

Specialist Certificate in Clinical Research (Informatics and Analysis)

School of Enterprise

1 Background

The School of Enterprise proposes to introduce a new post graduate award, known as the Specialist Certificate in Clinical Research (Informatics and Analysis) . This program would incorporate one new subject and one other subject which is already offered as part of the Master of Clinical Research from the School of Enterprise.

There is an increasing need for clinical researchers to be aware informatics as the amount of and variety of data required for research projects increases. This includes new types of data such as genetic and proteomic. It also includes the collection, storage and use of data from multiple institutions and across multiple disease domains, in order to achieve statistically significant cohorts of subjects and to allow analysis between formerly separate databases.

Finally clinical researchers must be aware of the statistical underpinnings of research projects and the correct design and analysis of clinical trials and other research.

2 Course/Program Objectives

Graduates of the Specialist Certificate in Clinical Research (Informatics and Analysis) will:

- Have an understanding of privacy, ethical, intellectual property issues as they relate to Clinical Trials and Bioinformatics research
- Have an understanding of basic Database models and terminology. (e.g. relational databases, tables, columns and rows, normalization, joins), including simple queries using SQL, and techniques for the extraction of data from a database for analysis in other tools (e.g. Excel, SPSS, SAS)
- Have an appreciation of "federated" data models such as the MMIM project, and their use in multi-institution, cross-disciplinary studies, including advantages and disadvantages
- Have an understanding of issues relating to research data including ownership, data quality and design of data collection mechanisms, linking of data from multiple research sources, linkage to Victorian and Australian public health databases, and techniques for de-identification of data
- Have an appreciation of the types and volumes of data that will be generated by new techniques in clinical research (e.g. genomic data, proteomic data)
- Gain a basic understanding of data mining techniques, their applicability to Clinical Research and their limitations, e.g. neural networks, genetic algorithms, clustering and optimisation techniques
- Become familiar with the current trends in Bioinformatics and how these relate to clinical research, e.g. the world-wide HAPMAP project
- Gain an understanding of the complexity and basic techniques used in analysis of pharmacogenetic data, such as analysis of SNPs and associated haplotypes, familial linkages and so on
- Have a working knowledge of the major publicly available medical, genetic and biological databases on the internet (e.g. GenBank, Swiss-Prot, OMIM, etc.)
- Have an appreciation of the variety of public software for use in specific Bioinformatics research (e.g. various versions of BLAST, MFOLD, etc.)

- Understand the other professionals that are involved in Clinical Research, and gain an appreciation of when and who to ask for specialist assistance (e.g. statisticians and other mathematical experts, database experts and general computing staff)

3 Entry Requirements

The entry requirements are equivalent to those of the Master of Clinical Research program, namely:

An undergraduate degree or equivalent qualification in medicine, an allied health profession, science or social science which is recognised by the University as evidence of adequate preparation for the course plus documented evidence of at least the equivalent of one year's full-time relevant professional work experience in a medical, scientific or allied health environment.

Please note that knowledge of information technology is not a pre-requisite.

4 Course/Program Structure

To satisfy the requirements of the Specialist Certificate in Clinical Research (Informatics and Analysis), students need to complete 25 points.

The course consists of two subjects:

360841 Applied Analysis of Clinical Trials

new subject: Clinical Research Informatics

5 Availability of Course

The course will be available from Semester 1, 2007, to fee-paying overseas students, fee-paying Australian students, and CSP students.