REGULATIONS FOR THE
POSTGRADUATE CERTIFICATE IN CLINICAL RESEARCH METHODOLOGY
(PCClinResMethodology)

(*See also General Regulations*)

M.63 Admission requirements

To be eligible for admission to the courses leading to the Postgraduate Certificate in Clinical Research Methodology, a candidate shall:

(a) comply with the General Regulations; and

(b) hold a Bachelor's degree with honours or equivalent from this University or from a comparable institution accepted for this purpose.

M.64 Qualifying examination

(a) A qualifying examination may be set to test the candidate's academic ability or his or her ability to follow the course of study prescribed.

(b) A candidate who is required to satisfy the examiners in a qualifying examination shall not be permitted to register until he or she has satisfied the examiners in the examination.

M.65 Length of curriculum

The curriculum shall extend over a maximum of one academic year of part-time study.

M.66 Completion of curriculum

To complete the curriculum, a candidate shall:

(a) follow instruction in the syllabuses prescribed for the course and complete satisfactorily all required written and practical work; and

(b) satisfy the examiners in the course by continuous assessments and by written examinations at the end of each teaching programme.

M.67 Examinations

(a) a candidate who has failed to satisfy the examiners in a course of instruction may be permitted:

  (i) to attend a supplementary examination; or

  (ii) to repeat the course or courses of instruction in the following academic year and to re-take the prescribed examination or examinations; or

  (iii) to re-take the prescribed examination or examinations in the following academic year without repeating the course or courses of instruction; or

(iv) to undertake the study of an alternative course or courses of instruction in the following academic year and to take the prescribed examination or examinations.

(b) A candidate who is not permitted to present himself or herself for re-examination in any subject or subjects in which he or she has failed to satisfy the examiners shall be recommended for discontinuation of studies under General Regulation G12.

M.68 Examination results

At the conclusion of the examination a pass list shall be published. A candidate who has shown exceptional merit in all the examinations may be awarded a mark of distinction and this mark shall be recorded on the candidate's postgraduate certificate.

SYLLABUS FOR THE
POSTGRADUATE CERTIFICATE IN CLINICAL RESEARCH METHODOLOGY

Candidates are required to choose either of the two streams below:

Streams I: Clinical Trials Research Methodology

MODULE 1 - CLINICAL TRIALS RESEARCH METHODOLOGY (20 hours)

- Introduction to Clinical Trials
- Features of Clinical Trials
- Outcome Measures
- Responsibilities and Study Documents
- Monitoring
- Ethics
- Data Analysis and Interpretation
- Sample Size Calculation
- Reports, Publications and Critical Review
- Reviews, Meta-analysis and Practice

MODULE 2 - GOOD CLINICAL PRACTICE (GCP) AND STUDY SITE MANAGEMENT (20 hours)

- Introduction and Overview
- About the Pharmaceutical Industry
- GCP Players and their Roles
- Responsibilities
- Investigator's Meeting and GCP Training
- The Clinical Trial Protocol

- The Investigator's Brochure
- Case Report Forms
- Study Organisation and Planning
- The Institutional Review Board
- Informed Consent
- Recruitment of Subjects
- Laboratory Investigations
- Research Pharmacy
- Blinding: Codes and Code Breaking
- Adverse Event Detection and Reporting
- Monitoring
- Data Clarification
- Study Closure
- Archiving
- Audits and Inspections

MODULE 3 - CLINICAL TRIAL PROTOCOL, STUDY PROTOCOL AND QUALITY OF LIFE (20 hours)

- Clinical Trial Protocol
- Essential Trial Documents
- Practical Site Management
- Ethics Committee Submissions
- Quality of Life

MODULE 4 - ETHICS, LAW, CONTRACTS, BUDGETS AND FINANCE (20 hours)

- IRB and ICH GCP
- Local regulatory Requirements / Law
- Contracts And Finance
- Practice in the Preparation of a Study Budget
- Audits and Inspections
- Fraud and Misconduct
- Clinical trial Role Play

Streams II: Medical Statistics

MODULE 1 - STATISTICAL METHODS (20 hours)

- Statistics in clinical practice I and II
- Measures for location and spread, normal distribution, probability and binomial distribution
- Logic in statistical inference, significance tests on the means
- Association, correlation, and simple regression analysis
- Multiple regression and analysis of variance
- Logistic regression and survival analysis
- Non-parametric methods; sample size determination

MODULE 2 - CLINICAL TRIALS RESEARCH METHODOLOGY (20 hours)

- Introduction to Clinical Trials
- Features of Clinical Trials
- Outcome Measures
- Responsibilities and Study Documents
- Monitoring
- Ethics
- Data Analysis and Interpretation
- Sample Size Calculation
- Reports, Publications and Critical Review
- Reviews, Meta-analysis and Practice

MODULE 3 - EPIDEMIOLOGY AND CRITICAL APPRAISAL (20 hours)

- Epidemiology: definitions, uses, concepts of health, disease and risk factors
- Measurements: rates, proportions, variation, validity and reliability
- Sources of information and vital statistics
- Descriptive Epidemiology: person, place and time
- Study designs in Epidemiology
- Screening, prevention and evaluation
- Critical appraisal, meta analysis and causality

MODULE 4 - STATISTICAL PRACTICE IN CLINICAL TRIALS (20 hours)

a) Important concepts of medical statistics in clinical trials
b) Solving of real life problems in clinical trials
    - Standardisation of quality of life instruments
    - Sample size determination
    - Efficacy analysis
    - Handling of missing values
    - Safety analysis
    - Brief report writing