

HREC FOR BUSY PEOPLE Clinical Trials

The fundamental knowledge needed for your role.



Promoting Ethics and Education in Research

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The solution for busy people

As a HREC member, it can be hard to upskill whilst meeting everyday work demands. For those new to the field, finding time to learn about this unique area is difficult and at times, overwhelming.

That's why we developed <u>HREC for Busy People</u>: a training solution for those who need to upskill but don't have time to do so.

HREC for Busy People - Clinical Trials includes an additional module focused on HREC's in a clinical trial context.

This course is a snapshot of our premium <u>HREC Essentials</u> course, providing you with the fundamental knowledge needed for your role.

About the course

This course consists of 3 modules - each 60 minutes in duration.

Module 1: An Introduction to Human Research Ethics

This module will introduce you to the meaning and role of human research ethics. It will start with some key definitions and the history of some concerning research practices that progressively shaped Australia's current framework for human research ethics review. In the second half of the module, you will learn about the role of Human Research Ethics Committees (HRECs) and their members. The module finishes by explaining the relationship between HREC review and other research approval processes, such as research governance.

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On completion of module 1, you will be able to:

- Define key terms related to human research, including 'research', 'research involving humans', and 'Human Research Ethics Committee (HREC)'
- Outline pivotal events in the development of Australia's current framework for human research ethics review
- Describe the role of HRECs and their members
- Distinguish between the role of HRECs and research governance

Module 2: The Values and Principles of Ethical Conduct

This module will explain the four values and principles of ethical conduct that guide ethical review under the National Statement on Ethical Conduct in Human Research (2007, updated 2018). You will learn the key questions that help assess the extent to which a research proposal satisfies each of these values and principles. The module explains two of the most important considerations when reviewing research involving humans.



On completion of module 2, you will be able to:

- Describe the four values and principles of ethical conduct required under the National Statement on Ethical Conduct in Human Research (2007, updated 2018)
- Formulate questions that will help assess if a research proposal satisfies the values and principles of ethical conduct
- Recognise a variety of research-related risks and benefits, and the role of Human Research Ethics Committees in balancing and presenting these risks to potential participants
- Outline the necessary elements for meaningful consent, as well as the situations in which research may be approved without participant consent.

Module 3: An Introduction to Clinical Trials

Clinical trials are essential for advancing the quality of health care in Australia, but also can raise distinct ethical considerations. This module will consider issues that commonly arise in the ethical review of clinical trials, including the assessment of risks and benefits, seeking consent, and ensuring compliance with regulatory requirements.

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On completion of module 3, you will be able to:

- Define a 'clinical trial' and some key clinical trial designs
- Describe the phases of clinical development and the implications of different phase trials for the role of the HREC
- Identify the application of common research ethics principles to clinical trials design
- Recognise additional responsibilities of ethics committees, including under the International Conference on Harmonisation of technical requirements for registration of pharmaceuticals for human use: Guideline for Good Clinical Practice (ICH:GCP) and therapeutic goods legislation

What is the difference between HREC for Busy People and HREC for Busy People -Clinical Trials?

HREC for Busy People - Clinical Trials includes an additional module focused on HRECs in a clinical trial context.

Who is this course for?

- If you are new to HRECs and need to upskill, but cannot commit to our longer HREC Essentials online course
- If you are familiar with HRECs, and need to do refresh your knowledge and skills
- Lay people and other volunteer committee members

What is the price?

\$495 + GST (3 online modules)

How long will it take?

The course is offered as 3 modules, each taking approximately 60 minutes to complete. You can complete each module as it suits you: in 30 min intervals or as a full module.

What qualification will I get?

After completing each module, you will get a certificate of completion that you can download. This can be used for accruing CPD points: 3 CPD points for each module.

HREC ESSENTIALS

This course is designed to provide HRECs with the baseline upskilling they need.

However, upgrading to our premium HREC Essentials course will provide you with the comprehensive knowledge you need to succeed in your role.

<u>HREC Essentials</u> is the ideal training solution for anyone new to Research Ethics or those wishing to upskill and increase their knowledge in this unique area of practice.

EXPLORE SERVICES

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Our training and education offers have been developed according to Australian and international best practice standards.

Our Research Essentials modules are built upon the competencies developed by the Harvard Multi-Regional Trials Centre (MRCT) and aligned to competencies recommended by the NHMRC.

These training offers are regarded as a benchmark for researchers, clinical trials, and healthcare professionals in Australia and internationally.