

# Clinical Trials at Victoria University

## When is research a 'clinical trial'?

*"Clinical trials are medical research studies that aim to find a better way to manage a particular disease. The purpose of a clinical trial is to evaluate new approaches to learn how people respond to them and what side effects might occur as a result".*

In this context, clinical trials involve human subjects.

Clinical trials include:

Treatment trials: These involve trials of experimental treatments, drugs or new approaches to surgery or radiation therapy.

Prevention trials: These consider new ways to prevent disease. They are usually less invasive and may include medicines, vaccines, vitamins or changes to lifestyle or behaviour.

Diagnostic or screening trials: These involve evaluating tests or procedures for diagnosing and detecting diseases or conditions<sup>1</sup>.

## Do I need special approval for a clinical trial?

Yes. As with all other human research projects, approval from an ethics committee is required. Question 3.1 (d) on the VU HREC ethics application form asks "Does the research involve a therapeutic intervention/treatment or clinical trial?".

If the answer is yes the application must go to Victoria University's high risk committee and the clinical trials process is triggered. Applicants must complete and submit 'Supplementary form A' with their application. You will need to read chapter 3.3 of the NHMRC National statement and the TGA's 'Australian Clinical Trial Handbook' when completing Supplementary form A.

## Registration of Research involving a Clinical Trial

All clinical trials must be registered.

You need not use any particular clinical trial registry but the 'Australian New Zealand Clinical Trials Registry' (ANZCTR) is commonly used. Registration is free and ANZCTR issues a registration number once it is satisfied that the information supplied is complete. Researchers are obliged to update information on each trial (including patient accrual, trial and publication status) regularly.

The ANZCTR registry records a trial's:

- objectives
- main design features
- sample size and recruitment status
- treatments under investigation
- outcomes being assessed

- principal investigators
- contact details for specific trial information
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Importantly, ANZCTR meets the requirements of the International Committee of Medical Journal Editors (ICMJE). This is essential to permit publication of findings in many key research journals.

Information provided to clinical trials is publicly available and searchable. Researchers should use this as a resource to ensure they are not unwittingly duplicating research already done elsewhere. The WHO provides a service, the ICTRP Search Portal, linking clinical trial registries into a single searchable database.

Responsibility for registering the clinical trial, and updating information in the registry, rests with the Principal Investigator. The HREC will require documentation to show this has been done. The Office for Research can provide advice if required.

### **Will I need to notify the Therapeutic Goods Administration (TGA) of my clinical trial?**

Notification under the CTN scheme (or application under the Clinical Trial Exemption (CTX) scheme) is required for clinical research which includes use of:

- any medicine or device not entered in the Australian Register of Therapeutic Goods, including any new formulation of an existing product or any new route of administration; or
- a marketed medicine, substance or device beyond the conditions of its marketing approval, including new indications extending the use of the product to a new patient group and/or the extension of doses or duration of treatments outside the approved range.

Clinical trials in which products are used within the conditions of their marketing approval are not subject to CTN or CTX requirements but will still need HREC approval before the trial may commence.

Responsibility for notifying the TGA of a clinical trial requiring CTN or CTX rests with the Principal Investigator. The HREC will require documentation to show this has been done. The Office for Research can provide advice if required.

### **Whats the difference between CTN and CTX?**

CTN is a notification scheme. The HREC takes responsibility for assessing the ethical issues and the scientific merit/safety issues of the research. The TGA does not make any assessment of the research in a CTN

CTX is an approval scheme where the TGA makes an assessment of scientific merit and safety issues.

In both cases HREC approval is also required. Almost all Australian clinical trials uses the CTN. Fees are charged for both but the CTN is much cheaper.

### **More information on Clinical Trials**

- National Statement on Ethical Conduct in Research Involving Humans (<http://www.nhmrc.gov.au/publications/synopses/e72syn.htm>)
- Australian Clinical Trial Handbook (<http://www.tga.gov.au/industry/clinical-trials-handbook.htm>)
- Therapeutic Goods Administration (<http://www.tga.gov.au>)

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<sup>i</sup> [https://www.chf.org.au/pdfs/chf/CHF-Clinical-trials\\_COL\\_\\_WEB.pdf](https://www.chf.org.au/pdfs/chf/CHF-Clinical-trials_COL__WEB.pdf)