

## CLRS90024 Clinical Trial Site Monitoring

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| <b>Credit Points:</b>                    | 12.5  |
| <b>Level:</b>                            | 9 (Graduate/Postgraduate)   |
| <b>Dates &amp; Locations:</b>            | 2016, Hawthorn<br>This subject commences in the following study period/s:<br>February, Hawthorn - Taught on campus.<br>July, Hawthorn - Taught on campus.   |
| <b>Time Commitment:</b>                  | Contact Hours: 24 contact hours Total Time Commitment: 170 hours per 12.5 credit point subject.   |
| <b>Prerequisites:</b>                    | To enrol in this subject, you must be admitted in N01AA, N34AA, or GC-CRMONIT. This subject is not available for students admitted in any other courses.  |
| <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 (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: <a href="http://www.services.unimelb.edu.au/disability/">http://www.services.unimelb.edu.au/disability/</a> |
| <b>Contact:</b>                          | <b>School of Melbourne Custom Programs</b><br>Currently enrolled and future students:<br># General information: <a href="http://www.commercial.unimelb.edu.au/courses">http://www.commercial.unimelb.edu.au/courses</a> ( <a href="http://www.commercial.unimelb.edu.au/courses">http://www.commercial.unimelb.edu.au/courses</a> )<br># Email: <a href="mailto:TL-ClinicalResearch@unimelb.edu.au">TL-ClinicalResearch@unimelb.edu.au</a> ( <a href="mailto:TL-ClinicalResearch@unimelb.edu.au">mailto:TL-ClinicalResearch@unimelb.edu.au</a> )  |
| <b>Subject Overview:</b>                 | Topics covered in this subject include:<br>• Overview of Drug Development<br>• Essential Good Clinical Practice Training for New Clinical Research Associates<br>• Managing Regulatory Documents  |
| <b>Learning Outcomes:</b>                | Students who successfully complete this subject will:<br>• Understand the drug development pathway and its link to clinical research<br>• Understand the role of the Clinical Research Associate in clinical research<br>• Understand the purpose and role of regulatory documents necessary for initiating and running a clinical trial<br>• Understand the purpose and operational responsibilities of a Clinical Research Associate in maintaining the quality standards defined by Australian legislation and Good Clinical Practice  |
| <b>Assessment:</b>                       | • One open book test representing 20% of the total mark, completed at the end of the first week of lectures.<br>• Two 1000 word assignment each representing 25% of the total mark (a combined total of 50%)<br>• One 1500 word workplace assignment representing 30% of the total mark. Each written essay is due progressively through the semester. A minimum score of 50% in each assessment is required for a student to pass this subject.  |
| <b>Prescribed Texts:</b>                 | All class materials will be provided.   |

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| <b>Recommended Texts:</b>            | NA   |
| <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>Links to further information:</b> | <a href="http://www.commercial.unimelb.edu.au/courses">http://www.commercial.unimelb.edu.au/courses</a>  |
| <b>Related Course(s):</b>            | Graduate Diploma in Clinical Research<br>Master of Clinical Research<br>Specialist Certificate in Clinical Research-Clinical Trials Monitoring |