CLRS90024 Clinical Trial Site Monitoring

Credit Points:	12.50
Level:	9 (Graduate/Postgraduate)
Dates & Locations:	2012, Hawthorn This subject commences in the following study period/s: February, Hawthorn - Taught on campus. July, Hawthorn - Taught on campus. Face-to-Face Lecture
Time Commitment:	Contact Hours: 24 contact 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:	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:	Topics covered in this subject include: • Overview of Drug Development • Essential Good Clinical Practice Training for New Clinical Research Associates • Managing Regulatory Documents
Objectives:	Students who successfully complete this subject will: • Understand the drug development pathway and its link to clinical research • Understand the role of the Clinical Research Associate in clinical research • Understand the purpose and role of regulatory documents necessary for initiating and running a clinical trial • 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:	• One open book test representing 20% of the total mark, completed at the end of the first week of lectures.• Two 1000 word assignment each representing 25% of the total mark (a combined total of 50%)• One 1500 word workplace assignment representing 30% of the total mark. Each written essay is due progressively through the semester.A minimum score of 50% in each assessment is required for a student to pass 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:	• Document management • Legislative compliance • Good clinical practice • Risk management
Links to further information:	www.mccp.unimelb.edu.au
Related Course(s):	Specialist Certificate in Clinical Research-Clinical Trials Monitoring