



# PPCT8001

## Clinical Trial Operations

Session 1, Online-flexible 2024

*Macquarie Medical School*

### Contents

---

|                                       |   |
|---------------------------------------|---|
| <u>General Information</u>            | 2 |
| <u>Learning Outcomes</u>              | 2 |
| <u>General Assessment Information</u> | 3 |
| <u>Assessment Tasks</u>               | 4 |
| <u>Delivery and Resources</u>         | 7 |
| <u>Policies and Procedures</u>        | 7 |
| <u>Inclusion and Diversity</u>        | 9 |
| <u>Professionalism</u>                | 9 |

---

#### **Disclaimer**

Macquarie University has taken all reasonable measures to ensure the information in this publication is accurate and up-to-date. However, the information may change or become out-dated as a result of change in University policies, procedures or rules. The University reserves the right to make changes to any information in this publication without notice. Users of this publication are advised to check the website version of this publication [or the relevant faculty or department] before acting on any information in this publication.

## General Information

Unit convenor and teaching staff

Unit Convenor

Rania Salama

[rania.salama@mq.edu.au](mailto:rania.salama@mq.edu.au)

Contact via [rania.salama@mq.edu.au](mailto: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 specialised unit discusses the key operational aspects of designing, implementing, and monitoring a clinical trial and how they impact the trial success. You will learn about the various roles facilitating the participants' ethical and safe journey. You will appreciate the importance of accurately documenting trial source notes and delegations, and how they are reflected in the trial databases, provide a record for monitors and auditors, and ensure the trial conduct and results are built on credible principles and valid data. You will learn why adverse event management is pivotal to participants' safety, how to classify and timely report adverse events. In addition, you will identify the practicalities of investigational product handling and tracking, safe handling of biological samples, as well as requirements of clinical trial equipment maintenance and calibration. 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. You will achieve a Dangerous Goods Handling certificate upon successful completion of PPCT8001.

## 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:** Interpret components of key regulatory, ethical, trial governance and monitoring

documents to ensure research integrity, validity, and participants welfare and confidentiality. (Capability 1 - Scientist and Scholar)

**ULO2:** Interpret medical notes, laboratory and scans reports and assess the need to escalate clinical and adverse events when necessary. (Capability 2 - Clinical Trial Practitioner)

**ULO3:** Demonstrate how to accurately document a clinical trial visit in source notes, data entry in electronic case reports and databases for archiving trial documents. (Capability 2 - Clinical Trial Practitioner)

**ULO4:** Evaluate the responsibilities and requirements for correct adverse events identification, classification and reporting in a clinical trial. (Capability 2 - Clinical Trial Practitioner)

**ULO5:** Evaluate the safety of handling of biological samples and dangerous goods, including compliance with international regulatory guidelines. (Capability 4 - Professional)

**ULO6:** Analyse clinical trial documentation to assess compliance of investigational product and biological sample handling, equipment maintenance and other trial aspects with study protocol, manuals and relevant regulations. (Capability 2 - Clinical Trial Practitioner)

## 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](#) (clause 128 and 129).

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                  |
|---|-----------|--------|----------------------|
| <a href="#"><u>Study Documentation</u></a>                    | 45%       | No     | Check on iLearn site |
| <a href="#"><u>Study Compliance Report</u></a>                | 40%       | No     | Check on iLearn site |
| <a href="#"><u>Dangerous Goods Shipping Quiz</u></a>          | 0%        | Yes    | Check on iLearn site |
| <a href="#"><u>Laboratory and Equipment Safety Report</u></a> | 15%       | No     | Check on iLearn site |

### Study Documentation

Assessment Type <sup>1</sup>: Case study/analysis

Indicative Time on Task <sup>2</sup>: 30 hours

Due: **Check on iLearn site**

Weighting: **45%**

You will appropriately document study trial notes from a variety of sources and then enter this data into an electronic format.

On successful completion you will be able to:

- Interpret components of key regulatory, ethical, trial governance and monitoring documents to ensure research integrity, validity, and participants welfare and

confidentiality. (Capability 1 - Scientist and Scholar)

- Interpret medical notes, laboratory and scans reports and assess the need to escalate clinical and adverse events when necessary. (Capability 2 - Clinical Trial Practitioner)
- Demonstrate how to accurately document a clinical trial visit in source notes, data entry in electronic case reports and databases for archiving trial documents. (Capability 2 - Clinical Trial Practitioner)
- Evaluate the responsibilities and requirements for correct adverse events identification, classification and reporting in a clinical trial. (Capability 2 - Clinical Trial Practitioner)

## Study Compliance Report

Assessment Type <sup>1</sup>: Report

Indicative Time on Task <sup>2</sup>: 29 hours

Due: **Check on iLearn site**

Weighting: **40%**

You will examine specific study site documentation and complete a monitoring visit report to ascertain the site is compliant with regulations and the study protocol.

On successful completion you will be able to:

- Interpret components of key regulatory, ethical, trial governance and monitoring documents to ensure research integrity, validity, and participants welfare and confidentiality. (Capability 1 - Scientist and Scholar)
- Interpret medical notes, laboratory and scans reports and assess the need to escalate clinical and adverse events when necessary. (Capability 2 - Clinical Trial Practitioner)
- Demonstrate how to accurately document a clinical trial visit in source notes, data entry in electronic case reports and databases for archiving trial documents. (Capability 2 - Clinical Trial Practitioner)
- Evaluate the responsibilities and requirements for correct adverse events identification, classification and reporting in a clinical trial. (Capability 2 - Clinical Trial Practitioner)
- Analyse clinical trial documentation to assess compliance of investigational product and biological sample handling, equipment maintenance and other trial aspects with study protocol, manuals and relevant regulations. (Capability 2 - Clinical Trial Practitioner)

## Dangerous Goods Shipping Quiz

Assessment Type <sup>1</sup>: Quiz/Test

Indicative Time on Task <sup>2</sup>: 5 hours

Due: **Check on iLearn site**

Weighting: **0%**

**This is a hurdle assessment task (see [assessment policy](#) for more information on hurdle assessment tasks)**

You will complete an external Dangerous Goods training module and an online self-assessment quiz. You will upload your training completion certificate as a proof of fulfilment of this assessment task.

On successful completion you will be able to:

- Evaluate the safety of handling of biological samples and dangerous goods, including compliance with international regulatory guidelines. (Capability 4 - Professional)

## Laboratory and Equipment Safety Report

Assessment Type <sup>1</sup>: Report

Indicative Time on Task <sup>2</sup>: 6 hours

Due: **Check on iLearn site**

Weighting: **15%**

You will demonstrate the effective application of relevant regulatory guidelines relating to laboratory handling and shipping of biological samples, dangerous goods and equipment maintenance.

On successful completion you will be able to:

- Evaluate the safety of handling of biological samples and dangerous goods, including compliance with international regulatory guidelines. (Capability 4 - Professional)
- Analyse clinical trial documentation to assess compliance of investigational product and biological sample handling, equipment maintenance and other trial aspects with study protocol, manuals and relevant regulations. (Capability 2 - Clinical Trial Practitioner)

---

<sup>1</sup> 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.

<sup>2</sup> 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

PPCT8001 Clinical Trial Operations 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 tablet, laptop or similar device.

## Policies and Procedures

Macquarie University policies and procedures are accessible from [Policy Central \(https://policies.mq.edu.au\)](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 \(https://students.mq.edu.au/support/study/policies\)](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 \(https://policies.mq.edu.au\)](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](https://ask.mq.edu.au) or if you are a Global MBA student contact [globalmba.support@mq.edu.au](mailto: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://students.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/](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, and when on external placement representing Macquarie University, 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](#)