CLRS90024 Clinical Trial Site Monitoring

Credit Points:	12.50
Level:	9 (Graduate/Postgraduate)
Dates & Locations:	2014, 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:	To enrol in this subject, you must be admitted in N01AA, N34AA, or GC-CRMONIT. 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 (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 Award Programs Team Phone: 61 3 9810 3245 Email: ClinicalResearch@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
Learning Outcomes:	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:	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 Monitoring