# Clinical Trial Research

## What is a clinical trial?

A clinical trial is 'any research project that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effect on health outcomes' (NS, 3.1.7). 'Interventions' include, but are not restricted to, drugs, cells and other biological products, surgical procedures, radiological procedures, devices, behavioural treatments, process of care changes or preventative care, etc.

Human research ethics review and approval is required for all clinical research. Due to risks associated with clinical trials and the added complexity of governance and ethics requirements, all clinical trial research at RMIT must be reviewed and approved by the Human Research Ethics Committee (HREC).

Clinical trials have specific requirements that need to be addressed to ensure responsible, legal and ethical conduct throughout the lifecycle of the research from application to post-completion. This guidance note will help you address those requirements. It has been informed by the guidelines set out in the National Statement on Ethical Conduct in Human Research (NS).

## What are some important considerations about clinical trials?

The NS has specific guidelines related to clinical trials that need to be addressed in an application. Sections 3.1.4-11 of the NS are relevant to clinical research and the HREC will assess applications against these provisions. In addition, the NS requires that trial participants are adequately informed of funding arrangements (NS, 5.2.18). The NS also describes the requirements for safety monitoring and reporting (NS, 5.5.3-6). For the post-approval stage, the NS also describes circumstances where it may be unethical for a researcher to continue a trial (NS, 5.5.9), of which researchers need to be aware.

Depending on the scope of the research, a clinical trial application may need to be reviewed by a non-RMIT HREC. For example, if the research involves a clinical population, then a non-RMIT HREC will most likely need to approve the application. Clinical drug trials (phase I-IV) are likely to require review by a health and medical HREC. Similarly, some trials for devices with health applications may also require review at a non-RMIT HREC. Researchers are advised to contact humanethics@rmit.edu.au for guidance on the appropriate review pathway before they commence an application. Note that if your application requires review and approval by a non-RMIT HREC you will need to submit the ethics application directly to the relevant institution and then register the project and the non-RMIT HREC approval with RMIT.

## Key things to remember when completing the submission:

In addition to reflecting the values and principles contained in the National Statement, if you are conducting a clinical trial the following requirements must also be met:

- You must read and meet the requirements for ICH Guideline for Good Clinical Practice (GCP) annotated by the Australian Therapeutic Goods Administration and contained in the Australian Clinical Trial Handbook.
- You must include a clinical trial protocol that is prepared in accordance with the GCP guidelines contained in the in the Australian Clinical Trial Handbook.
- You must use the Participant Information and Consent Form template developed by the National Health and Medical Research Council (NHMRC) for interventions. Do not use the RMIT template for PICFs for research involving clinical research; the NHMRC template has specific clinical trials information that is not present in the RMIT template.

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- The Chief Investigator must register the proposed clinical trial application on the Australian and New Zealand Clinical Trial Registry prior to submitting the human the research ethics application form
- Where the clinical trial uses an unapproved therapeutic good, you must notify the Therapeutic Goods Administration (TGA) via the Clinical Trial Notification (CTN) or Clinical Trial Approval (CTA) schemes.
    - The CTN scheme applies where the clinical trial sponsor (e.g., RMIT University) intends to sponsor a clinical trial involving an 'unapproved' therapeutic good.
    - The CTA scheme applies where a sponsor wishes to seek TGA approval to supply 'unapproved' therapeutic goods in a clinical trial.
- Notification must be made after HREC approval and prior to the use of the goods. Recruitment may not commence until the CTN, or CTA has been provided by the TGA if applicable. Applications for either a CTN or CTA is conducted via RMIT. You must contact humanethics@rmit.edu.au as soon as possible to facilitate this process.
- A Clinical Trial Research Agreement (CTRA) is required for sponsored collaborative and/or multi-site clinical research. A copy of the final CTRA must be provided to the HREC when it is available. The Research Contracts Team can assist with the development and/or review of CTRAs.
- Clinical trials involving assessment of the safety or performance of a medical device must be conducted in accordance with international standards of Good Clinical Practice.

**Insurance requirements**

Insurance and indemnity arrangements for clinical research may be different to other forms of research. Additional insurance arrangements may be required for a clinical trial. Requirements for clinical trials differ depending on whether the research is sponsored or not:

- **Unsponsored clinical research (i.e., RMIT researcher-initiated):** RMIT must be satisfied that University's insurance and compensation arrangements are appropriate and cover the clinical trial.
- **Sponsored research**: RMIT must be satisfied that the sponsor of the clinical trial has appropriate indemnity, insurance, and compensation arrangements in place, which align with the applicable regulatory requirements and RMIT policy.

Insurance arrangements will be affected if your trial involves participants aged under five years old or pregnant women or is being conducted overseas. It is recommended that in these cases you contact the HREC before finalising your application. Any relevant requirements will be addressed during the governance review stage of the ethics application.

## Additional Resources:

- Australian Therapeutic Goods Administration
- Australian Clinical Trial Handbook: A simple practical guide to the conduct of clinical trials to international standards of Good Clinical Practice in the Australian context
- Australian Clinical Trials
- ICH Guideline for Good Clinical Practice
- ISO 14155:2020 - Clinical investigation of medical devices for human subjects — Good clinical practice
- NHMRC Guidance: Safety monitoring and reporting in clinical trials involving therapeutic goods
- Note for guidance on clinical safety data management: definitions and standards for expedited reporting

## Further information

Further information can be found in the RMIT Research Policy: Human Research Ethics Procedure .

For further advice on this topic or other human research ethics matters, please email humanethics@rmit.edu.au. A Research Governance and Ethics Coordinator will assist you and may connect you to one of the CHEAN or HREC members in your discipline who can offer expert ethics advice.