NATS 7056 CLINICAL RESEARCH IN HEALTH SCIENCE

Credit Points 10

Legacy Code 800225

Coordinator Jerome Sarris (https://directory.westernsydney.edu.au/search/name/Jerome Sarris/)

Description This subject will teach students practical knowledge and skills for conducting clinical research within the field of Health Science. Students will learn ethical, methodological and practical considerations in applied quantitative and mixed- method research within the framework of a human clinical trial. Upon completion of the subject students will have an understanding of basic human clinical trial design, novel clinical trial designs, specialisation within various study fields. They will also have consideration of stakeholders and translational importance, trial governance, regulations and the Therapeutic Goods Administration (TGA), intellectual property, commercialisation, recruitment, and advertising and marketing. Finally, they will understand the importance of translational impact via publications and the media, and be able to synthesise trial data via knowing how to conduct systematic reviews and meta-analyses.

School Graduate Research School

Discipline Natural and Physical Sciences, Not Elsewhere Classified.

Student Contribution Band HECS Band 2 10cp

Level Postgraduate Coursework Level 7 subject

Restrictions

Students must be enrolled in a post-graduate program, Masters by Research, PhD or 8083 Bachelor of Research Studies

Learning Outcomes

On successful completion of this subject, students should be able to:

1. Apply ethical, regulatory, and governance considerations in conducting clinical trials
2. Utilise quantitative or mixed method trial designs (basic and novel)
3. Critically appraise recruitment procedures and protocols
4. Analyse and understand commercialisation options and understand IP considerations
5. Formulate ways to involve the community throughout the research process and enhance translational research impact of the research (especially via media involvement)
6. Utilise appropriate methods to conduct a systematic review or meta-analysis

Subject Content

- Overview of human clinical trial research (for natural products, integrative modalities, and pharmaceutical medicines [including IP/commercialisation considerations])
- Development of Bench-to-Beside research models (including drug development process and clinical trial phases)
- Ethical considerations in working with humans and specialised populations (e.g. medical conditions, children, mental illness, marginalised communities) and with specialised interventions (e.g. natural products or pharmaceuticals)
- Choosing a design for your research question: Key clinical trial design considerations (with a focus on maximising future translational impact)
- Novel human clinical trial designs (and Sample size calculations)
- Developing clinical trial protocols and case-report forms
- Data Monitoring and Management
- Recruitment and marketing strategies for hard-to-reach populations
- Specialisation within various study fields (differing interventions and medical fields)
- Consideration of stakeholders and translational importance (E&I)
- Trial governance, regulations and the TGA, Pharmaceutical Good Manufacturing Practice, Good Clinical Practice
- Having translational impact: media, and community engagement and dissemination
- How to conduct Systematic Reviews and Meta-analyses (using Comprehensive Meta-analysis program)

Assessment

The following table summarises the standard assessment tasks for this subject. Please note this is a guide only. Assessment tasks are regularly updated, where there is a difference your Learning Guide takes precedence.

Type	Length	Percent	Threshold	Individual/ Group Task
Four Quizzes	40 questions in total (4 spread across the semester)	40 (1 mark per correct answer)	Y	Individual
Presentation	10 minutes	30	Y	Individual
Applied Project	20-30 pages	30	Y	Individual

Teaching Periods