

## **REGULATIONS FOR THE POSTGRADUATE CERTIFICATE IN CLINICAL RESEARCH METHODOLOGY (PCClinResMethodology)<sup>1</sup>**

*(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.

<sup>1</sup> Not offered in 2005-2006.

- (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.

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### **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.

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## **SYLLABUS FOR THE POSTGRADUATE CERTIFICATE IN CLINICAL RESEARCH METHODOLOGY**

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

### **Streams I: Medical Statistics**

#### **MODULE 1 – CMED6100 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 – PAED6100 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 – CMED6200 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 – CTCE6010 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

### **Streams II: Clinical Trials Research Methodology**

## **MODULE 1 – PAED6100 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 – CTCE6070 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 – CTCE6080 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 – CTCE6090 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