Are you assigning human participants to a health-related intervention to evaluate the effect on health outcomes?

NO

You are not conducting a clinical trial.
Proceed with standard University Ethics and contracting processes

YES

Does your clinical trial involve a device, drug, biological product or substance?

NO

Your research involves a clinical trial using a non-therapeutic intervention
TGA CTN/CTX scheme does NOT apply

YES

Is the device, drug, biological or substance registered on the Australian Register of Therapeutic Goods (ARTG) for the intended use?

NO

Your research involves a clinical trial using an approved therapeutic intervention
TGA CTN/CTX scheme does NOT apply

YES

Your research involves a clinical trial using a ‘new’ therapeutic intervention OR a clinical trial using ‘modified use’ therapeutic intervention
TGA CTN/CTX scheme

Proceed with the University Standard Process for Clinical Trials