CLRS90025 Clinical Trial Site Management

Credit Points:	12.50
Level:	9 (Graduate/Postgraduate)
Dates & Locations:	2013, Hawthorn This subject commences in the following study period/s: February, Hawthorn - Taught on campus. July, Hawthorn - Taught on campus.
Time Commitment:	Contact Hours: 24 contact hours Total Time Commitment: In addition to face-to-face teaching time, students should expect to undertake a minimum of 120 hours research, reading, writing assignments and general study to complete this subject successfully.
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:	School of Melbourne Custom Programs Level 3, 442 Auburn Road Hawthorn VIC 3122 Phone - 03 9810 3245 Email - **postgrad@commercial.unimelb.edu.au** **(mailto:postgrad@commercial.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) • Research ethics and governance (3 hours) • Introduction to pharmacovigilance (3 hours) • How to effectively select investigational sites (3 hours) Capstone • Effectively managing your clinical research trial sites (14 hours)
Objectives:	Students who successfully complete this subject will: • Understand how to effectively manage clinical research sites • Understand and manage risk when working with clinical research sites • 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 assignment for the elective subjects, 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
Links to further information:	www.mccp.unimelb.edu.au
Related Course(s):	Graduate Diploma in Clinical Research Master of Clinical Research Specialist Certificate in Clinical Research-Clinical Trials Monitoring