

## CLRS90007 Clinical Immunisation Research

<b>Credit Points:</b>	12.50
<b>Level:</b>	9 (Graduate/Postgraduate)
<b>Dates &amp; Locations:</b>	2011, Hawthorn This subject commences in the following study period/s: Semester 1, Hawthorn - Taught on campus. Semester 2, Hawthorn - Taught on campus. Intensive Mode
<b>Time Commitment:</b>	Contact Hours: Twenty-four hours of lectures/seminars/workshops Total Time Commitment: Students should expect to undertake a minimum of 120 hours lectures, research, reading, writing etc (including face to face contact) to complete this subject successfully.
<b>Prerequisites:</b>	nil
<b>Corequisites:</b>	nil
<b>Recommended Background Knowledge:</b>	nil
<b>Non Allowed Subjects:</b>	nil
<b>Core Participation Requirements:</b>	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: <a href="http://www.services.unimelb.edu.au/disability/">http://www.services.unimelb.edu.au/disability/</a>
<b>Contact:</b>	Melbourne Consulting and Custom Programs Level 3, 442 Auburn Rd Hawthorn VIC 3122 Phone: 9810 3300 email: <a href="mailto:clinicalresearch@mccp.unimelb.edu.au">clinicalresearch@mccp.unimelb.edu.au</a> ( <a href="mailto:clinicalresearch@mccp.unimelb.edu.au">mailto:clinicalresearch@mccp.unimelb.edu.au</a> )
<b>Subject Overview:</b>	Topics covered include: Recruitment strategies for immunisation studies Population versus intervention studies Ethics of conduct of studies in the developed and developing worlds The informed consent process in immunisation The role of control arms and where they are appropriate Differences in immune responses with age How to conduct vaccine studies including immunogenicity, efficacy, effectiveness and safety Post marketing studies Specific diseases will be used as examples. These will include meningococcal, rotavirus, influenza and pneumococcal
<b>Objectives:</b>	Students who successfully complete this subject will be able to: # Understand the basic principles of immunisation # Understand the methods employed in the conduct of immunisation clinical trials # Understand ethical issues specific to immunisation clinical trials # Understand how endpoints of immunisation clinical trials are determined, including surrogate markers # Define surrogate markers, and identify their limitations # Understand the immunological, microbiological and laboratory assessment of immunisation clinical trials # Understand principles of safety monitoring and post-licensure surveillance systems # Understand vaccine study design

	# Design a research proposal in immunisation
<b>Assessment:</b>	Two assignments, each of 2000 words, and each worth 50 per cent
<b>Prescribed Texts:</b>	nil
<b>Recommended Texts:</b>	Students will be provided with articles and references that support the teaching program as part of their course materials
<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>	<p>Students who successfully complete this subject will be able to:</p> <ul style="list-style-type: none"> <li>Understand the basic principles of immunisation</li> <li>Understand the methods employed in the conduct of immunisation clinical trials</li> <li>Understand ethical issues specific to immunisation clinical trials</li> <li>Understand how endpoints of immunisation clinical trials are determined, including surrogate markers</li> <li>Define surrogate markers, and identify their limitations</li> <li>Understand the immunological, microbiological and laboratory assessment of immunisation clinical trials</li> <li>Understand principles of safety monitoring and post-licensure surveillance systems</li> <li>Understand vaccine study design</li> <li>Design a research proposal in immunisation</li> </ul>
<b>Links to further information:</b>	<a href="http://www.mccp.unimelb.edu.au/courses/award-courses/graduate-diploma/clinical-research">http://www.mccp.unimelb.edu.au/courses/award-courses/graduate-diploma/clinical-research</a>
<b>Related Course(s):</b>	<p>Graduate Diploma in Clinical Research  Master of Clinical Research  Specialist Cert.Clinical Research (Immunisation &amp; Infectious Diseases)</p>