made to approved projects (HREC, Executive Officer, Governance Officer)
- **Monitor** all research projects during the approval period (HREC Chair, Executive Officer, Governance Officer)

**Is there anything else you would like to know?**

Ask now or contact us:

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