POPH90119 Design of Randomised Controlled Trials

Credit Points:	12.5
Level:	9 (Graduate/Postgraduate)
Dates & Locations:	2016, Parkville This subject commences in the following study period/s: Semester 2, Parkville - Taught online/distance.
Time Commitment:	Contact Hours: None Total Time Commitment: 170 hours
Prerequisites:	POPH90014 Epidemiology 1 **OR** POPH90016 Epidemiology
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
Coordinator:	Prof John Carlin
Contact:	**john.carlin@unimelb.edu.au (mailto:john.carlin@unimelb.edu.au)** **Melbourne School of Population and Global Health** **OR** **Currently enrolled students:** # General information: **https://ask.unimelb.edu.au (https://ask.unimelb.edu.au)** # Email: **enquiries-STEM@unimelb.edu.au (mailto:enquiries-STEM@unimelb.edu.au)** **Future Students:** # Further Information: **http://mspgh.unimelb.edu.au/ (http://mspgh.unimelb.edu.au/)** # Email: **Online Form (http://mspgh.unimelb.edu.au/study/degrees/master-of-public-health/overview)**
Subject Overview:	Topics include: ethical considerations; principles and methods of randomisation in controlled trials; treatment allocation, blocking, stratification and allocation concealment; parallel, factorial and crossover designs including n-of-1 studies; practical issues in sample size determination; intention-to-treat principle; phase I dose finding studies; phase II safety and efficacy studies; interim analysis and early stopping ; multiple outcomes/endpoints, including surrogate outcomes, multiple tests and subgroup analyses, including adjustment of significance levels and P-values; missing data; reporting trial results and use of the CONSORT statement.
Learning Outcomes:	To enable students to understand and apply the principles of design and analysis of experiments, with a particular focus on randomised controlled trials (RCTs), to a level where they are able to contribute effectively as a statistician to the planning, conduct and reporting of a standard RCT.

Assessment:	Three written assignments submitted during the semester; Two worth 30% each (approx 10 hours work each) and one worth 40% (approx 12 hours work).
Prescribed Texts:	Piantadosi, S. Clinical Trials: A Methodological Perspective, 2nd ed, John Wiley & Sons, New York, 2005 (ISBN 978-0-471-72781-1) Resources Provided to Students: Printed course notes and assignment material by mail, email, and online interaction facilities.
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:	Independent problem solving, critical appraisal of research literature, clarity of written expression, sound communication of technical concepts
Links to further information:	http://www.mspgh.unimelb.edu.au
Notes:	This subject is not available in the Master of Public Health.
Related Course(s):	Graduate Certificate in Biostatistics Graduate Diploma in Biostatistics Master of Biostatistics Postgraduate Diploma in Biostatistics