PRAXIS AUSTRALIA

Promoting Ethics and Education in Research

RESEARCH ESSENTIALS

COMPETENCY UNIT

SCIENTIFIC CONCEPTS AND RESEARCH DESIGN

Module Overview

CODE	TITLE	DESCRIPTION
C1.02	Identifying and Formulating Research Questions	In this module, you will learn how to identify research questions that are important from clinical, social and political perspectives. This will help you to develop research projects that are most likely to create change, benefit society and to be funded.
C1.03	Evidence in Research	In this module, you will learn about the ways in which evidence is conceptualised in health and medicine. You will also explore the strengths and weaknesses of the well-known 'evidence-based practice' (EBP) paradigm.
C1.04	Differentiating Research from Innovation, Clinical Care, Audit and QA	This module will introduce you to the differing concepts of research and non-research activities and how to determine if a project falls under the remit of research.
C1.05	Research Design and Methods	Having a good understanding of research design will enhance the quality of any research project. This module will introduce you to the research process, different types of research methods and research designs.
C1.06	Designing a Research Proposal	This module will help you to easily identify appropriate inclusions in a research proposal depending on the type of research you are undertaking.
C1.07	Funding of Research in Australia	In this module you will become familiar with expenditure on research in Australia, sources of research funding, potential problems in research funding, and consider the research funding of non-scientific areas of research.

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ETHICAL CONSIDERATIONS IN RESEARCH

Module Overview

CODE	TITLE	DESCRIPTION
C2.01	Introduction to Ethics	In this module you learn about what ethics is (and what it is not), why it is important and how ethics relates to real world problems. You will also learn about different ethical systems and how to apply these to ethical dilemmas. As you shall see, ethics isn't just concerned with finding a single 'right answer' to situations, but identifying numerous ways of looking at a problem and finding common ground between different perspectives.
C2.03	The National Statement	This module will address the status and function and the conceptual origins of the National Statement and consider the National Statement principles and the manner in which these are applied in research.
C2.04	Organisation of HRECs in Australia	This module will introduce you to the roles and responsibilities of HRECs and the ethic review process in Australia.
C2.06	Cultural Safety in Research	In this module you will be introduced to the concept of culture and cultural safety within the health research context and will reflect on how biomedicine is itself part of a culture and develop an appreciation of cultural safety in your work.
C2.08	Ethics in Clinical Trials 1: Ethical issues in research design and conduct	This module will explore the close relationship between ethics and research methodology and the ethical issues raised by different types and phases of research and by different research strategies and techniques.
C2.09	Ethics in Clinical Trials 2: Identification of research populations, selection, recruitment, inclusion and exclusion criteria	This module will identify six types of intended outcomes in the selection, recruitment and retention of clinical trial participants and assist you to appreciate the ethical dilemmas during the population planning stages of a clinical trial.
C2.10	Consent to Research	This module will give you an understanding of the legal and ethical basis of consent in research. This will include an outline of the challenges surrounding consent, the processes and policies that can help ensure that consent is valid and meaningful and a description both of alternative models of consent and different strategies for obtaining consent.

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RESEARCH MANAGEMENT

Module Overview

CODE	TITLE	DESCRIPTION
C3.01	Management Concepts in Research	This module will introduce you to five different (5) management concepts and how they can be applied to research. It aims to assist students to become familiar with the basic premise of each of the concepts so that you can determine which is the most effective to assist in the management of your current and future projects.
C3.02	Principles of Project Planning	This module will introduce you to the basic principles of project management, some common methodologies and how they can be applied to best meet the needs of a project.
C3.03	Site Management in Clinical Trials	This module will introduce you to the tools and skills you will need to be an effective research manager, including understanding the trial feasibility process and how understanding all your available resources, such as staff, supporting departments and other projects will help you assess your priorities and capabilities.
C3.05	Research Monitoring and Audit: The Roles and Processes for the Monitoring of Clinical Trials	In this module you will learn about the roles and responsibilities of all individuals involved in the conduct and monitoring of clinical trials, including what is involved in the conduct of a clinical trial audit.
C3.06	Essential Documentation in Clinical Trials	In this module, you will learn about the key documentation requirements for Essential Documentation including source documents, trial site files, master files, case report forms and safety forms, each of which can be viewed as a discrete system of maintaining a particular set of Essential Documents critical to the conduct and management of clinical research.
C3.07	Quality Assurance for Clinical Trial sites	This module will introduce you to the tools and skills you will need ensure all your clinical research projects and trials are managed to the highest quality and adhere to applicable regulatory and Good Clinical Practice standards.

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DATA MANAGEMENT AND DISSEMINATION

Module Overview

CODE	TITLE	DESCRIPTION
C4.01	Data in research	This module will introduce you to different types of data used in research, and how to apply them. At the end of this module you will understand how each data type is collected and collated and be able to determine the most appropriate data type(s) to use in your study.
C4.03	Data management (1) Creating, processing and analysing data	Good data management is essential to the conduct of legally, ethically and scientifically sound research; and the skills and competencies involved are fundamental to research practice. This module will help you to take a proactive, organised and best practice approach.
C4.04	Data management (2) Privacy, security and governance across the lifecycle	In this module, we will introduce the Australian privacy laws, principles, and policies that govern research with human subjects. You will become familiar with those that are relevant to your research; and find out how to assess and manage privacy risks in your project.

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RESEARCH CONDUCT GCP AND RESEARCH INTEGRITY

Module Overview

CODE	TITLE	DESCRIPTION
C5.01	Principles of GCP	This module will introduce you to Good Clinical Practice standards and the roles and responsibilities of all those involved in conducting research. It will also help you understand the importance of research conduct and why following GCP leads to excellent science, quality data, reducing risk and keeping participants safe.
C5.04	Risk Management in Research	In this module you will be introduced to the basic concepts and principles of risk management as a tool to control and reduce risk and you will learn more about how these principles will be applied to projects and clinical trials. The last section will introduce you to the management of risk and benefit as they affect participants in clinical research.
C5.07	Research Integrity and Research Misconduct	In this module you will learn what is meant by research integrity, what characterises responsible research conduct and what constitutes research misconduct, through case studies and examples. You will become familiar with the guidelines that outline the responsibilities of Australian researchers and research institutions and how research misconduct should be managed. Importantly you will reflect on the causes of research misconduct, strategies to deter and prevent research misconduct and the importance of promoting high ethical standards in all research endeavours.
C5.08	Overview of Medical Device Regulations	In this module, we will consider the background and frameworks for the regulation of medical devices. An understanding of both modules C5.08 and C5.09, and the correct application of regulatory strategy and robust clinical trials are crucial for the delivery of medical devices which are safe and effective.
C5.09	GCP for Medical Devices - ISO 14155:2026	In this module, we will consider the background and frameworks for Good Clinical Practice and specifically how it applies to medical devices. Following ISO 14155 will ensure that your research is of a high standard and leads to excellent science, quality of data and reducing risk. All of which are crucial for the delivery of medical devices which are safe and effective.

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COMMUNICATION LEADERSHIP AND INTER-PROFESSIONALISM

Module Overview

CODE	TITLE	DESCRIPTION
C6.03	Multidisciplinary Research and Collaboration	This module will introduce you to different ways in which researchers and other parties work together in conducting research. This includes research that spans multiple disciplines (cross-disciplinary research) and multiple organisations (collaboration).
C6.06	Skills for 'Getting Published'	This module aims to introduce you to the basic skills and knowledge required to help you get your work published; and to help you develop a publication strategy for your current research.

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ELECTIVES

Module Overview

CODE	TITLE	DESCRIPTION
EC.02	Management of Investigational Products	This elective is structured to take you through the Investigational Product lifecycle, from manufacture/supply to transport, receipt, and storage, use of investigational products including dispensing / accountability then finally the return and destruction.
EC.03	Safety Monitoring and Reporting in Clinical Trials	Maintaining the rights, safety and wellbeing of clinical trial participants is the most important cornerstone of Good Clinical Practice (GCP). In this elective you will learn about the ways in which safety of clinical trial participants is monitored by the Investigator, Sponsor, Human Research Ethics Committees and regulatory authorities. You will also learn about safety reporting requirements for Investigators and Sponsors conducting clinical trials.
EC.04	Principles of Research Governance	This elective will introduce you to research governance principles and processes, the guiding documents, the key elements and critical factors that contribute to a timely and efficient review process, the authorisation steps and the importance of communication with key stakeholders.
EC.06	Regulation of Drugs and Medical Devices	In this elective, we will look at how new drugs and devices are regulated, both before and once they reach the market. We will also look at funding schemes that allow patients to access treatments and some current controversies surrounding access to medicines.
EC.09	Animal Research - Principles	This elective will introduce you to how animal research links into research involving human subjects and is used to inform the development and validation of clinical treatments, the ethical challenges that arise and the principles applied in the design and conduct of animal research
EC.10	Animal Research - Ethical Oversight in Australia	This elective will introduce you to how the principles of the Australian Code for the Care and Use of Animals for Scientific Purposes underpin the ethical oversight of animal research in this country and establish a governance framework within which those involved are responsible and accountable for their decisions and actions.

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ELECTIVES

Module Overview

CODE	TITLE	DESCRIPTION
EM.01	Research with Aboriginal and Torres Strait Islander People	This elective will provide you with a brief introduction to the implications of working and researching within the Aboriginal and Torres Strait Islander space. This module is predicated on an Indigenous world view: centred on the needs, aspirations and philosophical basis of the Aboriginal and Torres Strait Islander people. It will provide you with a precursory understanding about the importance of using Indigenous Knowledges research methodologies, a culturally specific framework. This elective is a guide for establishing critical thought about the ethics for collaboration.
EM.03	Clinical Trial Design: An Introduction to Clinical "Drug" Trials	In general, we rely on commerce for drug development and therefore, clinical drug trials are sponsored mainly by pharmaceutical companies. Understandably, these companies aim for global markets and this aim is largely responsible for an international uniformity in the design and execution of drug trials. This elective explores how a new investigational drug can move along different paths from laboratory to clinic according to decisions made at a multiplicity of check points.
EM.04	Research with Children	Research involving vulnerable people and populations is enormously challenging. But whereas in the past vulnerable populations have simply been excluded from research – this approach only serves to harm those we are seeking to protect. In this elective you will learn about the specific issues that arise in research with children – including those around recruitment, selection, consent, risk assessment, harm minimisation and ongoing care.
EM.07	Understand Data Linkage, e-Health Data and 'Big Data'	This elective aims to describe these three major sources of research data, introduce you to their potential applications, and consider some of the ethical and privacy issues raised by each.
EM.11	An Introduction to Statistical Methods	This module will introduce some basic terminology and statistical tests that will assist in you in both interpreting published research and analysing your own data.

FREQUENTLY ASKED QUESTIONS

Why should i do this course?

Researchers need to be skilled in all aspects of their craft and be able to respond to the demands for rapid innovation. This course allows members of the research workforce from a diverse range of disciplines to undertake flexible, affordable and contemporary training that is self-paced and individually tailored.

Can I choose my own Course or pathway of study?

Certainly! One of the benefits of the Research Essentials course is that it has inbuilt flexibility that enables participants to devise their own courses of study – from single modules right up to full programs.

How long does the course take to complete?

This will vary depending on what you require and/or choose.

A Course, Competency Unit, Skill Set, Elective or an individual Module all have different time requirements.

Some definitions are useful here:

COURSE A course is comprised of a combination of Modules and Electives.

CORE SKILLS SET To help make choosing your course of study easier we have suggested a pathway of learning comprised of a smaller number of modules and electives, selected from across the 6 core competency areas.

MODULE A Module is a single block of study that takes about 2 hours to complete. The number of Modules you select will affect how long your chosen study pathway takes to complete.

ELECTIVES Electives are individual blocks of study that either extend Modules or cover areas of interest outside them. An Elective takes about three to four hours to complete.

Can I complete the study in my own time and at my own pace?

Yes! You can choose the course of study that suits you and you can pace your learning to reflect your personal needs.

Is the course only available online?

Research Essentials has been designed for an online environment. We can however, also provide face to face workshops to deepen the learning experience and promote peer interaction and discussion. Talk to us about this at any time.

Do I need to have any pre-requisite skills and knowledge?

No – just a passion to learn!

Will support be available if I need help during the course?

At PRAXIS we are very proud of the level of support our students receive. This includes personal interactions with our course management staff, Directors and our pool of expert advisers as necessary.

How much does it all cost?

PRAXIS Australia is a not for profit company committed to supporting the research sector through the creation of new services. We recognise that cost can be a major barrier to access to professional education and have therefore priced this course well below current market prices for tertiary style programs. Actual costs are as follows:

Full Course $2759 (plus GST)

CORE SKILLS SET $1049 (plus GST) per skill set
(inclusive of all 9 modules and electives within a skill set)

Module $198 (plus GST) per module

Elective $279 (plus GST) per elective

Heavily discounted Institutional and group discounts are available via our specially designed licensing model. We can also create tailored packages for individuals or institutions. Talk to us about these options at any time.

Find out more

Our team is always happy to talk with you to answer your questions or provide guidance and assistance. Please contact us at any time if you require information or support.

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