

**FORM – Clinical Trial**

A copy of this form should be attached to an ethics application where you have selected “Interventional/Clinical Trials research” for the research methodology question of the HREA. To ensure research insurance remains up to date the CI will be asked to confirm the details of the project on an annual basis.

Researchers are advised to make themselves familiar with the TGA document [Human Research Ethics Committees and the therapeutic goods legislation.](https://www.tga.gov.au/publication/human-research-ethics-committees-and-therapeutic-goods-legislation)

# Section 1

**1.1. Title of Research Project:** Click here to enter text.

**1.2. Will the research require registration with the Therapeutic Goods Administration?** Choose an item.

**1.3. Will the trial seek registration as a CTN or CTX Trial?** Choose an item.

# Section 2

**2. Is this a Clinical Trial?**

To determine if this research fits the definition of a clinical trial, answer the following questions:

**2.1.** Does the nature of the study or research require that the investigator or any assistant must be a registered medical practitioner or other registered qualified health service provider? Choose an item.

If Yes:

2.1.1. Is the study or research to find out whether an intervention, such as treatments or diagnostic procedures,

that are believed may improve a person's health, actually do so? Choose an item.

2.1.2. Is the study or research to:

test a drug, a surgical or other therapeutic or preventative procedure Choose an item.

test a therapeutic, preventative or diagnostic device or service? Choose an item.

If Yes to 2.1.1 or 2.1.2. then it is a Clinical Trial for Clinical Trial Protection (insurance) purposes.

# Section 3

**3. Are Invasive Procedures Involved?**

**3.1.** Does the study or research require any invasive procedure (please note the definition below) to be undertaken by a registered medical practitioner or other registered qualified health service provider? Choose an item.

**Definition** of “invasive procedure”: any procedure involving ingestion, application (including application of laser therapy) or admission of any substance or material onto or into a human’s body.

Invasive procedure does not include:

(i) ingestion of drinks, food or fluids which are commercially available in the market place at the time of the ingestion; or

(ii) taking of blood samples.

For more information on insurance for Clinical Trials go to https://www.westernsydney.edu.au/finance\_office/finance/financial\_operations/uws\_insurances

Send this form to the Human Research Ethics Team – humanethics@westernsydney.edu.au