CLRS90011 Study Design in Clinical Research

Credit Points:	12.50
Level:	9 (Graduate/Postgraduate)
Dates & Locations:	2011, Parkville This subject commences in the following study period/s: Semester 2, Parkville - Taught on campus. Intensive mode
Time Commitment:	Contact Hours: 24 hours of lectures/seminars/workshops Total Time Commitment: Students should expect to undertake a minimum of 120 hours of lectures, research, reading, writing etc 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: clinicalresearch@mccp.unimelb.edu.au
Subject Overview:	The subject will introduce students to the principles of study design in clinical research. Key areas that will be covered are: • Study design principles • Design options including designs and issues specific to clinical research such as: o Oncology and survival studies o Phase I, Phase II and Phase III trials o Pharmaceutical trials o Surgical and device trials o Equivalence studies o Open label trials o Diagnostic trials o Screening trials o Preventive trials o Genetic / Biomarker trials • Sample size and power considerations • Effects of recruitment, retention and attrition on study design, planning & effectiveness • Matching study objectives with optimal study designs • Data management and interpretation • Critical analysis and review of published studies and study designs
Objectives:	The subject will introduce students to the principles of study design in clinical research, exploring the benefits and disadvantages of selected study designs. Students that successfully complete this subject will:

	• Be able to understand and explain the correlation between research objectives, study design, data analysis and clinical practice • Appreciate the inter-relatedness of each of these elements in good clinical study design. • Be able to critically evaluate published clinical research studies. • Be familiar with common study designs and the appropriate application of those designs in clinical research • Understand the impact that poor study design can have on research outcomes
Assessment:	The subject will have two assessments:1. A 2000-3000 word critical evaluation of a selection of published clinical research studies (50%) due 3 weeks after the completion of the subject 2. A 2000-3000 word assignment designing a clinical research study for a specified scenario (50%) due 8 weeks after the completion of the subject.
Prescribed Texts:	Foundations of Clinical Research (supplied to students).
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:	• Organisational skills • Written communication • Statistical reasoning • Interpretation and analysis • Critical thinking • Problem Solving Skills • Attention to detail • Synthesis and evaluation of data
Links to further information:	http://www.mccp.unimelb.edu.au/courses/award-courses/graduate-certificate/clinical-research
Related Course(s):	Graduate Certificate in Clinical Research Graduate Diploma in Clinical Research Master of Clinical Research Professional Certificate in Clinical Research