

What makes a research project a clinical trial?

The World Health Organisation (WHO) defines a clinical trial as: "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."

The following decision aid is designed to help you determine whether or not your research project is a clinical trial. At the University of Tasmania, all clinical trials must be submitted for governance authorisation in addition to ethics approval. Clinical trials of unapproved therapeutic goods are required to be notified to the Therapeutic Goods Administration (TGA) via a Clinical Trial Notification (CTN). Governance authorisation and CTN submission are required prior to trial commencement. See: <https://secure.utas.edu.au/research-admin/research-integrity-and-ethics-unit-rieu/clinical-trial-governance>

