PRAXIS AUSTRALIA

Promoting Ethics and Education in Research

RESEARCH ESSENTIALS

COMPETENCY UNIT

SCIENTIFIC CONCEPTS AND RESEARCH DESIGN

Module Overview

CODE	TITLE	DESCRIPTION
C1.01	Science and the Scientific Method	In this module you will be introduced to a few ways of thinking about science that challenge conventional notions of how science is best understood. This will call upon you to reflect critically on science and the scientific method, leading to a more critically informed perspective of science.
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.
C1.08	The Social Impact of Research	In this module you will be introduced to a few ways of thinking about the responsibility of researchers to consider the impacts of their research. This will require you to take a critical eye to the way that the duties of researchers have been traditionally framed, resulting in a more informed perspective on the duties of the researcher towards their society and beyond.

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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.
C2.02	History, Role and Purpose of Human Research Ethics	This module describes the historical and social events and philosophical ideas that have contributed to our thinking about how research should be conducted and the development of Codes and Guidelines for research ethics and research integrity.
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.
C2.05	International Guidelines	This module describes the ethical principles and guidelines that exist to regulate research in different countries and contexts and the obligations that researchers and sponsors have when conducting research in diverse and resource-poor countries.
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.
C2.07	Using Social Media in Research	This module will introduce you to social media in the research setting, and its potential role in clinical trials.
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.
C3.04	Managing Financial and Personnel Resources in Research	Writing a grant application for your research or wondering if a Sponsor's budget is adequate for the conduct of a trial at your site can be an onerous and circular activity, to the point where most of us will think that an estimate will do! Nothing could be further from the reality of research funding. This module will provide you with some introductory information and tools you will need to ensure your research endeavours are appropriately funded and resourced.
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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COMPETENCY UNIT

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.
C4.02	Cultural and conceptual influences on data	This module aims to help you to identify 'common biases and fallacies' which emerge in knowledge production systems and research evidence, and increase your critical awareness and understanding of scientific knowledge.
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.
C4.05	Data management (3) Preserving, sharing and re-using data	In this module, we will focus on the why, what and how of sharing your own and others' research data, by looking at data management activities undertaken to facilitate this during the Preserving and Giving access to data phases of the life cycle.
C4.06	Registries and Biobanks	This module will introduce you to the purpose and structure of registries and biobanks, their role in understanding and controlling disease, and how researchers in Australia can get access to their holdings.

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COMPETENCY UNIT

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.
C5.02	Global Regulation of Research	This module will give you an introductory insight into global regulations - with focus on the US and the European regulations - related to clinical research activities and how they affect clinical research management in Australia.
C5.03	Conflicts of Interests in Research	In this Module (which is also a lead-in to the more in-depth Elective on Industry Influence and Conflict of Interest), you will learn about the conflicts of interest that can arise from interactions between researchers and the 'industries' that fund research.
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.
C5.05	Legal Responsibilities in Research	This module introduces you to the basic concepts of law and their sources. It also provides a background to the legal structures that underpin the research environment and the responsibilities that they give rise to.
C5.06	Professional Guidelines in Research	In this module, you will learn about the history and definitions of professionalism, and consider its importance within the research process. You will also learn to identify professional guidelines and reflect upon their application to your area of 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.

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COMPETENCY UNIT

COMMUNICATION LEADERSHIP AND INTER-PROFESSIONALISM

Module Overview

CODE	TITLE	DESCRIPTION
C6.01	Principles of Leadership, Management and Mentorship	This module will introduce you to key elements, definitions and characteristics within leadership, management and mentorship and provide opportunity for personal reflection and recognition of these competencies.
C6.02	Building and Strengthening Teams	TBC
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).
C6.04	Publication and Authorship	The aim of research is to create new knowledge, or find new ways of using current knowledge. Translation of this new knowledge into improved practice requires the knowledge to be available in the public domain thus researchers should strive to get the results of their work published. Researchers also have a moral obligation to publish their findings, to justify the substantial, often tax-payer derived, funding they receive and the burden placed on research participants, both human and non-human. In this module we will discuss some of the ethical issues associated with the publication of research results
C6.05	Basics Presentation Skills	Presentation and public speaking skills are essential for many aspects of work and life, for self-development, and for a range of social and professional situations. This module will help you to develop the confidence and ability to prepare and deliver effective presentations targeted to your audience. Whether you are an experienced presenter or just beginning, there will be something in this module to help you improve.
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.
C6.07	Intellectual Property for Researchers	In this module we will explore different types of IP and then focus on patent fundamentals and the relevant considerations involved in obtaining patents, with a particular focus on the research sector.

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RESEARCH ESSENTIALS

COMPETENCY UNIT

ELECTIVES

Module Overview

CODE	TITLE	DESCRIPTION
EC.01	Working with Industry and Conflict of Interest	In this elective, you will learn about the conflicts of interest that can arise from interactions between researchers and the 'industries' that fund research. For the purposes of this elective, the term 'industries' will be used to refer to government departments (other than those that exist specifically to fund research), non-government organisations and private industries.
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.05	Development of Drugs and Medical Devices	TBC
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.07	Rational Prescribing and the Quality Use of Medicines	In this elective, you will learn about the rational use of medicines, and its opposite, the suboptimal use of medicines. For the purposes of this Elective, the term "rational use of medicines" will be used to encompass "quality use of medicines" as well as "responsible use of medicines".
EC.08	Business Management Skills	This elective explains some of the basic skills you need to run a successful business or project, how to identify your existing skills or the existing skills within your team and where you or your team may need further training.
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

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ELECTIVES

Module Overview

CODE	TITLE	DESCRIPTION
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.
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.02	Social Media Research	Healthcare organisations, clinical researchers and researchers generally need to invest in understanding and utilising the role of social media to accelerate research and improve healthcare and social outcomes. This elective will explore the impact risks and benefits of social media in research and research conducted with social media.
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.05	Introduction to Pharmacology	In this elective, you will learn about the science of pharmacology, or the study of drug action. This includes two components- the effect of a drug on the body (pharmacodynamics or PD) and how the body deals with drugs (pharmacokinetics or PK). In this module, the term "drug" refers to a substance of known chemical structure (other than a nutrient or essential dietary ingredient) which, when administered to a living organism produces a biological effect.

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ELECTIVES

Module Overview

CODE	TITLE	DESCRIPTION
EM.06	Introduction to Routine Data	Governments, public services and the private sector in Australia collect vast amounts of routine data. In this module, you will learn what routine data are, and are not; how they can help us understand and solve policy and practice problems; and, how to get access to and begin working with them.
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.08	Genetics Research- Basic concepts	This elective will introduce you to the basics of Genes, DNA and the genome; Genetic variation and mutations, inheritance patterns, and the use of genetic testing in health and disease.
EM.09	Genetics Research – Ethical issues	In this elective you will learn about some of the ethical issues that arise from human genetics research and how they may be managed effectively.
EM.10	Good Laboratory Practice	In this elective, you will learn about the key aspects of Good Laboratory Practice and explore ways to incorporate the quality system tools in your current and future roles.
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.
EM.12	An Introduction to Statistical Methods in Clinical Trials	TBC
EM.13	Systematic Reviews and Meta-Analysis	In this elective you will learn how systematic reviews summarise exiting knowledge and data on a particular topic, which in turn provides health professionals with the 'best available evidence' needed to make clinical decisions. We will start with some background information and then give you a brief step-by-step guide in conducting a systematic review.

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 offers a unique model of education that 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. This course offers a constant source of expanding modules and electives that reflect the changing nature of research in the Australian setting.

How does it work?
Through a purpose-built interface, our Research Essentials course allows you to design your own pathway of study across the various Competency Units, Modules and Electives. Alternatively, our system will design a course of study individually tailored, based on your needs, particular areas of interest and your current research role.
Design your own adventure or let our system design one for you!

How does the system choose the right Course for me?
On entry into our Learning Portal, you will be asked to provide some basic information, including your areas of interest and discipline and your current research role. Based on this information, the software will select an appropriate course of study from across the various Competency Units and Electives to ensure that you receive the training most appropriate to your needs.

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, Elective or a individual Module all have different time requirements.

Some definitions are useful here:

COURSE A course is comprised of a combination of Competency Units and Electives.

You can design your own Course by selecting from the array of Modules and Electives - or let our system choose a pathway of study for you. A "self-designed" course will have a minimum total of 30 Modules and Electives.

COMPETENCY UNIT
Six internationally accepted Competency Units are described overleaf. Each Unit is comprised of multiple Modules.

MODULE A Module is a single block of study that takes about an hour to complete. The number of Modules you select will affect how long your Course takes to complete.

ELECTIVES Electives are individual blocks of study that either extend Modules within the Competency Units or cover areas of interest outside them. An Elective takes about two hours to complete. The number of Electives available will expand as we continue to develop our resources and respond to the changing research landscape.

Can I complete the study in my own time and at my own pace?
Yes! The Research Essentials course has been designed to accommodate the competing commitments of a complex workforce. You can choose the course of study that suits you and you can pace your learning to reflect your personal needs. The course is designed to add value to your career, not to distract you from your other responsibilities!

Is the course only available online?
Research Essentials has been designed for an online environment. We will, however, also provide face to face workshops to deepen the learning experience and promote peer interaction and discussion.

What accreditation will I receive at the end?
Participants will receive certificates of completion from PRAXIS on completion of each Module, Elective, Competency Unit or Course, detailing the Modules studied that can be used to accrue CPD. We are also working with a number of professional bodies to have this course endorsed.

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 $2000

Competency Unit $750 per unit

Module $150 per module

Elective $250 per elective

Institutional and group discounts can also be negotiated, as can tailored packages for individuals or institutions.

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. We are also considering the addition of a mentoring component to this course at some point in the future.

How can I find out more information?
Our team is always happy to talk with you to answer your questions or provide guidance and assistance.

Talk to us or email | Please contact us at any time if you require information or support.

Call 08 8122 4576 |
during normal office hours or
Email info@praxisaustralia.com.au

Our website is full of information and avenues of contact...

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