CLRS90008 Good Clinical Practice and Applications

Credit Points:	12.50
Level:	9 (Graduate/Postgraduate)
Dates & Locations:	2012, Hawthorn This subject commences in the following study period/s: Semester 1, Hawthorn - Taught on campus. Semester 2, Hawthorn - Taught on campus. Intensive mode
Time Commitment:	Contact Hours: A total of 28 hours Total Time Commitment: A minimum of 120 hours, including contact time, on-line modules, pre-reading and assignments.
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 Rd Hawthorn VIC 3122 Phone: 03 9810 3245 Email: **clinical.research@commercial.unimelb.edu.au (mailto:clinical.research@commercial.unimelb.edu.au)**
Subject Overview:	The subject contains a core module in Good Clinical Practice (taught in the classroom) plus a selective based on the needs of the student. Electives are undertaken on-line. Students will choose one elective from the following list: The Electives are: 1. Clinical Trial Conduct I 2. Clinical Trial Conduct II Topics covered in the core Good Clinical Practice module include: # Development of investigational products # Good Clinical Practice (GCP), International Conference on Harmonization (ICH) and government regulations # European clinical trials # The informed consent process # Managing for independent ethics # Key principles of protection # Key factors for conducting IND studies # Key success factors for ensuring successful trials # The subject recruitment process # Electronic data capture, signatures and records # Inspection and compliance # Writing PICF in plain English

	# Therapeutic Goods Administration (TGA) vs. Food and Drug Administration (FDA) vs. ICH vs. EU vs. NZ regulatory requirements # Legal issues of privacy, confidentiality and indemnity # Regulatory requirements for varying trials Topics covered in Elective 1, Clinical Trial Conduct I, include: # Essential Documents in Clinical Research # Site Selection, Pre-Study and Initiation Visits # Study Drug Accountability # Routine Site Monitoring Visits # Subject Recruitment & Retention # Data Management Topics covered in Elective 2, Clinical Trial Conduct II, include: # Protocol Writing # Case Report Form (CRF) Design # Investigational Site Study Budget # Australian clinical trial applications (CTN / CTX applications) # Project Management Fundamentals # Integrated Project Management
Objectives:	Students who successfully complete the core GCP module of this subject will be able to: Review the evolution of Good Clinical Practice from its origins to currently acceptable standards and the imperative of keeping abreast of changing practices and regulations Define the major steps and phases of the drug development process Describe the main regulations governing the practice of clinical research and other applicable guidelines, including the EU Directive, Food and Drug Administration (FDA), Code of Federal Regulations (CFR), Data Privacy/Health Insurance Portability and Accountability Act (HIPAA), and International Conference on Harmonization (ICH) Examine the legal, professional and ethical constrains on various clinical research processes, such as the management of informed consent, Institutional Review Board (IRB) or Independent Ethics Committee (IEC) applications, disclosure of financial interests and electronic signatures Identify the tools and techniques for successfully managing and executing trials Analyse the international principles of ethical conduct and subject protection together with examples of acceptable and non-acceptable norms. Be conversant with the development of standard operating procedures Students who successfully complete Elective 1 of this subject will be able to: Be aware of important activities required for undertaking clinical research, including: Preparation for a clinical study Documentation that must be prepared and managed Accountability for study drugs and devices Site monitoring visits Data management Subject recruitment & retention Students who successfully complete Elective 2 of this subject will be able to: Understand how GCP applies to the following clinical trial activities Protocol Writing Case Report Form Design Site Contract & Budget Investigational Site Study Budget CTN / CTX Application Understand the fundamentals of Project Management and how to use these skills in a clinical trials environment
Assessment:	There are three components to the assessment:1. An in-class test following completion of the two day face-to face teaching component (25% of the total mark)2. On-line assessment associated with the on-line Elective modules (25% of the total mark, and completed as modules are finished)3. A 3000 word assignment due 4 weeks after the completion of the in-class and on-line Elective modules Alternately, students actively working in Clinical Research and who wish to obtain Association of Clinical Research Professional (ACRP) certification for Clinical Trial Investigator (CTI) or Clinical Research Associate (CRA) or Clinical Research Coordinator (CRC) may elect to undergo the following assessment:1. An in-class test following completion of the core GCP two day face-to face teaching component (25% of the total mark).2. Successful completion of the ACRP certification program as a CTI, CRA or CRC (75% of the total mark)

Prescribed Texts:	The required text from the Association of Clinical Research Professionals (ACRP) is provided to each student in addition to course lecture materials
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:	# Project management # Understanding of the Australian regulatory environment for clinical research # Scientific / laboratory record keeping # Development, use and value of Standard Operating Procedures # Basic understanding of the phases and major steps in drug development # Understanding of the fundamental activities and responsibilities for researchers undertaking clinical studies in human volunteers.
Links to further information:	http://www.mccp.unimelb.edu.au/subjects/good-clinical-practice
Related Course(s):	Graduate Diploma in Clinical Research Master of Clinical Research