# PPCT8002

## Clinical Trial Management

Session 2, Online-flexible 2024

*Macquarie Medical School*

# Contents

# General Information

Unit convenor and teaching staff
Unit Convenor
Rania Salama
rania.salama@mq.edu.au
By appointment only (online or in-person consultations)

Credit points
10

Prerequisites

Corequisites
PPCT8000

Co-badged status

Unit description
This is a specialised unit which focuses on the feasibility of conducting a clinical trial at a particular site and basic project management skills required throughout the trial. In this unit, you will gain an understanding of the human ethics submission process and required documentations. You will critically evaluate study protocols to understand the necessary resources required, such as staff, equipment and supporting departments, practicalities of study initiation, and the potential risks that might lead to the trial not being completed as planned. In this unit, you will gain skills in basic risk management, development of site-specific risk mitigation strategies to support the trial, optimisation of networks and collaborations and learn about the environmental impact of clinical trials. You will also explore the tools to develop a basic clinical trial budget taking into consideration the cost of implementing the protocol and estimation of resources required. Additionally, you will explore participant recruitment and retention strategies. This unit is co-designed with industry and offers pre-recorded industry expert lectures and interviews, real-world case studies, knowledge check quizzes and industry relevant assessments.

## Important Academic Dates

Information about important academic dates including deadlines for withdrawing from units are available at https://www.mq.edu.au/study/calendar-of-dates

# Learning Outcomes

On successful completion of this unit, you will be able to:

**ULO1:** Demonstrate the functional and operational requirements and project

management skills necessary to conduct effective clinical studies. (Capability 2 - Clinical Trial Practitioner)

**ULO2:** Critically examine study protocols for site selection and feasibility, risk mitigation strategies, budget development, and resources required including staff and equipment. (Capability 2 - Clinical Trial Practitioner)

**ULO3:** Discuss the human ethics committee submission requirements including legal responsibilities, liabilities and accountabilities which are involved in the conduct of clinical studies. (Capability 4 - Professional)

**ULO4:** Identify strategies to manage participant recruitment, retention, compliance and positive experience and differentiate between standard of care and clinical study activities. (Capability 4 - Engaged Global Citizen)

**ULO5:** Recognise the importance of quality management systems, data management and informatics principles including statistics, analysis, reporting, distribution of trial results, and archiving requirements. (Capability 1 - Scientist and Scholar)

# General Assessment Information

Grade descriptors and other information concerning grading are contained in the Macquarie University Assessment Policy.

All final grades are determined by a grading committee, in accordance with the Macquarie University Assessment Policy, and are not the sole responsibility of the Unit Convenor.

Students will be awarded a final grade and a mark which must correspond to the grade descriptors specified in the Assessment Procedure.

To pass this unit, you must demonstrate sufficient evidence of achievement of the learning outcomes, meet any ungraded requirements, and achieve a final mark of 50 or better.

Further details for each assessment task will be available on iLearn.

Late Submissions

Unless a Special Consideration request has been submitted and approved, a 5% penalty (OF THE TOTAL POSSIBLE MARK) will be applied each day an assessment is not submitted, up until the 7th day (including weekends). After the 7th day, a grade of '0' will be awarded even if the assessment is submitted. Submission time for all written assessments is set at 11.55pm. A 1-hour grace period is provided to students who experience a technical concern.

 For example:

| Number of days (hours) late | Total Possible Marks | Deduction | Raw mark | Final mark |
|---|---|---|---|---|
| 1 day (1-24 hours) | 100 | 5 | 75 | 70 |
| 2 days (24-48 hours) | 100 | 10 | 75 | 65 |
| 3 days (48-72 hours) | 100 | 15 | 75 | 60 |
| 7 days (144-168 hours) | 100 | 35 | 75 | 40 |
| >7 days (>168 hours) | 100 | - | 75 | 0 |

For any late submissions of time-sensitive tasks, such as scheduled tests/exams, performance assessments/presentations, and/or scheduled practical assessments/labs, students need to submit an application for Special Consideration.

# Assessment Tasks

| Name | Weighting | Hurdle | Due |
|---|---|---|---|
| Human Research Ethics Application | 30% | No | Check unit iLearn site |
| Study resources and budget | 30% | No | Check unit iLearn site |
| Recorded video presentation (Site Initiation Visit - SIV) | 40% | No | Check unit iLearn site |

## Human Research Ethics Application

Assessment Type [1]: Case study/analysis
Indicative Time on Task [2]: 25 hours
Due: **Check unit iLearn site**
Weighting: **30%**

Complete Human Research Ethics Application sections based on critical examination of a study protocol.

On successful completion you will be able to:
- Demonstrate the functional and operational requirements and project management skills

necessary to conduct effective clinical studies. (Capability 2 - Clinical Trial Practitioner)

- Critically examine study protocols for site selection and feasibility, risk mitigation strategies, budget development, and resources required including staff and equipment. (Capability 2 - Clinical Trial Practitioner)

- Discuss the human ethics committee submission requirements including legal responsibilities, liabilities and accountabilities which are involved in the conduct of clinical studies. (Capability 4 - Professional)

- Identify strategies to manage participant recruitment, retention, compliance and positive experience and differentiate between standard of care and clinical study activities. (Capability 4 - Engaged Global Citizen)

- Recognise the importance of quality management systems, data management and informatics principles including statistics, analysis, reporting, distribution of trial results, and archiving requirements. (Capability 1 - Scientist and Scholar)

## Study resources and budget

Assessment Type [1]: Report
Indicative Time on Task [2]: 15 hours
Due: **Check unit iLearn site**
Weighting: **30%**

Prepare and justify a study budget based on a critical examination of a given study protocol.

On successful completion you will be able to:
- Demonstrate the functional and operational requirements and project management skills necessary to conduct effective clinical studies. (Capability 2 - Clinical Trial Practitioner)

- Critically examine study protocols for site selection and feasibility, risk mitigation strategies, budget development, and resources required including staff and equipment. (Capability 2 - Clinical Trial Practitioner)

- Identify strategies to manage participant recruitment, retention, compliance and positive experience and differentiate between standard of care and clinical study activities. (Capability 4 - Engaged Global Citizen)

## Recorded video presentation (Site Initiation Visit - SIV)

Assessment Type [1]: Presentation

Indicative Time on Task [2]: 30 hours
Due: **Check unit iLearn site**
Weighting: **40%**

You will record a video role playing aspects of a site initiation visit. You will then review the videos of your peers.

On successful completion you will be able to:

- Demonstrate the functional and operational requirements and project management skills necessary to conduct effective clinical studies. (Capability 2 - Clinical Trial Practitioner)
- Critically examine study protocols for site selection and feasibility, risk mitigation strategies, budget development, and resources required including staff and equipment. (Capability 2 - Clinical Trial Practitioner)
- Discuss the human ethics committee submission requirements including legal responsibilities, liabilities and accountabilities which are involved in the conduct of clinical studies. (Capability 4 - Professional)
- Identify strategies to manage participant recruitment, retention, compliance and positive experience and differentiate between standard of care and clinical study activities. (Capability 4 - Engaged Global Citizen)
- Recognise the importance of quality management systems, data management and informatics principles including statistics, analysis, reporting, distribution of trial results, and archiving requirements. (Capability 1 - Scientist and Scholar)

[1] If you need help with your assignment, please contact:

- the academic teaching staff in your unit for guidance in understanding or completing this type of assessment
- the Writing Centre for academic skills support.

[2] Indicative time-on-task is an estimate of the time required for completion of the assessment task and is subject to individual variation

# Delivery and Resources

PPCT8002 Clinical Trial Management is an online unit. As a student enrolled in this unit, you will engage in a range of online learning activities, including readings, videos, online modules, etc. Details can be found on the iLearn site for this unit.

**Technology Used**

Active participation in the learning activities throughout the unit will require students to have access to a laptop, tablet, or similar device.

# Policies and Procedures

Macquarie University policies and procedures are accessible from Policy Central (https://policies.mq.edu.au). Students should be aware of the following policies in particular with regard to Learning and Teaching:

- Academic Appeals Policy
- Academic Integrity Policy
- Academic Progression Policy
- Assessment Policy
- Fitness to Practice Procedure
- Assessment Procedure
- Complaints Resolution Procedure for Students and Members of the Public
- Special Consideration Policy

Students seeking more policy resources can visit Student Policies (https://students.mq.edu.au/support/study/policies). It is your one-stop-shop for the key policies you need to know about throughout your undergraduate student journey.

To find other policies relating to Teaching and Learning, visit Policy Central (https://policies.mq.edu.au) and use the search tool.

## Student Code of Conduct

Macquarie University students have a responsibility to be familiar with the Student Code of Conduct: https://students.mq.edu.au/admin/other-resources/student-conduct

## Results

Results published on platform other than eStudent, (eg. iLearn, Coursera etc.) or released directly by your Unit Convenor, are not confirmed as they are subject to final approval by the University. Once approved, final results will be sent to your student email address and will be made available in eStudent. For more information visit ask.mq.edu.au or if you are a Global MBA student contact globalmba.support@mq.edu.au

# Academic Integrity

At Macquarie, we believe academic integrity – honesty, respect, trust, responsibility, fairness and courage – is at the core of learning, teaching and research. We recognise that meeting the expectations required to complete your assessments can be challenging. So, we offer you a range of resources and services to help you reach your potential, including free online writing and maths support, academic skills development and wellbeing consultations.

# Student Support

Macquarie University provides a range of support services for students. For details, visit http://stu

dents.mq.edu.au/support/

## The Writing Centre

The Writing Centre provides resources to develop your English language proficiency, academic writing, and communication skills.

- Workshops
- Chat with a WriteWISE peer writing leader
- Access StudyWISE
- Upload an assignment to Studiosity
- Complete the Academic Integrity Module

The Library provides online and face to face support to help you find and use relevant information resources.

- Subject and Research Guides
- Ask a Librarian

# Student Services and Support

Macquarie University offers a range of Student Support Services including:

- IT Support
- Accessibility and disability support with study
- Mental health support
- Safety support to respond to bullying, harassment, sexual harassment and sexual assault
- Social support including information about finances, tenancy and legal issues
- Student Advocacy provides independent advice on MQ policies, procedures, and processes

# Student Enquiries

Got a question? Ask us via AskMQ, or contact Service Connect.

# IT Help

For help with University computer systems and technology, visit http://www.mq.edu.au/about_us/offices_and_units/information_technology/help/.

When using the University's IT, you must adhere to the Acceptable Use of IT Resources Policy. The policy applies to all who connect to the MQ network including students.

## Inclusion and Diversity

Social inclusion at Macquarie University is about giving everyone who has the potential to benefit from higher education the opportunity to study at university, participate in campus life and

flourish in their chosen field. The University has made significant moves to promote an equitable, diverse and exciting campus community for the benefit of staff and students. It is your responsibility to contribute towards the development of an inclusive culture and practice in the areas of learning and teaching, research, and service orientation and delivery. As a member of the Macquarie University community, you must not discriminate against or harass others based on their sex, gender, race, marital status, carers' responsibilities, disability, sexual orientation, age, political conviction or religious belief. All staff and students are expected to display appropriate behaviour that is conducive to a healthy learning environment for everyone, including when on external placement activities.

# Professionalism

In the Faculty of Medicine, Health and Human Sciences, professionalism is a key capability embedded in all our courses.

As an adult learner, we respect your decision to choose how you engage with your learning, but we would remind you that the learning opportunities we create for you have been done so to enable your success, and that by not engaging you may impact your ability to successfully complete this unit. We equally expect that you show respect for the academic staff who have worked hard to develop meaningful activities and prioritise your learning.

Another dimension of professionalism is having respect for your peers. It is the right of every student to learn in an environment that is free of disruption and distraction. Please communicate respectfully when interacting on discussion forums and in group assignments (when applicable). Please treat your fellow students with the utmost respect. If you are uncomfortable participating in any specific activity, please let the relevant academic know.

---

Unit information based on version 2024.02 of the Handbook