

# POPH90138 Advanced Clinical Trials

<b>Credit Points:</b>	12.50																					
<b>Level:</b>	9 (Graduate/Postgraduate)																					
<b>Dates &amp; Locations:</b>	2010, Parkville This subject commences in the following study period/s: Semester 2, Parkville - Taught online/distance. Distance																					
<b>Time Commitment:</b>	Contact Hours: None Total Time Commitment: 8-12 hours total study time per week																					
<b>Prerequisites:</b>	- <table border="1" data-bbox="387 544 1485 981"> <thead> <tr> <th>Subject</th> <th>Study Period Commencement:</th> <th>Credit Points:</th> </tr> </thead> <tbody> <tr> <td>POPH90016 Epidemiology</td> <td>Semester 1, Semester 2</td> <td>12.50</td> </tr> <tr> <td>POPH90015 Mathematics B'Ground for Biostatistics</td> <td>Not offered 2010</td> <td>12.50</td> </tr> <tr> <td>POPH90017 Principles of Statistical Inference</td> <td>Semester 1, Semester 2</td> <td>12.50</td> </tr> <tr> <td>POPH90148 Probability and Distribution Theory</td> <td>Semester 1, Semester 2</td> <td>12.50</td> </tr> <tr> <td>POPH90119 Design of Randomised Controlled Trials</td> <td>Semester 2</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	Semester 1, Semester 2	12.50	POPH90015 Mathematics B'Ground for Biostatistics	Not offered 2010	12.50	POPH90017 Principles of Statistical Inference	Semester 1, Semester 2	12.50	POPH90148 Probability and Distribution Theory	Semester 1, Semester 2	12.50	POPH90119 Design of Randomised Controlled Trials	Semester 2	12.50	POPH90120 Linear Models	Semester 2	12.50
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<b>Corequisites:</b>	None																					
<b>Recommended Background Knowledge:</b>	None																					
<b>Non Allowed Subjects:</b>	None																					
<b>Core Participation Requirements:</b>	None																					
<b>Coordinator:</b>	Prof John Carlin																					
<b>Contact:</b>	Professor Val Gebski, University of Sydney Biostatistics Collaboration of Australia OR Academic Programs Office Melbourne School of Population Health Tel: +61 3 8344 9339 Fax: +61 3 8344 0824 Email: sph-gradinfo@unimelb.edu.au																					
<b>Subject Overview:</b>	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.																					
<b>Objectives:</b>	This elective subject extends and enhances the concepts developed in Design of Experiments and Clinical Trials (505-939). 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.																					

<b>Assessment:</b>	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)
<b>Prescribed Texts:</b>	None
<b>Recommended Texts:</b>	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).
<b>Breadth Options:</b>	This subject is not available as a breadth subject.
<b>Fees Information:</b>	Subject EFTSL, Level, Discipline & Census Date, <a href="http://enrolment.unimelb.edu.au/fees">http://enrolment.unimelb.edu.au/fees</a>
<b>Generic Skills:</b>	Independent problem solving, facility with abstract reasoning, clarity of written expression, sound communication of technical concepts
<b>Links to further information:</b>	<a href="http://www.sph.unimelb.edu.au">http://www.sph.unimelb.edu.au</a>
<b>Notes:</b>	This subject is not available in the Master of Public Health.
<b>Related Course(s):</b>	Master of Biostatistics Postgraduate Certificate in Biostatistics Postgraduate Diploma in Biostatistics