PPCT8001

Clinical Trial Operations

Session 2, Online-flexible 2026

School of Health Sciences and Nursing

Contents

General Information

Unit convenor and teaching staff
Unit Convenor
Rania Salama
rania.salama@mq.edu.au
Contact via Email
Level 5- 75 Talavera RD- Macquarie Park
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 successfully completing one of the unit's 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: 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.

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.

Short Extensions

Short Extension are available on some eligible assessments. This enables you to request an additional 3 calendar days to complete an eligible assessment.

No reason or evidence is required. Short Extensions are designed to give you a little more breathing space to complete your work, empower you to manage your study and life commitments and to support your overall well-being. To find out more click here.

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.

Special Consideration

If you are unable to complete an assessment task on or by the specified date due to circumstances that are unexpected, unavoidable, significantly disruptive and beyond your control, you may apply for special consideration. This is in accordance with the Special Consideration Policy. Applications for special consideration must be supported by appropriate evidence and submitted via Service Connect.

Assessment Tasks

Name	Weighting	Hurdle	Due	Groupwork/Individual	Short Extension	AI Approach
Study Documentation	40%	No	23/08/2026	Individual	Yes	Open
Study Compliance Report	40%	No	18/10/2026	Individual	Yes	Open

Name	Weighting	Hurdle	Due	Groupwork/Individual	Short Extension	AI Approach
Dangerous Goods, Laboratory and Equipment Safety Report	20%	No	01/ 11/ 2026	Individual	Yes	Open

Study Documentation

Assessment Type [1]: Professional task
Indicative Time on Task [2]: 30 hours
Due: **23/08/2026**
Weighting: **40%**
Groupwork/Individual: Individual
Short extension [3]: Yes
AI Approach: Open

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 [1]: Professional task
Indicative Time on Task [2]: 29 hours
Due: **18/10/2026**
Weighting: **40%**
Groupwork/Individual: Individual
Short extension [3]: Yes
AI Approach: Open

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)
- 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)

Dangerous Goods, Laboratory and Equipment Safety Report

Assessment Type [1]: Professional task
Indicative Time on Task [2]: 11 hours
Due: **01/11/2026**
Weighting: **20%**
Groupwork/Individual: Individual
Short extension [3]: Yes
AI Approach: Open

You will complete an external Dangerous Goods shipping training module and online self-assessment quiz to obtain a training completion certificate. You will then 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)

[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
- Academic Success 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.

[3] An automatic short extension is available for some assessments. Apply through the Service Connect Portal.

Delivery and Resources

PPCT8000 Foundations of Clinical Trials 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 connect.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://students.mq.edu.au/support/

Academic Success

Academic Success provides resources to develop your English language proficiency, academic writing, and communication skills.

- Ask a Study Coach
- 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 the Service Connect Portal, or contact Service Connect.

IT Help

For help with University computer systems and technology, visit https://students.mq.edu.au/support/technology/service-desk.

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.

Artificial Intelligence Tools

Macquarie University recognises that artificial intelligence (AI), especially generative AI, is rapidly reshaping education and the modern workplace. As AI becomes increasingly accessible, the University and your teaching staff are committed to preparing you to use these tools effectively, ethically, and with strong professional judgment. Rather than restricting technology, the emphasis is on helping you understand when and how AI can be used to enhance productivity, support learning, and reflect real-world professional practice. Across your degree, we will support you to develop the critical thinking, adaptability, and values-based decision-making skills required to navigate evolving AI tools responsibly, including acknowledging their use appropriately. You should always appropriately acknowledge when you have used AI tools within assessment tasks, including which AI tools you have used and how you have used them.

To provide clarity, Macquarie University uses a simple, two-tiered approach to AI in assessment:

- AI Open assessments allow you to fully incorporate AI, reflecting authentic tasks where AI would normally be used in professional settings.

- Observed with AI Optional assessments involve tasks where you either demonstrate essential knowledge without technology or show how you apply AI under supervision.

Across both categories, the goal is to ensure you build foundational knowledge, exercise sound judgment, and engage with AI in ways that uphold ethical, cultural, and university values.

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.

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 by communicating with them in advance if you are unable to attend a small group interactive session.

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 2026.01R of the Handbook