Registration of clinical research

It is a requirement of NHMRC that all clinical trials are registered prior to any subjects being recruited. The vast majority of journals will not publish data that is part of an unregistered trial. Registration promotes transparency and better science.

It can at times be unclear if a research activity needs registration. If in doubt register the activity. Note that “non-trials” can be registered as easily as trials and that increasingly many research institutions, funders and journals are encouraging registration of all clinical research regardless of whether or not it is a trial.

What studies need to be registered?

- Any research that meets the World Health Organization’s (2019) definition of a trial (see below) must be registered.

  For the purposes of registration, a clinical trial is any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes. Clinical trials may also be referred to as interventional trials. Interventions include but are not restricted to drugs, cells and other biological products, surgical procedures, radiologic procedures, devices, behavioural treatments, process-of-care changes, preventive care, etc. This definition includes Phase I to Phase IV trials.

- If a pilot study meets the WHO definition of a trial it must be registered.

  Some pilots are run to determine a rough estimate of efficacy, frequency or nature of outcomes after specific interventions. These are trials and need to be registered.

  Similarly pilots that measure safety or side effects of an intervention need registration. Pilots that "trial" an outcome measure after a researcher controlled intervention also needs registration as they are collecting health related outcomes - even if the study is not adequately powered/designed to produce valid results.

- If the administering institution classifies a project as a quality improvement project it still must be registered as a trial if the project meets the WHO definition of a trial.

Types of studies where it is difficult to decide if they should be registered

- Pilot studies conducted to determine the feasibility of delivering an intervention.
  - If no health outcomes are measured, except whether or not the participant completed the intervention, this would not meet the WHO definition of a trial and therefore registration is not required. Note that often these studies do collect some outcome data, in which case they need registration.
  - Studies where physiologic data are collected with novel applications of existing technologies where the aim is to further understanding of physiology rather than directly assess if the technology improves outcome.

What studies do not need to be registered?

- Observational research - This is not mandatory but recommended.

  Some journals, including The Lancet and BMF, encourage prospective registration of observational studies in order to consider manuscripts for publication. Prospective registration of observational studies in regarded as good research practice.

- Pilot studies that are purely observational. Two types of observational pilot studies are provided below:
  - A prospective pilot study measuring the frequency and nature of an outcome where there is no allocation by researchers
  - A pilot that has no intervention but involves "trialling" an outcome measure such as a survey to see how the participants fill it in to assess its performance.

The advice of the Research Ethics & Governance Office and Melbourne Children's Trials Centre is "If in doubt, register it". For further guidance about trial registration, including responsibilities and the process to follow, refer to
Standard Operating Procedure (SOP) Clinical Trial Registration of Investigator-Initiated Trials (IITs) available from the Clinical Research Development Office (CRDO) website at
https://www.mcri.edu.au/sites/default/files/media/clinical_trial_registration_sop_final_17oct2017.pdf