CLRS90015 Biomedical Research Management

Credit Points:	25
Level:	9 (Graduate/Postgraduate)
Dates & Locations:	2011, Hawthorn This subject commences in the following study period/s: Semester 2, Hawthorn - Taught on campus. Intensive mode
Time Commitment:	Contact Hours: 48 hours of lectures/seminars/workshops Total Time Commitment: In addition to face-to-face teaching time of 48 hours, students should expect to undertake a minimum of 160 hours research, reading, writing 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:	Melbourne Consulting and Custom Programs Level 3, 442 Auburn Rd Hawthorn VIC 3122 Phone: 9810 3300 Email: **mcccp.enquiries@mccp.unimelb.edu.au (mailto:mcccp.enquiries@mccp.unimelb.edu.au)**
Subject Overview:	Topics covered in this subject include: Pricing of protocols Funding models Project planning and development Project management Regulatory and legal issues Stakeholder management Project implementation Risk management Business and business plan developmen New frontiers in biomedical research management Scientific Writing
Objectives:	Students who successfully complete this subject will: # Understand and be conversant with the major activities involved in planning clinical research projects from start to finish; # Understand and be able to develop strategies to manage clinical research projects; # Understand the nuances, rationales, politics, risks and benefits of dealing with a variety of project stakeholders; # Understand the need to comply with regulatory requirements, the processes to fulfill this and be able to identify potential regulatory and legal pitfalls; # Be able to prepare and operate a budget for clinical research projects and adapt the budget to changing circumstances;

	# Understand what is required to develop a business plan for the commercial development of the outcomes of clinical research; # Have the knowledge and tools for clinical research project implementation, including ongoing review, adaptation and risk management; # Be aware of a variety of leading edge developments in the biomedical research field.
Assessment:	A 2 hour examination that assesses the learning from the course (20%), an assignment that prices a clinical research protocol and variations of a protocol according to a range of criteria (3,000 words) (30%) and a comprehensive implementation plan for a clinical research protocol that draws on the course contents in an integrated manner (5,000 words) (50%).
Prescribed Texts:	nil
Recommended Texts:	Students will be provided with articles and references that support the teaching program as part of their course materials
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:	Students who successfully complete this subject will: Understand and be conversant with the major activities involved in planning clinical research projects from start to finish Understand and be able to develop strategies to manage clinical research projects Understand the nuances, rationales, politics, risks and benefits of dealing with a variety of project stakeholders Understand the need to comply with regulatory requirements, the processes to fulfill this and be able to identify potential regulatory and legal pitfalls Be able to prepare and operate a budget for clinical research projects and adapt the budget for changing circumstances. Understand what is required to develop a business plan for the commercial development of the outcomes of clinical research Have the knowledge and tools for clinical research project implementation, including ongoing review, adaptation and risk management Be aware of a variety of leading edge developments in the biomedical research field
Links to further information:	http://www.mccp.unimelb.edu.au/subjects/biomedical-research-management
Related Course(s):	Graduate Diploma in Clinical Research Master of Clinical Research