

CLRS90022 Clinical Trial Site Coordination

Credit Points:	12.5
Level:	9 (Graduate/Postgraduate)
Dates & Locations:	2016, Hawthorn This subject commences in the following study period/s: February, Hawthorn - Taught on campus.
Time Commitment:	Contact Hours: 24 hours Total Time Commitment: 170 hours per 12.5 credit point subject.
Prerequisites:	To enrol in this subject, you must be admitted in N01AA, N34AA, or GC-CRCOORD. This subject is not available for students admitted in any other courses.
Corequisites:	nil
Recommended Background Knowledge:	nil
Non Allowed Subjects:	nil
Core Participation Requirements:	For the purposes of considering requests for Reasonable Adjustments under the Disability Standards for Education (Commonwealth 2005), and Students Experiencing Academic Disadvantage Policy, academic requirements for this course are articulated in the Course Overview, Objectives and Generic Skills sections of this entry. It is University policy to take all reasonable steps to minimise the impact of disability upon academic study, and reasonable adjustments will be made to enhance a student's participation in the University's programs. Students who feel their disability may impact on meeting the requirements of this course are encouraged to discuss this matter with the Student Equity and Disability Support Team: http://www.services.unimelb.edu.au/disability/
Contact:	School of Melbourne Custom Programs Currently enrolled and future students: # General information: http://www.commercial.unimelb.edu.au/courses (http://www.commercial.unimelb.edu.au/courses) # Email: TL-ClinicalResearch@unimelb.edu.au (mailto:TL-ClinicalResearch@unimelb.edu.au)
Subject Overview:	In this subject, students will select a minimum of 10 hours of electives depending on their needs plus a compulsory capstone component. Electives (minimum of 10 hours of teaching). <ul style="list-style-type: none"> • Assertiveness in the workplace (7 hours) or Managing and Resolving Conflict (7 hours) • Fundamentals of project management (7 hours) • Statistics for non-statisticians (14 hours) • Managing laboratories in clinical research (14 hours) • Effective management of GCP issues (3 hours) • Introduction to pharmacovigilance (3 hours) • Research ethics and governance (3 hours) Capstone <ul style="list-style-type: none"> • Coordinating single and multi-centre clinical research more effectively (14 hours)
Learning Outcomes:	Students who successfully complete this subject will: <ul style="list-style-type: none"> • Understand how to effectively coordinate research activities at a clinical research site • Understand and manage risk at a clinical research site • Understand the role of project management in good clinical practice • Be able to provide input in the implementation of clinical research studies within Australia • Understand the purpose and operational responsibilities of a Clinical Research Associate in maintaining the quality standards defined by Australian legislation and Good Clinical Practice

Assessment:	Assessment for this subject will be based around the individual modules, plus an overall assessment of the content of the two subjects. This will comprise: • 2,000 word assignments for the electives, with a total contribution of 40% of the marks for the subject. • 2,000 word assignment for the capstone module, representing 40% of the marks for the subject. • 1,000 word workplace assignment representing 20% of the marks for the subject. Each assessment piece is due four weeks after the relevant lecture. Students must achieve a mark of at least 50% in each of the assessments to achieve a pass grade for this subject.
Prescribed Texts:	All class materials will be provided.
Recommended Texts:	NA
Breadth Options:	This subject is not available as a breadth subject.
Fees Information:	Subject EFTSL, Level, Discipline & Census Date, http://enrolment.unimelb.edu.au/fees
Links to further information:	http://www.commercial.unimelb.edu.au/courses
Related Course(s):	Graduate Diploma in Clinical Research Master of Clinical Research Specialist Certificate in Clinical Research-Clinical Trials Coordination