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.

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

**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.

**Does the project assign participants to an intervention?** (this includes studies with only one arm, such as feasibility or pilot studies)
- **N**
  - The project is a clinical trial.
  - Contact the Clinical Trials Unit at clinicaltrials@mq.edu.au for advice and submission of relevant documents.

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

**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.

Is my project...

CLINICAL RESEARCH OR CLINICAL TRIAL?