360-796 Good Clinical Practice and Applications

Credit Points:	12.50
Level:	9 (Graduate/Postgraduate)
Time Commitment:	Contact Hours: Eighteen hours of lectures/seminars/workshops in addition to eight hours of pre- and post-course reading. Students should expect to undertake a minimum of 120 hours lectures, research, reading, writing etc (including face to face contact) to complete this subject successfully Total Time Commitment: Students need to complete GCP for research Professionals (2 full days) and GCP for Practical Applications (1 full day) + Assessment or the ACRP Certification Exam for Certified Physician Investigator (CPI), Clinical Research Coordinator (CRC), or Clinical Research Associate.
Prerequisites:	None
Corequisites:	None
Recommended Background Knowledge:	None
Non Allowed Subjects:	None
Core Participation Requirements:	For the purposes of considering request for Reasonable Adjustments under the Disability Standards for Education (Cwth 2005), and Student Support and Engagement Policy, academic requirements for this subject are articulated in the Subject Overview, Learning Outcomes, Assessment and Generic Skills sections of this entry. It is University policy to take all reasonable steps to minimise the impact of disability upon academic study, and reasonable adjustments will be made to enhance a student's participation in the University's programs. Students who feel their disability may impact on meeting the requirements of this subject are encouraged to discuss this matter with a Faculty Student Adviser and Student Equity and Disability Support: http://services.unimelb.edu.au/disability
Subject Overview:	Students who successfully complete 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.
Assessment:	Pre- & Post-test worth 50 per cent plus a selection of assignments, in total 3000 words, worth 50 per cent.
Prescribed Texts:	The required text from the Association of Clinical Research Professionals (ACRP) is provided to each student in addition to course lecture 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
Related Course(s):	Graduate Diploma in Clinical Research Master of Clinical Research