

POPH90138 Advanced Clinical Trials

Credit Points:	12.50																							
Level:	9 (Graduate/Postgraduate)																							
Dates & Locations:	This subject is not offered in 2013. Distance																							
Time Commitment:	Contact Hours: None Total Time Commitment: 8-12 hours total study time per week																							
Prerequisites:	-																							
	<table border="1"> <thead> <tr> <th>Subject</th> <th>Study Period Commencement:</th> <th>Credit Points:</th> </tr> </thead> <tbody> <tr> <td>POPH90016 Epidemiology</td> <td>Not offered 2013</td> <td>12.50</td> </tr> <tr> <td>POPH90015 Mathematics Background for Biostatistics</td> <td>Semester 2</td> <td>12.50</td> </tr> <tr> <td>POPH90017 Principles of Statistical Inference</td> <td>Semester 1</td> <td>12.50</td> </tr> <tr> <td>POPH90148 Probability and Distribution Theory</td> <td>Not offered 2013</td> <td>12.50</td> </tr> <tr> <td>POPH90119 Design of Randomised Controlled Trials</td> <td>Not offered 2013</td> <td>12.50</td> </tr> <tr> <td>POPH90120 Linear Models</td> <td>Semester 2</td> <td>12.50</td> </tr> </tbody> </table>	Subject	Study Period Commencement:	Credit Points:	POPH90016 Epidemiology	Not offered 2013	12.50	POPH90015 Mathematics Background for Biostatistics	Semester 2	12.50	POPH90017 Principles of Statistical Inference	Semester 1	12.50	POPH90148 Probability and Distribution Theory	Not offered 2013	12.50	POPH90119 Design of Randomised Controlled Trials	Not offered 2013	12.50	POPH90120 Linear Models	Semester 2	12.50		
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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 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.																							
Contact:	<p>Professor Val GebSKI, University of Sydney Biostatistics Collaboration of Australia Email: bca@ctc.usyd.edu.au Website: www.bca.edu.au</p> <p>OR</p> <p>Academic Programs Office Melbourne School of Population Health Tel: +61 3 8344 9339 Fax: +61 3 8344 0824 Email: sph-gradinfo@unimelb.edu.au</p>																							
Subject Overview:	Methods in RCTs for determining: stopping rules for interim analysis (O'Brien-Fleming, Peto), spending functions, stochastic curtailment; statistical principles encountered in relation to aspects of regulatory guidelines (ICH, FDA, EMEA), and related to reports prepared for data safety and monitoring committees (DSMC); design and analysis of cross-over trials (period effects, interactions); equivalence and non-inferiority trials; problems of defining and using surrogate endpoints as alternatives to direct clinical outcomes.																							
Objectives:	This elective subject extends and enhances the concepts developed in Design of Experiments and Clinical Trials (POPH90119). On completion of this subject, students have the knowledge and skills required at an advanced professional level to design and analyse clinical trials,																							

	including cross-over designs and equivalence trials, and to identify and implement statistical methods for trial monitoring and reporting, with appropriate knowledge of regulatory requirements.
Assessment:	Three written assignments to be submitted during semester, two worth 25% each (approx 8 hrs work each) and one worth 10% (approx 6 hrs work). One end of semester at-home examination worth 40% (approx 12 hours)
Prescribed Texts:	None
Recommended Texts:	Jennison, C. and Turnbull, B.W. Group Sequential Methods with Applications to Clinical Trials 1999, Chapman & Hall. (ISBN 978-0849303166) Senn S. Cross-over Trials in Clinical Research, 2nd edition 2002, Wiley. (ISBN 978-0471496533).
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, facility with abstract reasoning, clarity of written expression, sound communication of technical concepts
Links to further information:	http://www.sph.unimelb.edu.au
Notes:	This subject is not available in the Master of Public Health.
Related Course(s):	Master of Biostatistics Postgraduate Certificate in Biostatistics Postgraduate Diploma in Biostatistics