The clinical trial decision tool is provided to assist researchers in determining whether the research meets the definition of a clinical trial.

At UNSW, Clinical Trials are defined as any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions (which may include placebo or other control) where the primary aim of the research is to evaluate the effect of the intervention on health outcome.

|  |  |  |
| --- | --- | --- |
| 1. **Does the research involve the inclusion of human participants?**
 | [ ] Yes | [ ]  No |
| 1. **Does the research involve an intervention?**
* **Intervention:** An intervention is defined as manipulating a human participant or their environment to modify health-related medical procedures or behavioural processes. Examples of health-related interventions include:
* The administration or provision of medicine, medical device or the use of a surgical procedure.
* The delivery of mental health or counselling programs or therapies via the internet, telephone, interviews or using an app.
* The administration or delivery of exercise, cognitive, nutrition or change strategies, therapies, or programs.
 | [ ] Yes | [ ]  No |
| 1. **Is the intervention health-related?**
* **Health-Related Intervention:** An intervention is defined as manipulating a human participant or their environment to modify health-related medical procedures or behaviour processes. Examples of health-related interventions include:
* The administration or provision of medicine, medical device or the use of a surgical procedure.
* The delivery of mental health or counselling programs or therapies via the internet, telephone, interviews or using an app.
* The administration or delivery of exercise, cognitive, nutrition or change strategies, therapies or programs.
 | [ ] Yes | [ ] No |
| 1. **Does the research involve the modification of a health-related medical or behavioural outcome?**
* **Health-Related medical or behavioural outcome:** The pre-determined research aim(s) or conditions(s) that reflect the effect of the intervention(s) or behavioural outcome(s) on the human participant's behaviours or quality of life. Examples of health-related interventions include:
* Positive or negative responses or changes experienced by the human participant to administering medicine, medical device, or surgical procedure.
* Positive or negative psychological responses or changes experienced by the Human Participants.
* The improvement or decline in disease progression experienced by the human participant because of the intervention.
* The improvement or decline of quality of life experienced by the human participant because of the intervention.
 | [ ] Yes | [ ]  No |
| **If you answered yes to all questions 1 – 4 the proposed research is categorised as a clinical trial. If UNSW staff, students or researchers are responsible the clinical trial research governance** [**guidelines**](https://research.unsw.edu.au/clinical-trials-research-governance) **must be followed.** |
| 1. **Is the aim of the research to evaluate the effect of a health-related intervention for the development of a health-related treatment within Australia?**
 | [ ] Yes | [ ]  No |
| **If you answered yes to question 5 the clinical trial may require notification using the Therapeutic Goods Administration Clinical Trial Notification Process. If UNSW staff, students or researchers are responsible the clinical trial research governance** [**guidelines**](https://research.unsw.edu.au/clinical-trials-research-governance) **must be followed.** |