CLRS90013 Responsibilities and Ethics

Credit Points:	12.5
Level:	9 (Graduate/Postgraduate)
Dates & Locations:	2016, Parkville This subject commences in the following study period/s: August, Parkville - Taught on campus.
Time Commitment:	Contact Hours: Approx. 48 hours (4 day intensive block) Total Time Commitment: 170 hours per 12.5 credit point subject.
Prerequisites:	To enrol in this subject, you must be admitted in either N28AA, N12AA, N34AA or N01AA. This subject is not available for students admitted in any other courses.
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 (Commonwealth 2005), and Students Experiencing Academic Disadvantage Policy, academic requirements for this course are articulated in the Course Overview, Objectives 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 course are encouraged to discuss this matter with the Student Equity and Disability Support Team: http://www.services.unimelb.edu.au/disability/
Coordinator:	Assoc Prof Steve Farish
Contact:	**School of Melbourne Custom Programs** Currently enrolled and future students: # General information: **http://www.commercial.unimelb.edu.au/courses (http://www.commercial.unimelb.edu.au/courses)** # Email: **TL-ClinicalResearch@unimelb.edu.au (mailto:TL-ClinicalResearch@unimelb.edu.au)**
Subject Overview:	Ethics is more than just one part of Clinical Research. Ethics pervade every aspect of a trial, from the rationale in the first place through to the maintenance of data and its eventual destruction years after the publication of results. Ethical issues arise in the randomisation of subjects, the choice of outcome, the collection of data, access to that data, the analysis of the data, the reporting of results and the monitoring of the safety of participants. No Clinical Research can be conducted without a thorough and overarching ethical view of all that occurs.
Learning Outcomes:	Topics covered include: # Structure of Informed Consent documents # Meaning of Informed in the context of blinding and randomisation to allocated treatments. # Basic human rights in experimental settings # The human being as an experimental subject and unit of analysis # Data monitoring and safety committees # Exercises in complex ethical situations # Ethics committees structure; membership; terms of reference # Assessment of ethics applications (mock exercise)

	# Cultural differences in ethical viewpoints # Ethics under adverse conditions or under duress # Ethical responses to unlawful collection of data or specimens # Ethical issues of individual or volunteered experiments on the dying
Assessment:	Two assignments each of 2000 words (100%). Students will review an ethics proposal, identifying major concerns and problems within that proposal. Students will prepare an ethics application for a project within their workplace or other appropriate setting, detailing all major ethical issues that arise and their management.
Prescribed 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 be able to: # Demonstrate an sound understanding of the basic concepts in human ethics, including the principles of: - Autonomy - Justice - Beneficence - Malfeasance # Understand the need for integrity in both research and researchers # Understand the need to protect human rights in research # Appreciate the requirement for informed consent # Appreciate both sides of the risk-benefit tension # Understand the impact of different cultural perspectives on ethical issues
Links to further information:	http://www.commercial.unimelb.edu.au/courses
Related Course(s):	Graduate Certificate in Clinical Research Graduate Diploma in Clinical Research Master of Clinical Research Professional Certificate in Clinical Research