IS IT "RESEARCH" OR IS IT 'QUALITY IMPROVEMENT" YOU ARE PLANNING TO DO?

This section will help you decide.

Research is about creating new knowledge about medicine, health and health delivery; what works and what doesn't. It provides the foundations for national and/or local agreement about the kind of clinical treatment and care we *should* be providing, i.e. helps to answer the question **"what is best practice?"**

Quality Improvement asks whether we are doing the things we have agreed we *should* be doing or achieving the outcomes we have agreed we should be achieving, i.e. it answers the question **"are we following agreed best practice?"**

Criteria for Classifying a Project as Research or Quality Improvement:

Criterion	Audit/Quality Improvement	Research
Aim of project	Measurement of existing performance or practices	Confirmation of an hypothesis or answering a clinical research question
Patients studied	Audit is inclusive	Prospective or selective inclusion criteria
Patients included	No prospective recruitment	Prospective/selective inclusion criteria tailored to address research question/hypothesis
Direct effect on patient	Patient is unaware of audit and audit has no impact on present patient care	Patient follows prospective protocol, although some research may use existing data or samples
Data type	Generally descriptive	Comparative, explores associations and outcomes
Treatment type	Standard	Often experimental, although some research does not involve interventions or treatments (retrospective/observational)
Randomisation	None	Usual; exceptions are open label studies using historical controls, or studies of existing data sets/repositories to address a research question
Patient consent	General consent to treatment only	Specific consent usually mandatory; waiver of consent applies to use of existing deidentified data without need to recontact
Patient rights	No special rights	Right to be informed; to refuse consent; and to leave the study at any time (unless waiver of consent applies)
Ethics approval	Not required	Mandatory
QI Unit registration	Required	Not required
Legal liability	Normal precedents apply	Compensation and liability requirements more complex
Legal constraints	Normal duty of care	May require compliance with Therapeutic Drugs Act, privacy and other legislation

Government of **Western Australia**
Department of **Health**
North Metropolitan Area Health Service
Women and Newborn Health Service

To assist you with your decision about whether a project is research or quality improvement answer the following questions.

1.	Will the participants' personal information be used for a purpose other than the purpose for which it was collected?	☐ YES	☐ NO
2.	Does the proposed project pose any risks for patients beyond those of their routine care? Risks includes physical risks e.g. pain or discomfort; psychological risks e.g. embarrassment, guilt or fear; and social risks e.g. discrimination or stigmatisation.	☐ YES	☐ NO
3.	Does the proposed project impose a burden on patients beyond that experienced in their routine care e.g. persistent phone calls, additional hospital visits or lengthy questionnaires?	☐ YES	☐ NO
4.	Is the proposed project 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?	☐ YES	☐ NO
5.	Does the proposed project risk breaching the confidentiality of any individual's personal information, beyond that experienced in the provision of routine care?	☐ YES	☐ NO
6.	Does the proposed project involve any clinically significant departure from the routine clinical care provided to the patients?	☐ YES	☐ NO
7.	Does the proposed project involve randomisation or the use of a control group or a placebo?	☐ YES	☐ NO
8.	Does the proposed project seek to gather or collate information about the patient beyond that collected in routine clinical care?	☐ YES	☐ NO
9.	Does the proposed project potentially infringe the rights, privacy or professional reputation of carers, health care providers or institutions?	☐ YES	☐ NO
10.	Is it intended that the results of the proposed project will be published?	☐ YES	☐ NO

If the answer to questions 1-9 is **"NO"** **and/or** if <u>only</u> Question 10 is "**YES"** your project is a quality improvement project