CLNR 401: Introduction to Clinical Research

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Victoria University of Wellington and C&C District Health Board
Trimester 1, March 5th – June 8th, 2012.
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STAFF

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WELLINGTON SEMINAR AND TELECONFERENCE TIMETABLE

This course is taught mostly online, but there are two important face-to-face components of the course, which are compulsory:

1. Weekend Seminar (Wellington, 10 March 2012)
2. Teleconferences

See course timetable for details of teleconference times

HOW? To join the teleconference:

1. Dial 0800 084 460

2. Enter the PIN: 946 075 and press the # (hash) key

Teleconferences don’t cost you anything, but only students enrolled in this diploma may attend.

COURSE MATERIALS

There are no set texts for this course, and materials will not be posted to you. Course material will be uploaded onto the Blackboard site. For this reason, it’s important that you have access to a computer with internet connection.

Blackboard is a very important tool for this course and for other courses in the Diploma, so we recommend that you take time early on to familiarise yourself with how it works. You can use Blackboard to download course notes, access links to materials on the web, listen to recordings of teleconferences, and discuss topics with your fellow classmates.

COURSE AIMS

This course provides a broad framework for understanding clinical research including the critical appraisal of the literature, clinical trials’ planning, preparation and implementation.

On completion of this course students will have:

- a basic understanding of some of the key issues in clinical research
- the ability to consult existing literature to help define appropriate research questions
- the ability to plan clinical research, including clinical trials; and
- the understanding of the steps in obtaining approvals and implementation of a trial plan.
Curriculum for CLNR 401

Introduction to Clinical Research and Clinical Trial Practice

1. What is clinical research and why do we need clinical trials?
2. Literature searches
3. Critical appraisal of the literature
4. Study designs in clinical research
   a. Observational
      i. Case reports/series
      ii. Clinical audit
      iii. Cross sectional
      iv. Cohort
      v. Case control
   b. Experimental
      i. Randomised controlled trials
      ii. Cross over studies
5. Phases of clinical trials
   a. Phase I - IV
6. Key elements
   a. Inclusion / Exclusion criteria
   b. Blinding (and placebo use)
   c. Randomisation
   d. Control group
7. Confounding and Bias
8. Outcome measures
   a. True vs Surrogate
   b. Primary vs Secondary
   c. Clinical measurements
   d. Time to event
9. Design of clinical trials
   a. Choosing best design for research hypothesis
10. Setting up a clinical trial
    a. Regulations
    b. Funding
    c. Ethical approval (overview – detail in 402)
       i. Consent form
       ii. Patient information sheet
    d. Good clinical practice (covered in detail in 405)
    e. Trial protocol
       i. Standardisation
       ii. Data collection and Forms
       iii. Databases
       iv. Protocol violations
       v. Quality assurance
    f. Adverse events and Safety Monitoring
g. Registration and reporting  
   i. Clinical trials registry  
   ii. CONSORT statement

SEMINAR TOPICS & PRESENTERS

Structure of CLNR 401

This paper will be divided into a one day face-to-face seminar (as part of a 2 day weekend seminar for papers 401 and 402) and 4 modules delivered as distance based learning using interactive web-based platform “Blackboard” and a teleconference for each module. Each module will be three weeks.

- **Release of course material:** During the first two weeks of the module material will be posted on Blackboard for each student to look at and use. Some of this will require you to download and read, some will be exercises for you to complete, and some will be questions or situations posed by the module convenor for you to think about and discuss between you as a class on blackboard.

- **Online interaction:** You will have the opportunity to post questions on Blackboard. These may be picked up and answered by other classmates. There is a wide range of clinical experience in this programme, so asking questions or initiating online discussions is a good way of drawing on others’ experience, or contributing your own understandings, to better your understanding of course materials. The module convenor may in some cases answer questions directly, or in others may collect up themes of questions to address in the week three teleconference.

- **Teleconference:** In week three of each module there will be a teleconference. The timing of this may vary slightly between modules, but every effort will be made to keep this consistent. The standard time for the teleconference will be at 5.30pm on Thursday evenings and last for 90 minutes.

  During the teleconference there will be an opportunity to address questions that have come up during the module, there will be some additional tutorial style information and also a general opportunity for discussion as a class around the topics of that module.

Seminar Convener: Dr Jeremy Krebs

- Introduction to the diploma
- Introduction to the faculty
- Overview of the diploma
- Literature Search workshop (3 hours)
  - Literature review
Module 1  Convenor: Dr Jeremy Krebs
- Introduction to the diploma.
- Introduction to your classmates
- Overview of clinical research
- Development of a theme for each student

Module 2  Convenors: Sue D’Ath and Justin Cargill
- Create search strategy for given research theme
- Practice citation searching

Module 3  Convenor: Dr Shaun Holt
- Phases of clinical trials
- Key elements of clinical trials
- Outcomes
- Good clinical practice (introduction)

Module 4  Convenor: Dr Shaun Holt
- Clinical trials design and protocols
- Recruitment of study participants
- Data collection
- Data quality and quality assurance
- Consolidated Standards of Reporting Trials (CONSORT)

RESEARCH THEME

In this diploma you are asked to select a theme or an area of research that you are interested in. You will use this theme throughout the diploma. In paper 401 you will be required to develop and conduct a literature search around the topic you have chosen. You will then write a clinical trial protocol. In paper 402 you will be asked to consider aspects of special populations with respect to your trial design, the ethical issues and write a submission to the ethics committee for approval of your trial. In papers 403 and 404 you will continue the theme with your study design from 401, developing skills in quantitative and qualitative analysis and planning the appropriate methods. In paper 405 you will be required to consider aspects of project management, good clinical practice with respect to your trial. In Paper 580 you will pull all of these together and finally present the combined package including a full HRC style grant application and to prepare a manuscript for publication, and oral and poster presentation of your work. At the completion of the diploma it is
envisaged that you will have all of the necessary material that you can go on to submit your research trial to a funding body, the relevant ethics committee and be able to actually undertake the research you have designed.

MENTORS

In addition to the teaching staff you will need to obtain a mentor for your project. This will need to be a person who has expertise in clinical research and knowledge in the area of interest that you have identified as your theme for this diploma. This may be a person you work with directly, a previous lecturer or someone else you know. This relationship generally works best when you are able to identify the person yourself.

However if you are having difficulty, we will try to help you find a mentor. The role of your mentor will be to help guide you through the process of each of the stages of the diploma specifically relating your chosen theme to each paper.

ASSESSMENT

Assessment for this course has been designed to help you develop practical skills. By the time this course begins you should have selected your hypothetical study (which should be a randomised controlled trial) and a mentor who will be able to provide advice about your hypothetical study. Assessments for this course include a literature review and a protocol for your study.

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<tr>
<th>Task</th>
<th>Due Date</th>
<th>Grade</th>
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<tr>
<td>Attendance and participation at weekend seminar</td>
<td>10 March</td>
<td>10%</td>
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<tr>
<td>Attendance and participation in module teleconferences</td>
<td>8 June</td>
<td>10%</td>
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<tr>
<td>Completion of Online Quizzes and Production of an annotated bibliography</td>
<td>27 April</td>
<td>20%</td>
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<tr>
<td>Production of a CONSORT checklist for chosen study</td>
<td>22 June</td>
<td>10%</td>
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<tr>
<td>Research proposal</td>
<td>22 June</td>
<td>50%</td>
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PENALTIES & MANDATORY COURSE REQUIREMENTS
To pass CLNR 401, you must complete all of the mandatory course requirements and gain a mark of 50% or higher for the course as a whole. The mandatory requirements are:

- Submission of an annotated bibliography
- Submission of a CONSORT checklist
- Submission of a research proposal
- Attendance at teleconferences and weekend seminar

**COMMUNICATION OF ADDITIONAL INFORMATION**

We use Blackboard for course materials, communication of marks, online discussions, and announcements. You should ensure that you check Blackboard regularly for such information. Important messages will also be circulated by email.

**GENERAL INFORMATION**

**General University policies and statutes**
Students should familiarise themselves with the University’s policies and statutes, particularly those regarding assessment and course of study requirements, and formal academic grievance procedures.

**Student Conduct and Staff Conduct**
The Statute on Student Conduct together with the Policy on Staff Conduct ensure that members of the University community are able to work, learn, study and participate in the academic and social aspects of the University’s life in an atmosphere of safety and respect. The Statute on Student Conduct contains information on what conduct is prohibited and what steps can be taken if there is a complaint. For queries about complaint procedures under the Statute on Student Conduct, contact the Facilitator and Disputes Advisor. This Statute is available in the Faculty Student Administration Office or on the website at: www.vuw.ac.nz/policy/StudentConduct
The policy on Staff Conduct can be found on the VUW website at: www.vuw.ac.nz/policy/StaffConduct

**Academic Grievances**
If you have any academic problems with your course you should talk to the tutor or lecturer concerned or, if you are not satisfied with the result of that meeting, see the Head of School or the Associate Dean (Students) of your Faculty. Class representatives are available to assist you with this process. If, after trying the above channels, you are still unsatisfied, formal grievance procedures can be invoked. These are set out in the Academic
Grievance Policy which is published on the VUW website: www.vuw.ac.nz/policy/AcademicGrievances

Academic Integrity and Plagiarism
Academic integrity is about honesty – put simply it means no cheating. All members of the University community are responsible for upholding academic integrity, which means staff and students are expected to behave honestly, fairly and with respect for others at all times. Plagiarism is a form of cheating which undermines academic integrity. Plagiarism is prohibited at Victoria.

The University defines plagiarism as follows:

Plagiarism is presenting someone else’s work as if it were your own, whether you mean to or not.

‘Someone else’s work’ means anything that is not your own idea, even if it is presented in your own style. It includes material from books, journals or any other printed source, the work of other students or staff, information from the Internet, software programmes and other electronic material, designs and ideas. It also includes the organisation or structuring of any such material.

Plagiarism is not worth the risk.

Any enrolled student found guilty of plagiarism will be subject to disciplinary procedures under the Statute on Student Conduct (www.vuw.ac.nz/policy/studentconduct) and may be penalised severely. Consequences of being found guilty of plagiarism can include:

- an oral or written warning
- suspension from class or university
- cancellation of your mark for an assessment or a fail grade for the course.

Find out more about plagiarism and how to avoid it, on the University’s website at: www.vuw.ac.nz/home/studying/plagiarism.html

Students with Disabilities
The University has a policy of reasonable accommodation of the needs of students with disabilities. The policy aims to give students with disabilities an equal opportunity with all other students to demonstrate their abilities. If you have a disability, impairment or chronic medical condition (temporary, permanent or recurring) that may impact on your ability to participate, learn and/or achieve in meeting the course requirements, then please contact the Course Coordinator as early in the course as possible. Alternatively you may wish to approach a Student Adviser from Disability Support Services to confidentially discuss your individual needs and the options and support that are available. Disability Support Services are located on Level 1, Robert Stout Building, tel 463-6070, email: disability@vuw.ac.nz. The name of your School’s Disability Liaison Person can be obtained from the School Administrative Assistant or the School Prospectus.

Student Support
Staff at Victoria want students’ learning experiences at the University to be positive. If your academic progress is causing you concern, the following staff members will either help you directly or quickly put you in contact with someone who can.

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<th>Staff member</th>
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The Student Services Group is also available to provide a variety of support and services. Find out more at www.vuw.ac.nz/st_services/ or email student-services@vuw.ac.nz

VUWSA employs two Education Coordinators who deal with academic problems and provide support, advice and advocacy services, as well as organising class representatives and faculty delegates. The Education Office is located on the ground floor, Student Union Building, phone 463 6983 or 463 6984, email education@vuwsa.org.nz