Clinical Trial Application guidelines:

1. All clinical trials must be conducted in accordance with the Note for Guidance on Good Clinical Practice (CPMP/ICH135/95 – Annotated with TGA Comments) and the Good Clinical Practice (GCP) guidelines adopted in Australia. GCP is an international ethical and scientific standard for designing, conducting, recording and reporting trials that involve human participants.

2. When applying to the University's Human Research Ethics Committee (HREC), all clinical trials must be clearly identified and the "Clinical Trial" box must be ticked in Section 1 of the HREC Application Form.

3. Section 3 of the HREC Application Form must be filled in.

4. The Participant Information and Consent Form must clearly state that the proposed project is a clinical trial and provide clear and concise information about the trial's purpose, benefits, methods and instruments, participant involvement, risks, sponsors, confidentiality, withdrawal rights, data storage and contact details, including contact details of the Research Ethics & Integrity Unit.

5. Data collected during UC approved clinical trials must be stored for at least 15 years on password protected and secure UC computers and/or premises.

6. Clinical trials cannot be registered with the Australian New Zealand Clinical Trials Registry (ANZCTR) unless full approval has been received from the University's HREC. A link to the registration page must be provided to the HREC as soon as the registration of the trial has been finalised.

7. If approval has been received from another Ethics Committee (such as the ACT Health Ethics Committee) cross-institutional approval must be applied for and received before registering with the ANZCTR.

8. Applicants are required to register a clinical trial in a publicly accessible trials registry prior to enrolment of the first participant as a condition of ethics approval.

9. Please note that UC's HREC requires a progress report at least twice per year during the approval period.