CLRS90022 Clinical Trial Site Coordination

Credit Points:	12.50
Level:	9 (Graduate/Postgraduate)
Dates & Locations:	2011, Hawthorn This subject commences in the following study period/s: Semester 1, Hawthorn - Taught on campus. Semester 2, Hawthorn - Taught on campus. Face-to-Face Lecture
Time Commitment:	Contact Hours: 24 hours Total Time Commitment: Estimated total time commitment of 160 hours.
Prerequisites:	nil
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 (Cwth 2005), and Students Experiencing Academic Disadvantage Policy, academic requirements for this subject are articulated in the Subject Description, Subject Objectives, Generic Skills and Assessment Requirements of this entry. The University is dedicated to provide support to those with special requirements. Further details on the disability support scheme can be found at the Disability Liaison Unit website: http://www.services.unimelb.edu.au/disability/
Contact:	Melbourne Consulting and Custom Programs Level 3, 442 Auburn Rd Hawthorn VIC 3122 Phone: 9810 3185 Email: **clinicalresearch@mccp.unimelb.edu.au** **(mailto:clinicalresearch@mccp.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). • 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 • Coordinating single and multi-centre clinical research more effectively (14 hours)
Objectives:	Students who successfully complete this subject will: • 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:	nil
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
Generic Skills:	• Risk management • Project management
Links to further information:	www.mccp.unimelb.edu.au
Related Course(s):	Specialist Certificate in Clinical Research-Clinical Trials Coordination