CLRS90020 Clinical Research in Oncology

Credit Points:	25
Level:	9 (Graduate/Postgraduate)
Dates & Locations:	2012, Parkville This subject commences in the following study period/s: March, Parkville - Taught on campus.
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/
Coordinator:	Assoc Prof Michael Jefford
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:	Topics covered include: # A global overview of the burden of cancer / a public health perspective on cancer control # Career opportunities incorporating clinical research # Australian perspectives in cancer clinical research # Types of research in clinical oncology, including phase I, II and III drug trials, studies evaluating biological agents (incl vaccines), chemotherapy, radiation, combined chemoradiation, surgical and supportive care studies # Endpoints in oncology clinical trials – including overall survival, progression-free survival, response rate, quality of life benefit, clinical benefit, utility analysis (and economic evaluations), proof of efficacy (lab / surrogate endpoints) # Imaging modalities in oncology, including functional imaging # The process of new drug development, approval and marketing – how this may differ from other settings # Issues in clinical trial design for phase I, phase II and phase III studies – how this may differ from other settings # Cancer prevention studies # Cancer detection – screening and early detection # The concept outline / protocol development

	# Practical aspects involved in the conduct of clinical trials, including the development of case report forms, ethics submission, regulatory issues, start-up and ongoing maintenance of the study # Ethics and informed consent – aspects requiring special attention in oncology and palliative care studies # From data to publication / the CONSORT statement (consolidated standards of reporting trials) on reporting of research data
Objectives:	Students who successfully complete this subject will be able to: Understand the breadth of opportunity for clinical research in oncology Be familiar with all types of research design conducted within oncology clinical research Understand the various outcomes assessed by oncology clinical trials, including how and why these might differ from other disciplines Be familiar with surrogate endpoints, derived from laboratory and functional imaging studies Be familiar with ethical and legal considerations relevant to clinical research in oncology Understand all aspects of the concept outline / protocol development Understand the process and requirements for successful conduct of clinical research in oncology Critically appraise research presentations and publications in oncology research
Assessment:	Three 2,000 word assignments worth 20% each. One two hour examination worth 40%.
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:	Please refer to the website.
Links to further information:	http://www.mccp.unimelb.edu.au/subjects/clinical-research-in-oncology
Related Course(s):	Graduate Diploma in Clinical Research Specialist Certificate in Clinical Research (Oncology)