COURSE OUTLINE

BIM303 Introduction to Clinical Trial Coordination

Course Coordinator: Helen Faddy (hfaddy@usc.edu.au) **School:** School of Health and Behavioural Sciences

2021 | Session 8

USC Sunshine Coast
USC Moreton Bay

BLENDED LEARNING — Most of your course is on campus but you may be able to do some components of this course online.

Please go to the USC website for up to date information on the teaching sessions and campuses where this course is usually offered.

1. What is this course about?

1.1. Description

Clinical research professionals are employed in research institutes and in the broader therapeutics development industry to set-up and coordinate clinical trials within research institutions according to Australian and international research standards. This course introduces you to the principles of clinical research and regulatory affairs that are required for you to work as a Clinical Research Coordinator (CRC).

1.2. How will this course be delivered?

ACTIVITY	HOURS	BEGINNING WEEK	FREQUENCY
BLENDED LEARNING			
Tutorial/Workshop 1 – There will be 6-days of compulsory face-to-face tutorials, held during weeks 2 and 3 of session 8.	18hrs	Week 2	6 times
Fieldwork – A field trip will be organised for students in week 2 or 3 of session 8 to the USC Clinical Trial Centre at Morayfield.	8hrs	Week 2	Once Only
Online – Students will complete six online training modules in clinical trial coordination offered through Praxis Australia.	8hrs	Week 3	Once Only

1.3. Course Topics

1. Overview of the clinical trial process.
2. Role of the clinical trial coordinator (CRC) in clinical trials.
3. Principles of Good Clinical Practice (GCP).
4. Preclinical discovery and research.
5. The human research ethics process.
6. Regulation of drugs and devices.
7. Pharmacy in clinical trials.
8. Research monitoring and audit.
9. Essential documentation in clinical trials
10. Quality assurance and safety monitoring in clinical trials.
11. Principles of research governance.

2. What level is this course?

300 Level (Graduate)

Demonstrating coherence and breadth or depth of knowledge and skills. Independent application of knowledge and skills in unfamiliar contexts. Meeting professional requirements and AQF descriptors for the degree. May require pre-requisites where discipline specific introductory or developing knowledge or skills is necessary. Normally undertaken in the third or fourth full-time study year of an undergraduate program.

3. What is the unit value of this course?

12 units

4. How does this course contribute to my learning?

COURSE LEARNING OUTCOMES On successful completion of this course, you should be able to...		GRADUATE QUALITIES Completing these tasks successfully will contribute to you becoming...
1	Capably and confidently demonstrate knowledge of the process of drug development, from preclinical testing to regulatory approval.	Knowledgeable
2	Identify and apply professional responsibilities according to appropriate national decision making frameworks for human research ethics.	Ethical
3	Describe the current regulatory and ethical environment for trials with unapproved therapeutic goods and the role of the Clinical Research Coordinator (CRC) in this process.	Knowledgeable
4	Demonstrate proficiency in documentation practices required in the commencement of a clinical trial.	Empowered
5	Explain and describe the principles of Good Clinical Practice (GCP) in consent processes, quality data collection and compliance with reporting requirements.	Empowered
6	Develop tools to interact with various stakeholders involved in the conduct of clinical research.	Engaged
7	Critically evaluate technical documentation required to effectively commence and manage a clinical trial.	Creative and critical thinker

5. Am I eligible to enrol in this course?

Refer to the USC Glossary of terms for definitions of “pre-requisites, co-requisites and anti-requisites”.

5.1. Pre-requisites

BIM263 Introduction to Pharmacology.

5.2. Co-requisites

Not applicable

5.3. Anti-requisites

Not applicable

5.4. Specific assumed prior knowledge and skills (where applicable)

It is recommended that students have some prerequisite knowledge of pharmacology, research methods and basic statistics.

6. How am I going to be assessed?

6.1. Grading Scale

Standard Grading (GRD)

High Distinction (HD), Distinction (DN), Credit (CR), Pass (PS), Fail (FL).

6.2. Details of early feedback on progress

Students may seek guidance from the course coordinator on the structure and content of their Human Research Ethics Assignment (Task 1a) during the first week of the course. Also, students will complete the Review Quiz (Task 3a) at the end of the first week of the course, which will be based on theory covered during Tutorials 1 to 3.

6.3. Assessment tasks

DELIVERY MODE	TASK NO.	ASSESSMENT PRODUCT	INDIVIDUAL OR GROUP	WEIGHTING %	WHAT IS THE DURATION / LENGTH?	WHEN SHOULD I SUBMIT?	WHERE SHOULD I SUBMIT IT?
All	1	Written Piece	Individual or Group	30%	1500 words +/- 10%	Week 3	Online Assignment Submission with plagiarism check
All	2	Activity Participation	Individual	15%	Online training module quizzes with short answers and multi-choice questions.	Throughout teaching period (refer to Format)	Online Test (Quiz)
All	3a	Quiz/zes	Individual	15%	1-hour duration; multi-choice questions	Week 2	In Class
All	3b	Examination - Centrally Scheduled	Individual	40%	2-hour duration; multiple-choice and short answer questions. Total 100 marks.	Exam Period	Online Test (Quiz)

All - Assessment Task 1: Human Research Ethics Assignment

GOAL:	To provide you with an opportunity to demonstrate your understanding of the human research ethics process in Australia and your ability to make ethical decisions in relation to clinical research.
PRODUCT:	Written Piece
FORMAT:	You will be expected to complete and submit an assignment, either individually or with another student, in which you will address the ethical issues presented in a human ethics case study using an analytical essay structure. Your assignment will have a title, introduction, main body and conclusion. Guidance on how to address human ethical issues in clinical trials will be provided to you on the BIM303 Blackboard site. Your response to the case study will be a maximum of 1500 words (± 10%) in text, not including references, and is due at the end of the second week of the course (Week 3 of Session 8).
CRITERIA:	

No.		Learning Outcome assessed
1	Identification of the key ethical issues presented in the case study.	2
2	Analysis and decision making related to the ethical issues in the case study.	2 4 6
3	Quality of the overall structure of the assignment, including introduction, main body and conclusion.	4
4	Use of primary and secondary sources of literature selected for the assignment.	5
5	Overall presentation of the assignment, including word count, structure and formatting, quality of written expression (sentence structure, spelling and grammar), citations and referencing.	5

All - Assessment Task 2: Online Training Module Quizzes (Praxis Australia)

GOAL:	To provide you with an opportunity to demonstrate your knowledge of Australian regulatory requirements and Good Clinical Practice (GCP) as it applies to the CRC role. This assessment is part of the Praxis Australia clinical research certification process as set by an independent professional development association supporting people working in therapeutics development.
PRODUCT:	Activity Participation
FORMAT:	Completion of three (3) Praxis Australia online training modules (5% per module complete). Certification for each of the three training modules requires completion of a quiz that contains short answers and multiple-choice questions. The training modules will be available through Praxis Australia from the second week of the course (Week 3 of Session 8).
CRITERIA:	

No.		Learning Outcome assessed
1	Apply theoretical knowledge identified in the Praxis Australia Online Training Modules to solve problems.	1
2	Analyse information and explain important elements of the theories which underpin clinical research and regulatory affairs, and the role of the CRC in this process.	3 5
3	Use evidence-based reasoning from your knowledge and understanding of the materials in the online training modules to provide correct answers to multiple-choice questions.	3 4 7

All - Assessment Task 3a: Review Quiz

GOAL:	To provide you with an opportunity to demonstrate your knowledge of the drug development process, from preclinical testing through to regulatory approval.
PRODUCT:	Quiz/zes
FORMAT:	The review quiz will contain 30 multiple-choice questions and will examine the material covered during Tutorials 1 to 3 of the first week of the course (Week 2 of Session 8), in particular the clinical trial process and research design for clinical trials, human research ethics, and drug discovery and preclinical development. The review quiz will be held at the end of the first week of the course (Week 2 of Session 8). You will complete your answers to the multiple-choice questions on a mark sense sheet. The review quiz is closed book.
CRITERIA:	

No.		Learning Outcome assessed
1	Apply theoretical knowledge about the drug development process and study design for clinical trials as identified in the course face-to-face tutorials.	1
2	Use evidence-based reasoning from your knowledge and understanding of the course content to provide correct answers to multiple-choice questions.	1 7

All - Assessment Task 3b: End-of-Semester Exam

GOAL:	In this assessment task, you will be able to demonstrate, apply and evaluate your theoretical and practical knowledge of the principles of clinical research and regulatory affairs as they apply to the work undertaken by a Clinical Research Coordinator in clinical trial centres.
PRODUCT:	Examination - Centrally Scheduled
FORMAT:	The exam will consist of multiple-choice and short answer questions for a total of 100 marks and will be based on the materials covered in the course tutorials and online Praxis Australia training modules, including the clinical trial process, clinical trial design, principles of human research ethics, role of the CRC, pharmacy in clinical trials, quality assurance and safety in clinical trials, research monitoring and audit, essential documentation, GCP principles, safety monitoring and reporting, governance, and regulations of drugs and devices..

CRITERIA:	No.		Learning Outcome assessed
	1	Demonstrate and apply knowledge of the principles of clinical research and regulatory affairs.	1 3 5 7
	2	Analyse information and explain important elements involved in the conduct of clinical research.	2 4 5 7
	3	Use evidence-based reasoning from your knowledge and understanding of clinical trial coordination to provide correct answers to the multiple-choice and short answer questions.	3

7. Directed study hours

A 12-unit course will have total of 150 learning hours which will include directed study hours (including online if required), self-directed learning and completion of assessable tasks. Directed study hours may vary by location. Student workload is calculated at 12.5 learning hours per one unit.

7.1. Schedule

PERIOD AND TOPIC	ACTIVITIES
Introduction to clinical trials.	Overview of the clinical trial process. Phases I, II, III and IV clinical trials. Research design for clinical trials.
Drug discovery and preclinical development.	An overview of the drug development process. Key stakeholders in drug development. History of drug discovery. Target identification. Finding and optimising lead compounds. Preclinical (nonclinical) development. Pharmacological testing. The Investigator's Brochure.
Human research ethics and clinical trials.	What is human research ethics and why is it needed in clinical trials? Fundamental principles in human ethics underpinning the National Statement. Gaining ethics approval for human research. Roles of the Human Research Ethics Committee. Case studies in human research ethics.
Principles of research governance.	Ethical principles and guidelines for the responsible conduct of research in Australia. Elements of research governance. What needs to be considered by Australian institutions when governing research conducted under their auspices? What is site-specific assessment? Establishing a clinical trial agreement. The importance of insurance and indemnity in clinical trials.
Regulation of drugs and devices, and safety monitoring and reporting in clinical trials.	What is a therapeutic good and how are they marketed in Australia? The role of the Therapeutic Goods Administration (TGA). The Therapeutic Goods Act 1989. What is a clinical trial notification (CTN). Importance of current Good Manufacturing Practice (cGMP). Developing a safety profile of a therapeutic good. Pharmacovigilance in clinical trials. Adverse events and how they are reported in Australia.

PERIOD AND TOPIC	ACTIVITIES
Role of the Clinical Research Coordinator (CRC) and Pharmacist in clinical trials.	Specific responsibilities of the CRC in relation to study set-up and conduct of the study. Importance of Good Clinical Practice (GCP) for the CRC. Scheduling challenges faced by CRCs. Role of CRCs in overseeing quality assurance and safety in clinical trials, including minimising risk on treatment days. General role of the pharmacist in clinical trials. Pre-study activities of the pharmacist. Shipment and receipt of the Investigational Medicinal Product (IMP). Dispensing and accountability. Monitoring and study conclusion responsibilities.
Praxis Australia online training modules.	C3.05 Research monitoring and audit. The roles and processes for the monitoring of clinical trials. C3.06 Essential documentation in clinical trials. C5.01 Principle of Good Clinical Practice (GCP). This module will provide you with an internationally recognised Transcelerate accredited GCP certificate that is required by any professional working in clinical trials.

8. What resources do I need to undertake this course?

Please note: Course information, including specific information of recommended readings, learning activities, resources, weekly readings, etc. are available on the course Blackboard site– Please log in as soon as possible.

8.1. Prescribed text(s) or course reader

Please note that you need to have regular access to the resource(s) listed below. Resources may be required or recommended.

REQUIRED?	AUTHOR	YEAR	TITLE	PUBLISHER
Required	Praxis Australia	2019	Training modules (see BIM303 Blackboard site for description of the modules)	Praxis Australia

8.2. Specific requirements

There are no prescribed textbooks for the BIM303 course. You will be provided access to the online training modules offered by Praxis Australia (https://praxisaustralia.com.a/) via the BIM303 Blackboard site. In addition, you will be referred to government websites that contain important documents that outline guidelines and information associated with monitoring and managing clinical trials in Australia. There also will be readings that you will need to download from the BIM303 Blackboard site for the tutorial classes.

9. How are risks managed in this course?

Health and safety risks for this course have been assessed as low. It is your responsibility to review course material, search online, discuss with lecturers and peers and understand the health and safety risks associated with your specific course of study and to familiarise yourself with the University's general health and safety principles by reviewing the online induction training for students, and following the instructions of the University staff.

10. What administrative information is relevant to this course?

10.1. Assessment: Academic Integrity

Academic integrity is the ethical standard of university participation. It ensures that students graduate as a result of proving they are competent in their discipline. This is integral in maintaining the value of academic qualifications. Each industry has expectations and standards of the skills and knowledge within that discipline and these are reflected in assessment.

Academic integrity means that you do not engage in any activity that is considered to be academic fraud; including plagiarism, collusion or outsourcing any part of any assessment item to any other person. You are expected to be honest and ethical by completing all work yourself and indicating in your work which ideas and information were developed by you and which were taken from others. You cannot provide your assessment work to others. You are also expected to provide evidence of wide and critical reading, usually by using appropriate academic references.

In order to minimise incidents of academic fraud, this course may require that some of its assessment tasks, when submitted to Blackboard, are electronically checked through SafeAssign. This software allows for text comparisons to be made between your submitted assessment item and all other work that SafeAssign has access to.

10.2. Assessment: Additional Requirements

Your eligibility for supplementary assessment in a course is dependent of the following conditions applying:
- The final mark is in the percentage range 47% to 49.4%.
- The course is graded using the Standard Grading scale.
- You have not failed an assessment task in the course due to academic misconduct.

10.3. Assessment: Submission penalties

Late submission of assessment tasks may be penalised at the following maximum rate:
- 5% (of the assessment task's identified value) per day for the first two days from the date identified as the due date for the assessment task.
- 10% (of the assessment task's identified value) for the third day - 20% (of the assessment task's identified value) for the fourth day and subsequent days up to and including seven days from the date identified as the due date for the assessment task.
- A result of zero is awarded for an assessment task submitted after seven days from the date identified as the due date for the assessment task. Weekdays and weekends are included in the calculation of days late. To request an extension you must contact your course coordinator to negotiate an outcome.

10.4. Study help

For help with course-specific advice, for example what information to include in your assessment, you should first contact your tutor, then your course coordinator, if needed.

If you require additional assistance, the Learning Advisers are trained professionals who are ready to help you develop a wide range of academic skills. Visit the Learning Advisers web page for more information, or contact Student Central for further assistance: +61 7 5430 2890 or studentcentral@usc.edu.au.

10.5. Wellbeing Services

Student Wellbeing provide free and confidential counselling on a wide range of personal, academic, social and psychological matters, to foster positive mental health and wellbeing for your academic success.

To book a confidential appointment go to Student Hub, email studentwellbeing@usc.edu.au or call 07 5430 1226.

10.6. AccessAbility Services

Ability Advisers ensure equal access to all aspects of university life. If your studies are affected by a disability, learning disorder mental health issue, , injury or illness, or you are a primary carer for someone with a disability or who is considered frail and aged, AccessAbility Services can provide access to appropriate reasonable adjustments and practical advice about the support and facilities available to you throughout the University.

To book a confidential appointment go to Student Hub, email AccessAbility@usc.edu.au or call 07 5430 2890.

10.7. Links to relevant University policy and procedures

For more information on Academic Learning & Teaching categories including:

- Assessment: Courses and Coursework Programs
- Review of Assessment and Final Grades
- Supplementary Assessment
- Administration of Central Examinations
- Deferred Examinations
- Student Academic Misconduct
- Students with a Disability

Visit the USC website: http://www.usc.edu.au/explore/policies-and-procedures#academic-learning-and-teaching

10.8. General Enquiries

In person:

- **USC Sunshine Coast** - Student Central, Ground Floor, Building C, 90 Sippy Downs Drive, Sippy Downs
- **USC Moreton Bay** - Service Centre, Ground Floor, Foundation Building, Gympie Road, Petrie
- **USC SouthBank** - Student Central, Building A4 (SW1), 52 Merivale Street, South Brisbane
- **USC Gympie** - Student Central, 71 Cartwright Road, Gympie
- **USC Fraser Coast** - Student Central, Student Central, Building A, 161 Old Maryborough Rd, Hervey Bay
- **USC Caboolture** - Student Central, Level 1 Building J, Cnr Manley and Tallon Street, Caboolture

Tel: +61 7 5430 2890
Email: studentcentral@usc.edu.au