Is my project...

CLINICAL RESEARCH OR CLINICAL TRIAL?

CLINICAL RESEARCH
As per the National Statement on Ethical Conduct in Human Research, clinical research includes studying different health-related matters, such as disease prevention and causation, diagnostic methods, treatments, and effects of and response to illness, in human subjects. Examples include: observational studies, innovations in clinical practice, and lifestyle-modification interventions.

CLINICAL TRIAL
A clinical trial is a form of human research designed to find out the effects of an intervention, including a treatment or diagnostic procedure. A clinical trial can involve testing a drug, a surgical procedure, other therapeutic procedures and devices, a preventive procedure, or a diagnostic device or procedure.

The flowchart below is designed to help you determine the nature of your research and the best contact for advice.

Does the project involve at least one health intervention?*

Y

Does the project involve direct interaction with human participants?

N

This is clinical research, but NOT a clinical trial.
Contact the Clinical Research Manager at clinical.research@mqhealth.org.au for advice on relevant documents and approvals required, eg governance, ethics.

N

Does the project assign participants to an intervention? (this includes studies with only one arm, such as feasibility or pilot studies)

Y

The project is a clinical trial.
Contact the Clinical Trials Unit at clinicaltrials@mq.edu.au for advice and submission of relevant documents.

N

Your project might be quality assurance (QA), clinical audit or evaluation. Check relevant guidelines on FMHS website.

*EXAMPLES OF HEALTH INTERVENTIONS INCLUDE:
• Testing a drug,
• Use of cells or other biological products,
• A surgical procedure or other therapeutic procedures,
• Medical device/s,
• A preventive care or procedure,
• Diagnostic device or procedure,
• Health-related educational intervention.

Note: MQ Health governance endorsement is required before submission for ethics review.