

## 2008–09

**Important document – please read**

Please read this booklet with care. It contains important information that governs your registration as an External student and your programme of study

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### MSc and Postgraduate Diploma in Clinical Trials

(Including short courses)



## **Important document – please read**

Regulations are reviewed and published annually, and are subject to change. Examinations, for example, are governed by the Regulations in force at the time of the examination and not at the time that a student initially registered. Students must, therefore, refer to the Regulations for the current year at all times.

All students are required to comply with the regulations, as well as the procedures, deadlines and instructions issued by the University in, for example, the student handbook/manual and Notice to candidates. The University is not responsible for any consequences arising from a student's failure to comply with these Regulations, procedures, deadlines or instructions.

Copies of the publications, proceedings and other documentation referred to in these Regulations may be obtained, on request, from the External Programme.

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# MSc and Postgraduate Diploma in Clinical Trials

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# Programme Regulations

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The MSc degree and Postgraduate Diploma in Clinical Trials are governed by these Programme Regulations – which are specific to these awards – and the *General Regulations for Degrees and Other Awards at Masters Level* which govern all awards at Masters level. The Programme Regulations and General Regulations should be read together.

## 1. Introduction

1.1 The University awards the degree of Master of Science in Clinical Trials, hereafter called the MSc degree in Clinical Trials. A Postgraduate Diploma in Clinical Trials is also awarded. The award of the degree and the diploma to External students is controlled by these Programme Regulations and the General Regulations for Awards at Masters Level.

1.2 The MSc degree and the Postgraduate Diploma in Clinical Trials are awarded without classification. At the discretion of the Board of Examiners a mark of distinction will be awarded to those students who have completed the examination and who have shown exceptional merit.

1.3 A student registered for the MSc degree in Clinical Trials may also receive the award of the Postgraduate Diploma in Clinical Trials provided they satisfy the requirements for that award.

1.4 The date of the award of the MSc degree and Postgraduate Diploma to successful students will be **1 November**.

## 2. Programmes of study

2.1 The Postgraduate Diploma consists of **four** compulsory core modules.

2.2 The MSc degree consists of the following:

- **four** compulsory core modules
- **one** compulsory advanced module
- **five** further advanced modules
- **one** Integrating module, which comprises an unseen written examination and an Integrating report.

Full details of the structure are given in Schedule A.

2.3 Not all advanced modules will necessarily be available every year.

2.4 The Course Director retains the right to consider the appropriateness of a student's selection of the advanced modules for the MSc degree and, with good reason, may restrict the options chosen by any student.

2.5 Students registered for an advanced module who have either not attempted the examination for that module or have failed the examination at the first attempt, may change to another option. Up to **two** advanced modules only may be changed in this way. Students who change their choice of advanced module (s) will be required to pay the full advanced module fee for each new module.

## 3. Rules of progression

### Students registered for the Postgraduate Diploma

3.1 In any one year, students registered for the Postgraduate Diploma may choose to study and be examined in a minimum of **one** and a maximum of **four** core modules.

3.2 In order to be able to transfer their registration to the MSc degree, students registered for the Postgraduate Diploma must normally obtain a pass at the required level (See Schedule C) in each of the **four** Postgraduate Diploma core modules, and receive a recommendation from the Examiners that they may proceed to the advanced modules of the MSc.

3.3 At the discretion of the Examiners, students who have been examined in, and have passed, **three** modules (which must include **CT101 Fundamentals of clinical trials**) may be permitted to progress to the MSc degree and proceed to the advanced modules. Students will be required to take the examination for the remaining core module in the following year.

### Students registered for the MSc degree

3.4 In any one year, students registered for the MSc degree may choose to study and be examined in a maximum of *either four* core modules *or six* advanced modules plus the **Integrating module**. A student who has been given permission to carry a core module (see paragraph 3.5) may, with the agreement of the Course Director, be examined in the core module in the same year as up to **six** advanced modules and the **Integrating module**. Re-sit attempts may be made in addition to the maximum number of modules stated above.

3.5 In order to proceed to the advanced modules and **Integrating module** of the MSc degree, students registered for the degree must normally have passed **four** core modules, and receive a recommendation from the Examiners that they may proceed to the remaining modules for the Masters degree. At the discretion of the Examiners, students who have been examined in, and have passed, **three** core modules only (which must include **CT101 Fundamentals of clinical trials**) may be permitted to proceed to the advanced modules. Students will be required to take the examination for the remaining core module in the following year.

3.6 Students should study for the **Integrating module** by attempting the unseen written paper and submitting the Integrating report in the same year that they attempt the last of the written papers, except where they have applied to the Course Director, and have been given permission, to submit the **Integrating module** in an alternative year (see also paragraph 7.9).

## Progression from a short course

3.7 Successful completion by formal assessment of a short course may be taken into account for credit towards the MSc degree or Postgraduate Diploma. Students progressing from a short course will be required to satisfy the rules of progression for the MSc degree and/or Postgraduate Diploma.

3.8 Students must follow the sequence of modules given under the individual module outlines, except where the modules are advisory only or may be studied with the special permission of the Course Director.

## 4. Entrance requirements

4.1 In order to be eligible to register for the MSc degree or Postgraduate Diploma in Clinical Trials, an applicant must satisfy the entrance requirements given in paragraphs 4.2 and 4.3.

4.2 An applicant must have:

### MSc degree

*Either*

(a) A first or second class honours degree, or the equivalent, from a university or other institution acceptable to the University of London, in a subject appropriate to the course

*or*

(b) An appropriate professional or technical qualification, together with at least three years' relevant experience, which satisfies the University as a qualification equivalent to a second class honours degree.

### Postgraduate Diploma

*Either*

(a) A first degree from a university or other institution acceptable to the University of London, in a subject appropriate to the course or in another discipline which has, in the opinion of the University, included suitable preliminary training

*or*

(b) previous education and experience without a first degree, which satisfies the University that the applicant has obtained a level of academic proficiency equivalent to a first degree.

4.3 For all applicants an advanced level of ability to work in English is required. Applicants may be required to pass or to have passed within the last five years, at the appropriate level, a test of proficiency in English acceptable to the University – for example a TOEFL score of 600 (or 250 in the computerised test) and a minimum of 5 in the TWE or a British Council (IELTS) overall score of 7 or over with a minimum of 7 in the written sub-test.

4.4 All students will be required to have access to a computer with minimum hardware requirements and have regular internet and email access (see prospectus and Student Handbook). Students are responsible for ensuring adequate system maintenance. Students will also require a calculator (see also paragraph 6.14).

## 5. Period of registration

5.1 The minimum period of registration for the MSc degree is **two** academic years from the effective date of registration for the degree. The maximum period of registration is **five** academic years from the effective date of registration for the degree.

5.2 The minimum period of registration for the Postgraduate Diploma is **one** academic year from the effective date of registration for the Postgraduate Diploma. The maximum period of registration is **five** academic years from the effective date of registration for the Postgraduate Diploma.

5.3 An application for an extension of registration may be considered under paragraph 5 of the General Regulations. A fee will be payable.

5.4 Students who have not completed all the requirements of the programme for which they are registered within the maximum period of registration may apply for a renewal of registration for a further full period, in accordance with paragraph 5.3 of the General Regulations.

5.5 The effective date of a student's registration shall be **1 September** in the year in which he or she is initially registered.

## 6. Assessment

6.1 Each compulsory **core** module will be assessed by one two-hour unseen written paper, with the exception of **CT104 Reporting and reviewing clinical trials** which will be assessed by one two-hour unseen written paper and written assignment(s), and will be weighted on the scale **50:50**.

6.2 Each advanced module will be assessed by one two-hour unseen written paper and written assignment(s), weighted on the scale **80:20**, with the exception of the compulsory advanced module **CT201 Protocol development** which will be assessed by one two-hour unseen written paper and written assignment(s), weighted on the scale **20:80**.

6.3 The **Integrating module** on a specified topic will be assessed by one two-hour unseen written paper and by the submission of a written Integrating report, weighted on the scale **50:50**.

6.4 In all examinations (by both written paper and written assignments) students will be examined both on the module outlines and on the study materials that are current for the year of the examination concerned. As module outlines and study materials are subject to change in advance of each academic year, students must ensure that they have the correct outlines and materials by returning their completed continuing registration form annually. Further information is given in the Student handbook.

6.5 Examinations by written paper, wherever held, will take place on one occasion each year, normally in **June**.

### Assignments

6.6 Assignments must be submitted to be received by the deadlines given in the guidelines for the assignments and the Student handbook.

6.7 Where the examination of a module comprises both a written paper and assignment(s), students are expected to submit

the assignment(s) in the same academic year as they attempt the written paper for that module.

6.8 The mark awarded for modules that comprise a written paper and assignment(s) will be based on the mark obtained in the written paper and the mark for the assignment(s), weighted on the scales indicated in paragraphs 6.1 and 6.2. Students who attempt only one element of the assessment for a module within the same academic year may be permitted to carry forward the grade awarded for the element attempted *for one year only* at the discretion of the Board of Examiners.

6.9 Extensions to the deadline for the receipt of assignments will only be granted in extenuating circumstances, and will only be considered if the student has made a written application, to the Course Director, before the deadline. An assignment received after the deadline, without an agreed extension, will **not** be considered.

6.10 Assignments must be submitted electronically (unless otherwise specified in the assignment guidelines). For information on submitting assignments electronically, students should consult the guidelines for the assignments and the Student handbook.

### **Integrating module**

6.11 The **Integrating module** comprises one unseen written paper and an Integrating report.

6.12 The Integrating report must be submitted to be received by the deadlines given in the guidelines for the assignments and the Student handbook.

6.13 Students are expected to submit the Integrating report in the same academic year as they attempt the written paper. The mark awarded for the **Integrating module** will be based on the mark obtained in the written paper and the mark for the Integrating report, weighted on the scales indicated in paragraph 6.3.

6.14 The Integrating report must be submitted electronically (unless otherwise specified in the assignment guidelines). For information on submitting the Integrating report electronically, students should consult the guidelines for the assignments and the Student handbook.

### **Calculators**

6.15 Students may use their own electronic calculators in the examination where specified in the admission notice. Any calculator must be of the hand-held type, quiet in operation and compact, and must have its own power supply. Programmable calculators may be used. Personal digital assistants (PDAs), mobile phones or other devices which may have a wireless or internet connection are strictly forbidden. Students are entirely responsible for ensuring that their calculators are in working order for the examination and for providing in advance for alternative means of calculation in the event of the calculator failing during the examination.

## **7. Number of attempts permitted**

7.1 Details of the number of attempts permitted are given in paragraph 8 of the General Regulations.

7.2 Students who fail **CT104 Reporting and reviewing clinical trials** or an advanced module, having failed both the assignment and the unseen written paper, will be required to re-sit both elements of the examination.

7.3 Students who fail **CT104 Reporting and reviewing clinical trials** or an advanced module, having passed one element but not the other, will be required to re-sit the failed element. Students are not permitted to re-sit an element they have already passed.

7.4 A student who attempts the unseen written paper for **CT104 Reporting and reviewing clinical trials** or an advanced module but fails to submit the assignment will be considered to have made a first attempt at the examination.

7.5 A student who re-sits the assignment element of an examination (see paragraphs 7.3 to 7.5) will be required to submit a fresh assignment in answer to a new question or assignment topic.

### **Integrating module**

7.6 Students who fail the **Integrating module**, having failed both the unseen written paper and the Integrating report, will be required to re-sit both elements of the examination.

7.7 Students who fail the **Integrating module**, having passed one element but not the other, will be required to re-sit the failed element. Students are not permitted to re-sit an element they have already passed.

7.8 If a student submits the Integrating report of the **Integrating module** which is otherwise adequate but requires minor amendment, the Examiners may require the student to make any amendments required by them and to re-submit the report within a period of four weeks, unless otherwise specified by the Examiners.

7.9 A student who re-sits the Integrating report element of the **Integrating module** will be required to submit a fresh report in answer to a new question or report topic.

7.10 A student who sits the unseen written paper for the **Integrating module** but then fails to submit the Integrating report will be considered to have made a first attempt at the examination.

## **8. Fees**

8.1 The fees for the MSc degree and Postgraduate Diploma in Clinical Trials are of two kinds:

- (a) in order to register, students are required to pay a registration fee which is valid for a period of five years
- (b) students are also required to pay a module fee for each module they study. This fee includes the entry to the first examination for that module. An additional fee is payable in the event of re-entry (see paragraph 8.6)

8.2 Fees may be paid in one of two ways:

*either*

(a) on registration, a single payment covering the registration fee and all module fees, that is,

MSc	£9,095
Postgraduate Diploma	£5,360

*or*

(b) in the first year, the registration fee plus the fees for the modules to be studied that year. In subsequent years, only the fees for any **new** modules studied are payable.

(i)	registration	£780
(ii)	fee per core module	£1,145
(iii)	fee per advanced module	£415
(iv)	fee for integrating module	£1,245

In order to register a student must pay at the same time both the registration fee and the fee for at least **one** module.

8.3 With either method of payment the relevant fees must be paid not later than **31 August** (or as soon as the results of any examinations taken in that year have been published). No study materials will be despatched until the relevant fees have been received.

8.4 The fees outlined refer to the 2008-2009 academic year only.

8.5 A fee is normally levied by all examination centres (other than London) and Overseas Examination Centres. This fee is payable by students each time they make an examination entry. The University cannot be responsible for this fee nor can it influence the level of fee charged.

### **Examination re-entry**

8.6 Students who enter an examination on a second occasion, having failed on the first occasion, are liable to pay an examination re-entry fee of £140 for a core module or £66 for an advanced module. The deadline for payment of an examination re-entry fee is **1 February** in the year of the examination.

### **Transfer of registration**

8.7 Students who transfer from the Postgraduate Diploma to the MSc degree will be required to pay the relevant module fees for completion of the MSc degree.

### **Refunds**

8.8 Registration fees will not be refunded except as provided below:

8.9 If a student dies or is prevented from pursuing his or her studies through a disabling illness or that of a near relative for whose care he or she is responsible, a proportion of the registration fee which has been paid may be refunded at the discretion of the University provided that:

- the application is made within two years of the effective date of the student's registration
- no entry has been made to an examination for the MSc degree or the Postgraduate Diploma
- such medical or other evidence as may be required is submitted.

8.10 A refund of module fees will be given where the fee has been paid but no study materials have been despatched. Such refund will be subject to a charge determined by the University (currently £50).

## Schedule A / Structures

### Postgraduate Diploma

#### Four compulsory core modules

*CT101 Fundamentals of clinical trials* [9160CT101]  
*CT102 Basic statistics for clinical trials* [9160CT102]  
*CT103 Clinical trials in practice* [9160CT103] †  
*CT104 Reporting and reviewing clinical trials*  
[9160CT104] †

### MSc degree

#### Four compulsory core modules

*CT101 Fundamentals of clinical trials* [9160CT101]  
*CT102 Basic statistics for clinical trials* [9160CT102]  
*CT103 Clinical trials in practice* [9160CT103] †  
*CT104 Reporting and reviewing clinical trials*  
[9160CT104] †

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#### Notes:

† Students are advised to study **CT101 Fundamentals of clinical trials** and **CT102 Basic statistics for clinical trials** before studying these modules.

\* Except with the special permission of the Course Director, students must study **CT208 Further statistical methods in clinical trials** or **EP304 Advanced statistical methods in epidemiology** before studying this module.

◇ Except with the special permission of the Course Director, students must study **CT207 Design and analysis of epidemiological studies** before studying these modules.

- The examination numbers are appended to the module titles and these numbers should be used when completing examination entry forms.
- Not all advanced modules will necessarily be available every year.
- The Course Director retains the right to consider the appropriateness of a student's selection of the advanced modules for the MSc degree and, with good reason, may restrict the options chosen by the student.

#### One compulsory advanced module

*CT201 Protocol development* [9160CT201]

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#### Five optional advanced modules

Five advanced modules selected from the following list. Of these five advanced modules, students must select at least **three** Clinical Trials advanced modules. A maximum of **two** other advanced modules may be selected.

#### Clinical Trials advanced modules

*CT202 Trial designs* [9160CT202]  
*CT203 Project management and research co-ordination* [9160CT203]  
*CT204 Regulatory affairs, good clinical practice and ethics* [9160CT204]  
*CT205 Data management* [9160CT205]  
*CT206 Data monitoring and interim analyses*  
[9160CT206]  
*CT207 Design and analysis of epidemiological studies* [9160CT207]  
*CT208 Further statistical methods in clinical trials*  
[9160CT208]  
*CT209 Cluster randomised trials* [9160CT209] \*

#### Other advanced modules

*EP301 Epidemiology of communicable diseases*  
[670E301] ◇  
*EP303 Epidemiology of non-communicable diseases*  
[670E303] ◇  
*EP304 Advanced statistical methods in epidemiology*  
[670E304] ◇  
*EP305 Molecular and genetic epidemiology*  
[670E305] ◇  
*PH204 Economic evaluation* [953P204]  
*PH207 Health care evaluation* [953P207]

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#### A compulsory Integrating module [9160CT210]

## Schedule B / Module outlines

The examination numbers are appended to the module titles and these numbers should be used when completing examination entry forms.

### **CT101 Fundamentals of clinical trials [9160CT101]**

This module will provide students with a solid understanding of the main issues in the design and interpretation of clinical trials. The module will outline the fundamental principles of comparative clinical trials in investigating effectiveness, efficacy and safety of treatments; and compare the benefits of clinical trials in comparison to alternative study designs. The main features of clinical trials, including methodological and organisational considerations, and the principles of trial conduct and reporting will be described. Key decisions surrounding design (including sample size), delivery and assessment of clinical trials will be explored.

*Assessment: one two-hour unseen written paper.*

### **CT102 Basic statistics for clinical trials [9160CT102]**

This module will introduce the basic statistical methods used in clinical trials. In particular, students will learn how to select and apply appropriate statistical methods to analyse data from clinical trials, presenting, interpreting and discussing the analyses clearly and concisely. The module will define probability and describe examples of its use. Normal and binomial distributions and their application will be explored, and the principles of statistical inference, including point and interval estimation, and the role of sampling variation, will be explained. As part of this introduction, students will have the option to carry out basic data analyses from clinical trials using the computer-based Stata software package.

*Assessment: one two-hour unseen written paper.*

### **CT103 Clinical trials in practice [9160CT103]**

*Students are advised to study CT101 Fundamentals of clinical trials or already studied a similar syllabus, as deemed acceptable by the Course Director, before studying this module.*

The key steps in implementing a clinical trial are investigated in this module, including clarifying and operationalising the primary and secondary objectives of clinical trials, the implications of design choices for implementation of a trial, trial governance, clearances (including research and ethical clearance), and data collection and recruitment methods. The module will explore quality assurance and control, and investigate data processing and management issues.

*Assessment: one two-hour unseen written paper.*

### **CT104 Reporting and reviewing clinical trials [9160CT104]**

*Students are advised to study CT101 Fundamentals of clinical trials and CT102 Basic statistics for clinical trials or have already studied similar syllabuses, as deemed acceptable by the Course Director, before studying this module.*

This module will cover both writing up completed trials, including guidelines for authors (such as the CONSORT Statements for reporting), and also guidelines for readers to aid their critical appraisal of trial reports. Ideally future policy, practice and further research will be guided by the reports not merely of one trial but by the totality of the evidence. A major component of the module will therefore be the role of systematic

reviews, including principles and procedures for conducting systematic reviews, problems and limitations; issues in the identification of randomised controlled trials; assessing trial quality; meta-analysis including cumulative meta-analysis; exploring heterogeneity; investigating for selection bias; and reporting of systematic reviews.

*Assessment: one two-hour unseen written paper and written assignment(s).*

### **CT201 Protocol development [9160CT201]**

**The phrasing of this syllabus has changed. However, this is a change in wording only; the content of the module remains the same as previous years.**

Material in this compulsory module will build on the work of the core modules<sup>1</sup>, but will go further into the steps to be taken for preparing the protocol for a trial. Working in small groups, students will critically appraise a systematic review and start drafting the background section for a trial protocol. Students can then use this as a basis for developing a draft protocol for assessment.

*Assessment: one two-hour unseen written paper and written assignment(s).*

### **CT202 Trial designs [9160CTC202]**

By the end of this module students should be able to appreciate the use of different trial designs such as non-inferiority and equivalence, cross-over, factorial, multi-armed trials and cluster randomised trials in assessing interventions and therapies, including complex interventions. The strengths and weaknesses of each design will be discussed, together with their implications for sample size requirements, analytic methods, interpretation and reporting.

*Assessment: one two-hour unseen written paper and written assignment(s).*

### **CT203 Project management and research co-ordination [9160CT203]**

This module will provide students with a full understanding of project and business management theory in the context of a clinical trial. Students will learn how to develop a project management plan, identify key milestones and develop delivery plans. The module will explore implementation and co-ordination of the project plan with an emphasis on communication and project promotion and monitoring. It will also consider the major challenge of identifying barriers to implementation and creating deliverable solutions.

*Assessment: one two-hour unseen written paper and written assignment(s).*

### **CT204 Regulatory affairs, good clinical practice and ethics [9160CT204]**

The module will cover the regulatory legislation and associated approvals and permissions required to conduct high quality single-centre, national and international clinical trials. Integral to

<sup>1</sup> Modules CT202 to CT205 may also be useful but are not prerequisites.

the legislation is Good Clinical Practice (GCP). Students will gain a solid understanding of GCP and will explore ways of implementing GCP, including risk assessment and trial monitoring. Although the focus will be on trials of medicinal products, a variety of clinical and geographical settings will be examined. Ethical issues will be considered throughout the module.

*Assessment: one two-hour unseen written paper and written assignment(s).*

### **CT205 Data management [9160CTC205]**

**The phrasing of this syllabus has changed. However, this is a change in wording only; the content of the module remains the same as previous years.**

This module covers the principles and practices required to ensure that the patient data collected as part of a clinical trial are of high quality prior to analysis. Compliance with regulatory requirements and International Conference on Harmonisation (ICH) Good Clinical Practice (GCP) is emphasised. Students will learn how to establish the necessary infrastructure (the computing environment and its controls), and how to obtain the necessary skills and resources required to manage a successful data management project.

*Assessment: one two-hour unseen written paper and written assignment(s).*

### **CT206 Data monitoring and interim analyses [9160CT206]**

This module will cover issues relating to the on-going monitoring of the data in a study in order that sufficient data are available to answer the trial's question reliably without recruiting more patients than necessary, or exposing them to unacceptable risks. The module will therefore focus on the ethical context of decisions about whether or not to continue entering patients into trials. A number of different statistical approaches will be explored, and the role and conduct of data monitoring committees in this process will be examined.

*Assessment: one two-hour unseen written paper and written assignment(s).*

### **CT207 Design and analysis of epidemiological studies [9160CT207]**

Epidemiological studies often provide important background information prior to initiating a trial. Additionally, trial datasets may prove to be the basis for further epidemiological research. In this module students will be introduced to the key considerations in planning and designing epidemiological studies. This will include descriptions and interpretations of epidemiological measures, including disease frequency and effect, and the relative merits of different study designs. Strategies for addressing sampling error, bias and confounding in epidemiological studies will be demonstrated. Students will consider a range of analytic methods including stratified and multivariable approaches, and be able to critically appraise the design, analysis and interpretation of published epidemiological studies. Students studying this module will be able to register for additional advanced epidemiology modules.

*Assessment: one two-hour unseen written paper and written assignment(s).*

### **CT208 Further statistical methods in clinical trials [9160CT208]**

This module will build on module CT102 Fundamentals of clinical trials to cover more advanced statistical methods used in clinical trials. Topics covered will include the concept of likelihood and regression analyses including logistic, Poisson and Cox regression. The module will also cover adjustment for covariates, analyses of repeated measures and other correlated data, missing data, sub-group analyses and sensitivity analyses. Data analyses will be carried out using Stata.

*Assessment: one two-hour unseen written paper and written assignment(s).*

### **CT209 Cluster randomised trials [9160CT209]**

*Except with the special permission of the Course Director, students must study CT208 Further statistical methods in clinical trials or EP304 Advanced statistical methods in epidemiology before studying this module. Module CT202 may also be useful but is not a prerequisite.*

Trials in which individuals are randomised in groups (clusters) are being increasingly utilised, especially in the fields of infectious diseases, implementation research, and public health and complex interventions. This module will consider the advantages and disadvantages of the use of cluster trials, with particular emphasis on statistical considerations for their design and analysis, as well as the implications for informed consent and reporting.

Please note: students studying this module should have access to Microsoft Excel 97 or later.

*Assessment: one two-hour unseen written paper and written assignment(s).*

### **EP301 Epidemiology of communicable diseases [670E301]**

*Except with the special permission of the Course Director, students must study CT207 Design and analysis of epidemiological studies before studying this module.*

This module covers the factors that suggest a disease has an infectious cause, those determining the spatial, temporal and social distributions of communicable diseases, and the measurement of the transmissibility of infections. By the end of the module, students should be able to design, carry out, analyse, interpret and report an outbreak investigation, understand the principles underlying mathematical models of communicable diseases, methods for the evaluation of vaccine efficacy, and practical applications of epidemiological methods through the study of specific diseases.

*Assessment: one two-hour unseen written paper and written assignment(s).*

### **EP303 Epidemiology of non-communicable diseases [670E303]**

*Except with the special permission of the Course Director, students must study CT207 Design and analysis of epidemiological studies before studying this module.*

This module will provide an overview of non-communicable diseases in both developed and developing country settings, the global burden of such diseases, temporal trends in mortality from cardiovascular diseases and cancer, diet and cancer and the epidemiology and prevention of mental disorders. By the end of the module, students will be able to develop and criticise

strategies for prevention of cardiovascular disease at the community and individual level.

*Assessment: one two-hour unseen written paper and written assignment(s).*

### **EP304 Advanced statistical methods in epidemiology [670E304]**

*Except with the special permission of the Course Director, students must study CT207 Design and analysis of epidemiological studies before studying this module.*

This module will cover regression methods for the analysis of case-control and cohort studies, using appropriate computer software. By the end of the module the student should be able to plan a strategy of analysis for an epidemiological data-set, using an appropriate choice of methods, appreciate the effects of correlated data on epidemiological analysis, and the use of statistical methods which take account of such correlations, and interpret and criticise the statistical methodology presented in published epidemiological papers.

*Assessment: one two-hour unseen written paper and written assignment(s).*

### **EP305 Molecular and genetic epidemiology [670E305]**

*Except with the special permission of the Course Director, students must study CT207 Design and analysis of epidemiological studies before studying this module.*

By the end of this module students should be able to understand papers which describe molecular and genetic epidemiological findings and appreciate the roles of molecular techniques in furthering our understanding of the epidemiology of diseases. The module will include the application of basic epidemiological principles to the critical interpretation of molecular and genetic epidemiological studies. Students will be able to demonstrate understanding of fundamental concepts of genetics, and to appreciate the study designs and the methods of statistical analysis used to evaluate the role of genetic inheritance in the occurrence of human disease, and to determine the location of the gene(s)/allele(s) responsible for a disease.

*Assessment: one two-hour unseen written paper and written assignment(s).*

### **PH204 Economic evaluation [953P204]**

This module aims to allow students to understand and apply current methods in the economic evaluation of health interventions. Topics include: measurement; valuation and analysis of costs; techniques for measuring and valuing health outcomes; the presentation of cost and effect data; and critical appraisal of economic evaluation in health care decision making. *Assessment: one two-hour unseen written paper and written assignment(s).*

### **PH207 Health care evaluation [953P207]**

This module will consider how the principles of scientific evaluation can be applied to the dimensions of effectiveness, efficiency, humanity and equity. The module will cover the quantitative (including both experimental and observational designs) and qualitative methods used in evaluation of these four dimensions. It will also consider the challenge of measuring key outcomes such as disease, health status and quality of life and address the issues involved in measuring costs.

*Assessment: one two-hour unseen written paper and written assignment(s).*

### **Integrating module [9160CT210]**

The aim of this compulsory module is to bring together material from the different Clinical Trials study modules, and hence will generally be taken in the same year that students attempt the last of the written papers. A written report comprising original work by the student is required. This may consist of a critique of specific aspects of a completed trial or conducting and commenting on further analyses based on the data provided. *Assessment: by one two-hour unseen written paper and by a written Integrating report weighted on the scale 50:50. The integrating module is equivalent to three study modules.*

## Schedule C / Scheme of award

**Note: the term ‘course’ referred to in this Schedule is equivalent to the term ‘programme’ referred to in the General Regulations.**

In order to be awarded the MSc degree or Postgraduate Diploma, students are required to satisfy the Examiners in the assessment for the components of the degree/diploma listed in Schedule A.

The Board of Examiners will classify a student accordingly once the criteria for that award have been satisfied. A student who has reached this stage will **not** be permitted to make any further attempts at any modules.

### 1. Calculation of grades for unseen written papers

- Questions that are graded directly will be assigned one of six grades (A, B+, B, C, D or E).
- Individual questions or sections of a paper of a numerical nature or with a number of yes/no answers (including multiple choice questions - MCQs) may be marked numerically to give a final percentage for that question/section. This will then be converted to a letter grade using a scheme agreed in advance by the markers.
- The final grades of all the questions are then converted to Grade Points (GPs) using Table 1 and then combined to give a Grade Point Average (GPA) for the exam paper as follows:

$$\sum (\text{Question GP} \times \text{Question weighting}) = \text{GPA for whole paper.}$$

All grade point averaging will be done to two decimal places to avoid rounding errors later.

Grade	GP
A	5
B+	4
B	3
C	2
D	1
E	0

Table 1

### 2. Core modules

- The unseen written papers are graded as set out in paragraph 1.
- The overall GPA for the core module CT104 Reporting and Reviewing Clinical Trials is calculated as follows:-  
(assignment GP  $\times$  0.5) + (unseen written paper GPA  $\times$  0.5) = core module CT104 GPA.
- The final core module result is then reported back to the student by converting the GPA back to a letter grade using Table 2.

GPA	Grade
4.6-5.0	A
3.65-4.59	B+
2.65-3.64	B
2.00-2.64	C
0.65-1.99	D
0-0.64	E

Table 2

### 3. Advanced modules

#### 3.1 CT advanced modules:

- The unseen written paper is graded as set out in paragraph 1.
- Assessed assignments are graded by two markers and the grades reconciled to produce an agreed letter grade, which is converted to a GP as set out in Table 1.
- The overall GPA for the module CT201 Protocol development is calculated as follows:-  
(assignment GP  $\times$  0.8) + (unseen written paper GPA  $\times$  0.2) = advanced module CT201 GPA.
- The overall GPA for advanced modules except CT201 is calculated as follows:-  
(assignment GP  $\times$  0.2) + (unseen written paper GPA  $\times$  0.8) = advanced module GPA.
- The result of the overall advanced module is then reported back to the student by converting the overall advanced module GPA back to a letter grade using Table 2.

#### 3.2 EPP and PH advanced modules:

- The unseen written paper is graded as set out in paragraph 1.
- Assessed assignments are graded by two markers and the grades reconciled to produce an agreed letter grade, which is converted to a GP as set out in Table 1.

- Assessed assignments are compulsory elements of examination and must be awarded a minimum of a D grade. If the assessed assignment is awarded grade E the student will be informed that the module grade is considered to be a fail and they must resit the assessed assignment.
- The overall GPA for the module is calculated as follows: (assignment GP  $\times$  0.3) + (examination GPA  $\times$  0.7) = advanced module GPA.
- The result of the overall advanced module is then reported back to the student by converting the overall advanced module GPA back to a letter grade using Table 2.
- Where an advanced module is assessed solely via an assessed assignment, the assignment will be graded by two markers and the grades reconciled to produce an agreed letter grade which is converted to a GP as set out in Table 1.

#### 4. Integrating module

- The unseen written paper grade is converted to a GP using Table 1.
- The integrating report is graded by two markers and the grades reconciled to produce an agreed letter grade, which is converted to a GP as set out in Table 1.
- The overall GPA for the integrating module is calculated as follows:-  
(integrating report GP  $\times$  0.5) + (unseen written paper GPA  $\times$  0.5) = Integrating module GPA.
- The final Integrating module result is then reported back to the student by converting the GPA back to a letter grade using Table 2.

#### 5. Calculation of the final result

All modules are of equal weight, with the exception of the Integrating module which is equivalent to three modules. The final outcome (fail, pass or distinction) is determined by the final course GPA which is calculated as follows:-

##### 5.1 For the Postgraduate Diploma award:

(Total GPA of 4 core modules)  $\div$  4 = final Diploma course GPA

##### 5.2 For the MSc award:

[(Total GPA of 4 core modules) + (total GPA of 6 advanced modules) + (Integrating module GPA  $\times$  3)]  $\div$  13 = final course GPA

5.3 The final outcome of the award (fail, pass/permission to proceed to the MSc or distinction) is determined using *first* the rules below -1a and 1b for core modules (i.e. Postgraduate Diploma/permission to proceed to MSc) and 2a-2c for advanced modules (i.e. MSc) - and *then* Table 3.

##### 5.3.1 Rule 1a

If, on examining all modules that contribute to the award of the Postgraduate Diploma or to satisfying the requirements for proceeding to the MSc (i.e. the four core modules), any one module GPA is below 0.65, then, regardless of the final course GPA, an uncompensatable fail has occurred.

##### 5.3.2 Rule 1b

If, on examining the GPAs for the modules that contribute to the award of the Postgraduate Diploma or to satisfying the requirements for proceeding to the MSc (i.e. the core modules) any two modules' GPAs are below 2.00, then, regardless of the final course GPA, an uncompensatable fail has occurred.

Note that course-specific restrictions may additionally require that a GPA greater than 2.00 must be obtained in one or more modules and that a GPA below 2.00 for such a module(s) may not be compensated for by higher GPAs for other modules (see appendix 1).

##### 5.3.3 Rule 2a

If, on examining the GPAs for the advanced modules that contribute to the award of the MSc, any one module GPA is below 0.65, then, regardless of the final course GPA, an uncompensatable fail has occurred.

##### 5.3.4 Rule 2b

If, on examining the GPAs for the advanced modules that contribute to the award of the MSc any two modules' GPAs are below 2.00, then, regardless of the final course GPA, an uncompensatable fail has occurred.

Note that students can at most compensate for one GPA below 2.00 on the core modules plus at most one GPA below 2.00 on advanced modules (i.e. "unused" compensation cannot be carried forward from the PG Diploma to the MSc).

Note also that course-specific restrictions may additionally require that a GPA greater than 2.00 must be obtained in one or more modules and that a GPA below 2.00 for such a module(s) may not be compensated for by higher GPAs for other modules (see appendix 1).

##### 5.3.5 Rule 2c

For students registered for the MSc, GPAs of 2.00 or better must be obtained for the Integrating module for the degree to be awarded. These elements cannot be used for compensation.

<b>Final course GPA</b>	<b>Outcome</b>
0-1.99	Fail
2.00-4.29	Pass
4.30-4.49	Consider distinction
4.50-5.00	Distinction

Table 3

## 6. Reporting students' results

Students' results will be reported using grades rather than the GPA, converted back using Table 2.

<b>Distinction</b>	<b>A</b>
<b>Pass</b>	<b>B+, B, C</b>
<b>Fail</b>	<b>D, E</b>

## Appendix 1

Course specific restrictions on compensation:

<b>Restriction</b>
<b>Postgraduate Diploma/MSc students must pass the following module at grade C or higher (this module is non-compensatable):</b>
<ul style="list-style-type: none"> <li>CT101 Fundamentals of clinical trials</li> </ul>
<b>MSc students must pass the following component at grade C or higher:</b>
<ul style="list-style-type: none"> <li>Integrating module</li> </ul>

## Schedule D / Assessment criteria

Letter grade	Word grade	General criteria
A	Excellent	A comprehensive analysis and discussion of the topic giving all relevant information, showing in-depth critical understanding of the topic, going beyond conventional answers, and bringing in additional ideas or material
B+	Very good	A full analysis and discussion of the topic that includes all relevant information and critical evaluation
B	Good	The major points are analysed and discussed, but relevant though less important considerations are omitted
C	Satisfactory (MSc and Diploma level pass)	Sufficient relevant information is included but not all major points are analysed and discussed, and there may be some errors of interpretation
D	Unsatisfactory	A few points are included but real lack of understanding shown and often use irrelevant points
E	Very poor	None of the major points present, many irrelevant points included, serious lack of understanding

# General Regulations for Degrees and Other Awards at Masters Level

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These General Regulations govern all degrees and other awards placed at the Masters Level of the *Qualifications Framework for the External System* of the University of London, and the programmes of study leading to those awards.

## 1. The Regulations

### Introduction

1.1 These General Regulations govern all degrees and other awards placed at the Masters Level of the *Qualifications Framework for the External System*, as listed in paragraph 2.1. Individual programmes of study leading to degrees and other awards at those levels are governed by both these General Regulations and specific Programme Regulations.

1.2 The rules within these General Regulations apply, in their entirety, to all of the awards listed in paragraph 2.1, except where indicated otherwise.

1.3 Registered External students are required to comply with these General Regulations and the appropriate Programme Regulations. They must also comply with the procedures, deadlines and instructions issued by the University in, for example, the student handbook/manual and Notice to Candidates. The University is not responsible for any consequences arising from failure to comply with these Regulations, procedures, deadlines or instructions.

1.4 It is a student's responsibility to ensure that his or her choice of subjects complies with the Regulations that are current for that year.

1.5 The rules relating to a particular programme of study in any given year are those included in the Regulations for that current year and not in the year in which the student initially registered (see also paragraph 1.8).

1.6 On all matters concerning the interpretation of these Regulations, or on which they are silent, the decision of the University shall be final.

### Changes to the Regulations

1.7 The Regulations are reviewed and published annually, and are subject to change.

1.8 Two years' notice will normally be given to registered students of any major amendment of the Regulations. Five years' notice will be given to registered students should the University be required to withdraw the programme of study for which they are registered.

### Terminology and definitions

1.9 The programmes of study leading to degrees and other awards may be referred to, in the Regulations, as 'programmes'. Postgraduate Certificates are referred to as 'certificates', and Postgraduate Diplomas as 'diplomas'. Postgraduate degrees are referred to as 'degrees'.

1.10 These General Regulations describe the individual elements of a degree or diploma as 'subjects'. In the Programme Regulations, these may be called 'courses', 'units', 'modules' or 'sections'.

1.11 The term 'examination' used in these Regulations refers to the entire assessment for a subject, and includes not only the written paper for that subject but also any coursework, project, dissertation or online participation that contributes towards the final assessment.

1.12 'Credit' for a subject, on the basis of the same or an equivalent subject previously passed, may be awarded to a student who has been registered with the University of London for a programme of study. The mark obtained at the examination at which the subject was passed will be carried forward to the student's record and will contribute towards his or her award, in accordance with the criteria for awards given in the respective Programme Regulations.

1.13 'Exemption' from a subject may be granted to a student who has studied **either** for an award with another institution **or** for a programme of study with the University of London, where the subject passed is not sufficiently equivalent for credit to be awarded. The mark obtained at the examination at which the subject was passed will **not** be carried forward to the student's record and therefore will not contribute towards his or her award.

1.14 The 'Admission Notice' is provided to each student who has made an entry to an examination. The Admission Notice contains the student's candidate number and confirmation of the dates and time of the examination(s) for which he/she has entered.

1.15 The 'Notice to Candidates' contains prescribed rules for the examinations. The Notice to Candidates is provided to students together with their Admission Notice.

### Student complaints procedure

1.16 The University has a *Procedure for External student complaints* which can be found in the student handbook/manual (or the equivalent publication) and on the External System web site.

## 2. Awards to External students

2.1 The University grants the following awards at Masters Level to External students:

- Postgraduate Certificates
- Postgraduate Diplomas
- Postgraduate (or Master's) degrees.

2.2 The definition, level, volume and learning outcomes of these awards are described in the *Qualifications Framework for the External System*, which can be accessed via the External System web site.

2.3 The degrees, diplomas and certificates listed in paragraph 2.1 are awarded without classification, although some may be awarded with a mark of Distinction or Merit (see paragraph 1 of the Programme Regulations).

2.4 A certificate under the seal of the University will be delivered to each successful student who is granted a degree or other award. The date of the award will be as indicated in paragraph 1 of the Programme Regulations concerned.

2.5 External students are examined to the same standard as that required of students enrolled at individual Colleges or Institutes of the University. The Ordinances and Regulations of the University state that “*candidates granted degrees and other awards shall have attained the same academic standard irrespective of mode or place of study or examination.*”

2.6 To be eligible for an award of the University as an External student, a student must have:

- registered with the University as an External student **and**
- satisfied the requirements for the relevant award and complied with the Regulations for the programme concerned in all respects **and**
- made satisfactory payment to the University of all due fees and accounts.

The University reserves the right not to grant the award to students who fail to satisfy any of these conditions.

2.7 To register for a programme of study as an External student, an applicant must satisfy the conditions given in paragraph 4 of the relevant Programme Regulations. In addition, an applicant who was previously either registered as an External student or enrolled at a constituent College or Institute of the University of London must have made satisfactory payment to the University or College/Institute of all due fees and accounts. An applicant who fails to satisfy this condition will **not** be permitted to register, or to register again, as an External student.

2.8 An intermediate award or awards (i.e. a related certificate or diploma), if applicable, may be granted to a student registered for a diploma or degree in the following circumstances:

- (a) At the discretion of the Board of Examiners, and as indicated in paragraph 3 of the Programme Regulations, a student registered for a diploma or degree who does not complete the programme of study **or** who does not satisfy the Examiners (at the level required for the award) in all subjects may be awarded a related certificate or diploma (if applicable). Such students will be required to have satisfied the Examiners (at the level required for the award concerned) in the subjects that comprise the certificate or diploma.
- (b) At the discretion of the University, and where permitted in Paragraph 1 of the Programme Regulations, a student registered for a diploma or degree, and in circumstances other than those described in (a), may be considered for the award of a related certificate or diploma (if applicable), provided that he or she has satisfied in full the requirements for the certificate or diploma concerned.

The award of the certificate or diploma will be with effect from the year in which the requirements for the certificate or diploma were satisfied.

2.9 An External student who has successfully completed the examinations for a certificate or diploma and has not accepted that award, may apply to transfer his or her registration to a related diploma or degree (if applicable) subject to the rules of progression in paragraph 3 of both these and the Programme Regulations. A student who has accepted the award of the certificate or diploma may also apply to transfer his or her registration unless the Programme Regulations state otherwise.

2.10 An applicant who has previously received an award of the University of London, or whose registration with the University was terminated because he or she had exhausted the permitted number of attempts at an examination, may apply to register again as an External student for a programme of study in a different subject or field of study.

2.11 Unless paragraph 1 of the relevant Programme Regulations states otherwise, an applicant who has previously received an award of the University of London, or whose registration with the University was terminated because he or she had exhausted the permitted number of attempts at an examination, may apply to register again for a programme of study in the same subject or field of study. All applications will be considered on an individual basis. Permission to register in these circumstances will be given at the discretion of the University and will be subject to any further conditions specified in these General Regulations and in the relevant Programme Regulations, or by the University.

2.12 A former student of the University who is applying to register again as an External student under the provisions of paragraphs 2.10 or 2.11 will be required to satisfy the entrance requirements for the programme of study for which he or she is applying and the conditions given in paragraph 2.7.

### **3. Application, entrance requirements and exemptions**

#### **Application**

3.1 In order to be considered for registration as an External student, applicants are required to submit an application in accordance with the procedures and deadlines given in the relevant prospectus.

#### **Entrance requirements**

3.2 To be eligible to register as an External student for a programme of study leading to an award at Masters Level, an applicant must satisfy in full the entrance requirements specified in paragraph 4 of the relevant Programme Regulations.

3.3 The University reserves the right to request applicants to provide evidence acceptable to the University of oral and written competence in English before an offer of registration can be made.

#### **Exemptions**

3.4 At the discretion of the University, students who satisfy the relevant entrance requirements to register for a programme of study and are appropriately qualified may apply for exemption from specified subjects. Applications will be considered on the basis of studies successfully completed at a level considered by the University to be appropriate.

3.5 Where permitted in paragraph 4 of the Programme Regulations students can be considered for exemption from up to **one third** of the programme concerned. Exemption can be granted from core and optional subjects, but cannot be granted from the dissertation, project or final examination (as appropriate) of the programme.

3.6 No exemption will be granted unless the student has made an application in accordance with the University's procedures and deadlines.

3.7 Applications for exemption cannot be considered after a student has made entry to the examination for the subject concerned. Students who have failed an examination may not, at a later stage, apply for exemption from that examination.

3.8 A fee is payable for all applications for exemption (see paragraph 11).

3.9 All exemptions are granted at the discretion of the University.

3.10 Exemptions are valid only for a limited time and as indicated in the offer of exemption. If a student does not enter an examination within this period, then the exemption will lapse and it will be necessary to make a fresh application.

3.11 Exemptions are valid only for the particular programme of study and subject for which they have been awarded. Exemptions will no longer be valid if the programme is withdrawn before the student registers. Students who transfer their registration to another programme may be required to submit a further application for exemption.

3.12 Students who are exempt from a specific subject are not required or permitted to offer the same, or equivalent, subject at a later stage.

## 4. Rules of progression

### Progression within a programme of study

4.1 Students are required to comply with the rules of progression given in paragraph 3 of the Programme Regulations.

4.2 Students are not required to enter examinations every year nor to enter on the date they indicate at the time of registration, unless the Programme Regulations state otherwise.

### Progression from a certificate or diploma to a related award

4.3 There is no automatic progression between certificates, diplomas and degrees. Satisfactory completion of a certificate or diploma does not in itself guarantee entry to a related diploma or degree. In order to proceed to a related award, a student registered for a certificate or diploma must normally successfully complete all the prescribed certificate/diploma subjects at the required level and receive a recommendation from the Examiners that he or she may proceed.

4.4 A student who progresses from a certificate or diploma to a related award will be credited the same or equivalent subjects passed. Any restriction on the use of credited subjects is given in the Programme Regulations.

4.5 The attempts at any failed subjects which are common to the diploma or degree to which the student progresses will be carried forward and will count towards the number of attempts permitted at those subjects.

### Progression from a short course

4.6 Successful completion by formal assessment of a short course or courses may be taken into account for admission to a related or unrelated certificate, diploma or degree (with the exception of the LLM degree under the Old Regulations).

4.7 Successful completion by formal assessment of a short course or courses may be taken into account for credit towards a certificate, diploma or degree, provided that the application is made within **three** years of the completion of the relevant course or courses.

4.8 Successful completion of a short course or courses does not in itself automatically satisfy entry requirements for any certificate, diploma or degree or ensure credit.

4.9 A student who does not successfully complete the formal assessment for a short course will be permitted to proceed to a certificate, diploma or degree **provided** he or she satisfies the entrance requirements for the certificate, diploma or degree concerned.

4.10 All applications for progression from a short course to a certificate, diploma or degree will be considered on an individual basis and permission to progress, and, where appropriate, to receive credit, will be at the discretion of the University.

## 5. Period of registration

5.1 The minimum and maximum periods of registration are described in paragraph 5 of the individual Programme Regulations. No reduction in the prescribed minimum period of registration will be permitted, except within the parameters given in paragraph 5.2 and at the discretion of the University.

5.2 Postgraduate Certificates may not be completed in less than **six months**. Master's degrees and Postgraduate Diplomas may not be completed in less than **one year**.

5.3 Where permitted in paragraph 5 of the Programme Regulations, application for a renewal of registration for a further period may be made by students who have not completed all the requirements of the programme for which they are registered within the maximum period of registration. The University will take into account the progress made by the student during registration. A fee will be payable if renewal is granted.

5.4 Where permitted in paragraph 5 of the Programme Regulations, an application for an extension of registration of **one** year beyond the prescribed maximum period may be made by students who have not completed all the requirements of the award for which they are registered. A fee may be payable.

5.5 Renewal of registration and extension of registration are approved only at the discretion of the University and will be subject to the Regulations in force at the time of renewal or extension.

5.6 Students who are permitted to proceed from a certificate or diploma to a related diploma or degree (see paragraph 4) will have the maximum period of registration for the related award counted from the effective date of initial registration for the certificate or diploma for which they were initially registered.

5.7 Students who are permitted to proceed from a short course to a certificate, diploma or degree will be given a new period of registration as an External student, effective from the date of registration for the certificate, diploma or degree concerned. The maximum period of registration permitted will be the same as for all other students registered for the same programme, as indicated in paragraph 5 of the relevant Programme Regulations.

5.8 The University reserves the right to apply *The Disciplinary Procedure* and the *Suspension and Termination of Registration of Students in Debt* process as described in the University of London Ordinances (Ordinances 26 and 28 respectively).

## 6. Transfer

### Transfer of External students to different programmes at Masters Level, and within the same programme

6.1 Unless otherwise prohibited by the Programme Regulations concerned, an External student registered for a programme of study at Masters Level who wishes to change to another programme at one of those Levels may apply to transfer his or her registration. The student will be required to satisfy the regulations and entrance requirements for the programme to which he or she wishes to transfer.

6.2 A student registered for a programme of study with more than one 'scheme' or 'route' may apply to transfer between those schemes or routes.

6.3 The rules in paragraphs 6.4 to 6.9 apply both to students transferring between different programmes of study and to students transferring within the same programme. Further rules are given in the relevant Programme Regulations.

6.4 All applications to transfer will be considered on an individual basis, and permission to transfer will be at the discretion of the University and subject to the Programme Regulations concerned. Students may be required to cancel their registration and register afresh.

6.5 Any additional fees payable (see also paragraph 11.5) and any period of transferred registration granted shall be at the discretion of the University. Any refund of fees already paid will be subject to the conditions in paragraph 11.

6.6 An application to transfer which is submitted after a student has made entry to any examination will **not** be considered until after the result of that examination has been published. The result of that examination will then be taken into account by the University in instances when permission to transfer is dependent on the student's examination record and/or where the student is applying to transfer between the routes or schemes of the same programme of study.

6.7 In certain circumstances, students who transfer may receive credit for subjects already passed. Details of such credit arrangements are given in the Programme Regulations.

6.8 Students who receive credit for subjects passed will not be permitted to re-enter the examination for those subjects. The marks obtained at the examinations at which the subjects were passed will contribute towards the student's award, in accordance with the criteria for awards given in the respective Programme Regulations.

6.9 Students who are not permitted to transfer to a particular programme but who wish to register for that programme must cancel their registration for the other award and apply to register afresh, subject to satisfying the requirements of paragraph 4 of the Programme Regulations. Students who are permitted to register afresh in this way:

- will **not** be permitted to carry credit for any subjects previously passed either to the programme concerned, or, in the event of a subsequent transfer, to another programme **and**
- will **not** be permitted to carry any failed attempts at subjects from their previous registration.

### Transfer of External students to a programme at Certificate, Intermediate or Honours Level

6.10 Students registered for a programme of study at Masters Level (see paragraph 2.1) are not permitted to transfer their registration to a programme at Certificate, Intermediate or Honours level. Students will instead be required to cancel their existing registration and to submit a fresh application for registration and comply with the Regulations for the programme concerned.

### Registration and credit transfer of College-based students

6.11 A student in attendance at a College or Institute of the University of London may apply to complete their studies for the same award as an External student and may be considered for credit and/or exemption for subjects previously passed. All applications for credit and/or exemption will be considered on an individual basis and at the discretion of the University.

6.12 Students who receive credit for subjects passed will not be permitted to re-enter the examination for that subject. The mark obtained at the examination at which the subject was passed will contribute towards the student's award, in accordance with the criteria for awards given in the respective Programme Regulations.

6.13 The rules concerning exemptions are given in paragraph 3.

## 7. Assessment

7.1 Students are required to satisfy the assessment requirements for the subject(s) taken and may not make more than the number of attempts permitted in paragraph 8.

7.2 An examination is governed by the Regulations in force at the time of the examination and not at the time that a student was initially registered or first attempted the examination concerned (but see also paragraph 1.8).

7.3 In order to sit an examination, a student must:

- have completed the relevant application and registration/enrolment procedures with the University by the appropriate deadlines and be registered as an External student for the programme concerned **and**

- have made an examination entry in accordance with both the University's and the appropriate examination centre/Overseas Examination Centre's instructions and deadlines.

7.4 Except in the circumstances of paragraph 7.5, all examinations by written paper, wherever held, will take place on the same date and at the same time. The University reserves the right to set different papers in the same subject in separate countries and in different time zones.

7.5 In the event of any unavoidable delay in the arrangement of examinations in a country other than the United Kingdom, the Overseas Examination Centre will arrange for the relevant papers to be taken with as little deviation as possible from the original dates and times assigned to them. Students are required to abide by any such revised arrangements. The University reserves the right not to mark a paper taken at a different time from that prescribed.

7.6 Where it is deemed necessary, Examiners may change the format or rubric of a written paper, from that of a previous year, without prior notice to students.

7.7 Except where the syllabus/course outline or rubric for a written paper for a particular subject indicates otherwise, all answers to examinations must be written in English.

### Examination centres

7.8 Examinations by written paper are held at established examination centres worldwide.

7.9 Outside the United Kingdom and Republic of Ireland, examinations are conducted by independent bodies known as Overseas Examination Centres.

7.10 In countries where an established Overseas Examination Centre exists, students must use the facilities provided by that Centre. The University will not establish an alternative centre in those countries.

7.11 All examinations are held at the discretion of the examination centre/Overseas Examination Centre and are subject to any conditions they may impose.

7.12 Students are required to apply to the relevant examination centre/Overseas Examination Centre for permission to sit an examination. The University can accept no responsibility for making examination arrangements on behalf of a student. It is entirely at the discretion of the examination centre or Overseas Examination Centre to accept or refuse an entry to an examination.

7.13 A fee is normally levied by all examination centres (other than London) and Overseas Examination Centre. This fee is payable by students each time they make an examination entry. The University cannot be responsible for this fee nor can it influence the level of fee charged.

## 8. Number of attempts permitted

8.1 A student who fails to satisfy the Examiners in an examination, and who has not yet satisfied the conditions for the Board of Examiners to determine his or her final result, will be permitted or required to make **one** further attempt at that examination. The maximum number of attempts permitted at any examination is **two**.

8.2 A student who enters an examination hall to attempt a written paper will be considered to have made an examination attempt. Unless otherwise stated in the Programme Regulations, absence from an examination will not count as an attempt.

8.3 The mark or grade awarded for a second attempt at an examination will supersede any previously awarded mark or grade for that examination, unless the Programme Regulations state otherwise.

8.4 If a student fails to satisfy the Examiners at a second attempt at any examination his or her registration will cease unless the Programme Regulations permit the student to proceed as the requirements for that award may still be satisfied, in which case the mark or grade obtained on the latest occasion may be carried forward and may count towards the final award.

8.5 Except as otherwise provided for by the University, students may not make a further attempt at any subject already passed or for which credit has been awarded.

## 9. Students with a disability and/or special needs

9.1 The University has a policy for External students with a disability and/or special needs and a statement explaining this policy is given on the External System web site.

9.2 As part of its policy, the University will make every reasonable effort to accommodate the requirements of a student with a disability and/or special needs by, wherever possible, providing any study materials in a different format (e.g. large print) or another medium, and/or by making special examination arrangements. If the University is unable to provide the study materials in the format which has been requested, the University will endeavour to make an alternative suggestion.

### Special examination arrangements

9.3 The University has a Panel which considers special examination arrangements for students with a disability and/or special needs. The aim of the Panel is to make sure that a student with a disability and/or special needs is neither disadvantaged nor advantaged when compared to other students. The University cannot guarantee that special examination arrangements will be possible in every case.

9.4 Applications from students with a disability and/or special needs may be considered for the use of special aids or for extra time in the examinations.

9.5 Special arrangements for examinations at an *ad hoc* centre may be made in very exceptional circumstances and then only in the United Kingdom. Arrangements **cannot** be made for oral or practical examinations to be held at an *ad hoc* centre, although in exceptional cases it may be possible to permit the use of special aids. Arrangements for examinations in a student's home are **not** made. Additional fees may be payable for arrangements at an *ad hoc* centre.

9.6 A student who finds handwriting difficult due to medical or learning difficulties must apply to the University for special arrangements to be made. The University will not transcribe illegible scripts. Any script deemed illegible by the Board of Examiners will be assigned a mark of zero and a fail result will be given. This will count as an attempt at the examination.

## 10. Conduct of examinations

10.1 All students sitting examinations are required to comply with the rules governing the conduct of examinations given below and in the Notice to Candidates accompanying the Admissions Notice.

### Representations about examinations

10.2 Students who wish the Board of Examiners to know of any illness or other adequate cause which they think may have affected their performance must **immediately** inform the Examinations Office and furnish a supporting medical certificate or other supporting certification obtained at the time of illness. Notification received more than **three weeks** after the date of the last examination will **not** be taken into account by the Examiners.

10.3 Appeals against the results of examinations **may not be made** on academic grounds. The University will consider representations concerning examination results made on the grounds of administrative error or where there is concern that the examination may not have been conducted in accordance with the relevant Instructions and/or Regulations. An administration fee (currently £50 per paper) is payable for the consideration of such representations (refundable in the event that an error is found). Any representation must be made within **one month** of the publication of the decision of the Board of Examiners to which it relates and should be addressed to the Head of Special Examination Services and be accompanied by payment of the administration fee. Representations must state the grounds on which the appeal is made and provide evidence to support it. Further information on the procedure may be obtained from the Head of Special Examination Services.

### Permitted materials

10.4 A student may use in the examination only such books, notes, statutes, statistical tables, instruments, or other materials as are specifically permitted in the **Admission Notice/timetable**. No other books, notes, instruments, or other materials or aids whatsoever may be introduced into an examination room or be handled or consulted during an examination. Any such materials or aids in the possession of a student on entry to the examination room must be deposited immediately with the Invigilator before the examination starts. It is an examination offence to introduce unauthorised materials into the examination room.

10.5 The use of calculators in the examinations is strictly controlled. Students may use their own electronic calculators in the examinations provided that:

- a) the Programme Regulations permit this
- b) the calculator complies with the specification given in paragraph 10.6
- c) where no such permission is given in the Programme Regulations, calculators may **not** be used.

10.6 Where calculators are permitted, the following specification will apply, unless the Programme Regulations state otherwise:

- Non-programmable. The use of a calculator or other electronic device that communicates, stores textual or numerical information, or displays textual (except error) messages, graphical or algebraic information is strictly forbidden. The use of a calculator with alphabet and/or symbol keys not listed below is strictly forbidden.
- PDAs, mobile phones or other devices are forbidden
- Hand held
- Compact

- Portable
- Solar and/or battery powered
- Quiet in operation
- The use of calculators with the following symbols and functions **only** are permitted:
  - Digit keys 0 to 9 and decimal point;
  - Keys for basic arithmetical functions of addition, subtraction, multiplication, division and equals;
  - Percentage key;
  - Square root key;
  - Basic 3 key memory (MRC, M-, M+);
  - Clear keys (C, AC);
  - On/off key.

10.7 The use of any calculator other than the type specified in the paragraph 10.6 of the General Regulations, or in paragraph 6 of the Programme Regulations, will constitute an examination offence and will be subject to the provisions in paragraph 10.16 of these regulations. Students are responsible for ensuring that their calculators are in working order for the examination. Students must ensure that they have alternative means of calculation in the event of the calculator failing during the examination, either through the use of a second calculator, which complies with the specification given in the Programme Regulations, or to continue the examination without the use of a calculator. If students use electronic calculators in examinations they must indicate on their examination scripts the name and type of machine used. Calculators will **not** be provided by the University.

### Examination offences

10.8 It is an examination offence to introduce into, or use in the examination room, unauthorised materials or aids. Any unauthorised materials or aids brought into an examination room and not deposited with the Invigilator (see paragraph 10.4) must be surrendered to the Invigilator on request. Any materials or aids so surrendered may be handed over by the Invigilator to the University which may make copies of them. The original materials or aids (together with all such copies) may be retained by the University at its absolute discretion.

10.9 Students must not pass any information from one to another during an examination of a written paper. A student may not act in collusion with another student or any other person, nor copy from another student, nor engage in any similar activity. Any of these activities constitutes an examination offence.

10.10 Plagiarism is the presentation of another person's thoughts or words as if they were the student's own: for example, copying from text books and other sources (including the Internet) without due acknowledgement that the passages quoted are copied and without giving the source of those passages (see paragraph 10.12). Plagiarism is an examination offence.

10.11 All work submitted as part of the requirements for any examination must therefore be expressed in the student's own words and incorporate his or her own ideas and judgements.

10.12 Direct quotations from the published or unpublished work of another person must always be clearly identified as such and a full reference to the source must be provided in the proper form. A series of short quotations from several different sources, if not clearly identified as such, constitutes plagiarism in the same way as an unacknowledged quotation from a single source. Equally, if another person's ideas or judgements are summarised, the student must refer to that person in the text, and give details of the work to which reference is made.

Further instructions on acknowledging other people's work and the extent to which other sources may be quoted is given in student handbooks/manuals.

10.13 It is an examination offence to submit work which has been written jointly by two or more persons, unless expressly permitted in the relevant Programme Regulations.

10.14 Assignments, essays, projects, reports, dissertations and other similar work must therefore be the student's own work and must be written without the assistance of other people, except where expressly permitted in the Programme Regulations. Students will be required to submit a signed declaration for all such work submitted, stating that they understand what is meant by plagiarism, and confirming that the work submitted is entirely their own and that the use of published or unpublished works of other people has been acknowledged in accordance with the University's requirements.

10.15 It is the responsibility of the student to safeguard his or her assignments, essays, projects, reports, dissertations and other similar work and to prevent them from being copied by other students.

10.16 The examination offences listed in the foregoing paragraphs will be treated as cheating or irregularities of a similar character under the provisions of the Regulations for Proceedings in respect of Examination Offences by Candidates for University Awards, except as otherwise provided for in the relevant Programme Regulations. Under the Regulations for Proceedings in respect of Examination Offences by Candidates for University Awards students found to have committed an offence may have the results of their examinations withheld, and may be excluded from all future examinations of the University. A copy of these Regulations may be obtained from the Head of Student Assessment.

## **Other matters**

10.17 The University reserves the right to require students sitting an examination for a written paper to remain within the examination hall or its precincts for the duration of the relevant paper.

10.18 All examination scripts are the property of the University and will not be returned to students. Answers to assignments, essays, course projects and other similar work written in the student's own time will only be returned to the student as described in the relevant Programme Regulations. Final reports on research projects or dissertations will not be returned to students, unless indicated otherwise in the Programme Regulations.

10.19 All question papers will be retained by the University.

## **11. Fees**

11.1 Students are required to pay the fees that are due in any particular year in full at the time when they fall due. Fees must be paid in accordance with the University's procedures and deadlines given in the prospectus and Student handbook/manual or equivalent publication (as applicable).

11.2 The University reserves the right to amend previously announced fees. The University also reserves the right to make additional charges (see paragraph 8 of the Programme Regulations).

11.3 Students who are permitted to proceed from a certificate or diploma to a related diploma or degree (see paragraph 4) will be required to pay the fees indicated in paragraph 8 of the Programme Regulations.

11.4 Students who are permitted to proceed from a short course to a certificate, diploma or degree (see paragraph 3) will be required to pay the registration fee for the relevant programme of study and the fee for the remaining subjects, unless indicated otherwise in the Programme Regulations.

11.5 Students who are permitted to transfer their registration to another programme of study (see paragraph 6) shall be required to pay the relevant fees, for the programme concerned, in order to do so. Any additional fee payable shall be at the discretion of the University. Any refund of fees already paid will be subject to the conditions in paragraphs 11.8 and 11.9.

11.6 Students who cancel their registration for one programme of study and register afresh for another programme of study (see paragraph 6.2) will be required to pay the relevant fees, for the programme concerned, in order to do so. Any refund of fees already paid will be subject to the conditions in paragraphs 11.8 and 11.9.

11.7 Students who are permitted to renew their registration at the expiry of the initial period of registration (see paragraph 6) will, as applicable, be required to pay a further full registration fee. Students who are permitted to renew their registration for a programme of study which is being phased out will be required to pay a proportion of the full registration fee (as applicable), the amount depending on the number of years remaining before the last examination for the programme concerned. In addition to the registration fee, **all** students will be required to pay the appropriate subject fees, under the Regulations in force at that time.

## **Refunds**

11.8 Fees will only be refunded in exceptional circumstances and at the discretion of the University (but see also paragraphs 11.9 and 11.10). All refunds will be subject to an administrative charge determined by the University. Any further information is given in paragraph 8 of the Programme Regulations.

11.9 Exemption application fees are **not** refundable.

11.10 Examination entry fees where applicable are **not** refundable nor can they be transferred from one examination to a later one. A student is liable for the full fee at any subsequent entry, in accordance with the Regulations then in force.

# Programme Regulations for Short Courses

**These Programme Regulations apply to the short course programme that is related to the MSc degree and Postgraduate Diploma in Clinical Trials.**

## 1. Introduction

1.1 The University offers individual modules of the MSc degree and Postgraduate Diploma in Clinical Trials as credit bearing short courses.

1.2 The rules governing this short course programme are given in both these Programme Regulations and the General Regulations for Short Courses that follow.

## 2. Short course programme of study

2.1 The following modules are offered as credit bearing short courses under this short course programme:

*The following modules accommodate 125-150 notional study hours*

- CT101 Fundamentals of clinical trials
- CT102 Basic statistics for clinical trials
- CT103 Clinical trials in practice
- CT104 Reporting and reviewing clinical trials

*The following modules accommodate 80-100 notional study hours*

- CT201 Protocol development
- CT202 Trial designs
- CT203 Project management and research co-ordination
- CT204 Regulatory affairs, good clinical practice and ethics
- CT205 Data management
- CT206 Data monitoring and interim analyses
- CT207 Design and analysis of epidemiological studies
- CT208 Further statistical methods in clinical trials
- CT209 Cluster randomised trials

2.2 Students may take up to **three** modules as short courses (see also paragraph 2.2 of the Short Course General Regulations).

2.3 Not all modules will necessarily be available in every year.

2.4 In addition, as there are limits to the number of students who can be registered for each module in any year, the University cannot guarantee that a student's preferred choice of modules will always be available. On registration, therefore, students will be asked to indicate their alternative choices.

2.5 A student's selection of modules may be subject to the agreement of the Course Director.

2.6 Any prerequisites and/or advice on previous modules a student would be expected to have studied in order to undertake a particular module as a short course is given under the individual relevant module outlines in Schedule A.

## Period of registration

2.7 All students registering for a short course will be registered for a maximum period of **two** years (Short Course General Regulations paragraph 4.1). The minimum period of registration for students who choose to be assessed in a short course on this programme is **one** year.

2.8 Further information on the period of registration is given in paragraph 4 of the Short Course General Regulations.

## Computer requirements

2.9 All students will be required to have access to a computer with minimum hardware requirements and to email (see prospectus and Student handbook). Students are responsible for ensuring adequate system maintenance.

2.10 For each individual module taken as a short course students are required to contribute satisfactorily to the computer-conferencing discussion groups.

## 3. Progression to the related awards

3.1 Students who successfully complete the assessment for one or more of the short courses in this short course programme may be considered for progression to the following related awards: MSc degree in Clinical Trials and the Postgraduate Diploma in Clinical Trials. Students progressing from a short course will be required to satisfy the rules of progression for the MSc degree and/or Postgraduate Diploma.

3.2 Students who are permitted to progress may be credited with any short courses successfully completed.

3.3 Further rules governing progression to the degree or diploma is given in paragraph 3 of the Short Course General Regulations.

## 4. Entrance requirements

4.1 In order to be eligible to register for a short course governed by these Regulations, an applicant must have:

*Either*

(c) A first or second class honours degree, or the equivalent, from a university or other institution acceptable to the University of London, in a subject appropriate to the course

*or*

(d) An appropriate professional or technical qualification, together with at least three years' relevant experience, which satisfies the University as a qualification equivalent to a second class honours degree.

4.2 If an applicant does not satisfy the entrance requirements given in paragraph 4.1, the University may still consider the application but will require evidence of the applicant's ability to undertake an advanced course of study.

4.3 For all applicants an advanced level of ability to work in English is required. Applicants may be required to pass or to have passed within the last five years, at the appropriate level, a test of proficiency in English acceptable to the University – for example a TOEFL score of 600 (or 250 in the computerised test) and a minimum of 5 in the TWE or a British Council (IELTS) overall score of 7 or over with a minimum of 7 in the written sub-test.

4.4 All students will be required to have access to a computer with minimum hardware requirements and to email (see prospectus and Student handbook). Students are responsible for ensuring adequate system maintenance. Students who choose to be assessed will also require a calculator (see also paragraph 5.13).

## 5. Assessment

5.1 Students may choose whether or not to be formally assessed in the credit bearing short course for which they are registered. Students who choose to be formally assessed will be examined to the same standard as that required by students registered for the related degree or diploma (see paragraph 3.1). **Paragraphs 5.2 to 5.15 apply to all students who wish to be assessed.**

5.2 The assessment of each module taken as a short course varies. Full details of assessment are given under the individual module outlines in Schedule A.

5.3 For each individual module students are required to contribute satisfactorily to the computer-conferencing discussion groups and to attempt the written paper in the year of registration for the module concerned, unless they have been given permission to defer one or more of these elements.

5.4 Examinations by written paper, whenever held, will take place on one occasion each year, normally in **June**.

5.6 A student who fails to satisfy the Examiners in an examination at the first attempt will be permitted to make **one** further attempt at that examination. The maximum number of attempts permitted at any examination is **two** (Short Course General Regulations, paragraph 6.1) *provided* the student's registration has not expired.

5.7 In all examinations (by both written paper and written assignments) students will be examined both on the module outlines and on the study materials that are current for the year of the examination concerned. As module outlines and study materials are subject to change in advance of each academic year, students must ensure that they have the correct outlines and materials by returning their completed continuing registration form annually. Further information is given in the Student handbook.

5.8 Assignments must be submitted to be received by the deadlines given in the guidelines for the assignments and the Student handbook.

5.9 Where the examination of a module comprises both a written paper and assignment(s), students are expected to submit the assignment(s) in the same academic year as they attempt the written paper for that module.

5.10 The mark awarded for modules that comprise a written paper and assignment(s) will be based on the mark obtained in the written paper and the mark for the assignment(s), weighted on the scales indicated under the individual module outlines in Schedule B. Students who attempt only one element of the assessment for a module within the same academic year may be permitted to carry forward the grade awarded for the element attempted *for one year only* at the discretion of the Board of Examiners.

5.11 Extensions to the deadline for the receipt of assignments will only be granted in extenuating circumstances, and will only be considered if the student has made a written application, to the Course Director, before the deadline. An assignment received after the deadline, without an agreed extension, will **not** be considered.

5.12 Assignments must be submitted electronically (unless otherwise specified in the assignment guidelines). For information on submitting assignments electronically, students should consult the guidelines for the assignments and the Student handbook.

### Calculators

5.13 Students may use their own electronic calculators in the examination where specified in the admission notice. Any calculator must be of the hand-held type, quiet in operation and compact, and must have its own power supply. Programmable calculators may be used. Personal digital assistants (PDAs), mobile phones or other devices which may have a wireless or internet connection are strictly forbidden. Students are entirely responsible for ensuring that their calculators are in working order for the examination and for providing in advance for alternative means of calculation in the event of the calculator failing during the examination.

### Marks

5.14 The pass mark for a short course is C.

5.15 Information on assessment criteria and how a mark achieved for a credit-bearing short course might contribute to a related award, for students who progress to such an award, are given in Schedules C and D of the Programme Regulations for the awards.

## 6. Fees

6.1 The fees payable to the University are as follows:

### Modules CT101 to CT104:

Fee per module taken as a short course

£1530

Examination re-entry fee per module taken as a short course

£140

*(Payable by students who enter an examination on a second occasion, having failed on the first occasion.)*

### Modules CT201 to CT209:

Fee per module taken as a short course

£800

Examination re-entry fee per module taken as a short course

£66

*(Payable by students who enter an examination on a second occasion, having failed on the first occasion.)*

6.2 The fee payable per short course must be paid not later than **31 August**. No study materials will be despatched until all fees due have been received. The deadline for payment of an examination re-entry fee is **1 February** in the year of the examination.

6.3 The fees above refer to the 2008-09 academic year only.

6.4 A fee is normally levied by all examination centres (other than London) and Overseas Examination Centres. This fee is payable by students who choose to be assessed each time they make an examination entry. The University cannot be responsible for this fee nor can it influence the level of fee charged.

### **Progression to an award**

6.5 When a student progresses from a short course to the related Postgraduate Diploma or MSc degree, the following additional fees shall be payable:

- a registration fee to register for the Postgraduate Diploma or MSc degree
- the relevant module fees.

### **Refunds**

6.6 A refund of the short course fee will be given where the fee has been paid but no study materials have been despatched. Such refund will be subject to a charge determined by the University (currently £50).

## Schedule A / Module outlines

The examination numbers are appended to the module titles and these numbers should be used when completing the examination entry forms.

### **CT101 Fundamentals of clinical trials [9160CT101]**

This module will provide students with a solid understanding of the main issues in the design and interpretation of clinical trials. The module will outline the fundamental principles of comparative clinical trials in investigating effectiveness, efficacy and safety of treatments; and compare the benefits of clinical trials in comparison to alternative study designs. The main features of clinical trials, including methodological and organisational considerations, and the principles of trial conduct and reporting will be described. Key decisions surrounding design (including sample size), delivery and assessment of clinical trials will be explored.

*Assessment: one two-hour unseen written paper.*

### **CT102 Basic statistics for clinical trials [9160CT102]**

This module will introduce the basic statistical methods used in clinical trials. In particular, students will learn how to select and apply appropriate statistical methods to analyse data from clinical trials, presenting, interpreting and discussing the analyses clearly and concisely. The module will define probability and describe examples of its use. Normal and binomial distributions and their application will be explored, and the principles of statistical inference, including point and interval estimation, and the role of sampling variation, will be explained. As part of this introduction, students will have the option to carry out basic data analyses from clinical trials using the computer-based Stata software package.

*Assessment: one two-hour unseen written paper.*

### **CT103 Clinical trials in practice [9160CT103]**

*Students are advised to study CT101 Fundamentals of clinical trials or have already studied a similar syllabus, as deemed acceptable by the Course Director, before studying this module.*

The key steps in implementing a clinical trial are investigated in this module, including clarifying and operationalising the primary and secondary objectives of clinical trials, the implications of design choices for implementation of a trial, trial governance, clearances (including research and ethical clearance), and data collection and recruitment methods. The module will explore quality assurance and control, and investigate data processing and management issues.

*Assessment: one two-hour unseen written paper.*

### **CT104 Reporting and reviewing clinical trials [9160CT104]**

*Students are advised to study CT101 Fundamentals of clinical trials and CT102 Basic statistics for clinical trials or have already studied similar syllabuses, as deemed acceptable by the Course Director, before studying this module.*

This module will cover both writing up completed trials, including guidelines for authors (such as the CONSORT Statements for reporting), and also guidelines for readers to aid their critical appraisal of trial reports. Ideally future policy, practice and further research will be guided by the reports not merely of one trial but by the totality of the evidence. A major component of the module will therefore be the role of systematic

reviews, including principles and procedures for conducting systematic reviews, problems and limitations; issues in the identification of randomised controlled trials; assessing trial quality; meta-analysis including cumulative meta-analysis; exploring heterogeneity; investigating for selection bias; and reporting of systematic reviews.

*Assessment: one two-hour unseen written paper and written assignment(s), weighted on the scale 50:50.*

### **CT201 Protocol development [9160CT201]**

**The phrasing of this syllabus has changed. However, this is a change in wording only; the content of the module remains the same as previous years.**

*Students are advised to study the four core modules of the Postgraduate Diploma/MSc degree in Clinical Trials or have already studied similar syllabuses, as deemed acceptable by the Course Director, before studying this module.*

Material in this compulsory module will build on the work of the core modules<sup>2</sup>, but will go further into the steps to be taken for preparing the protocol for a trial. Working in small groups, students will critically appraise a systematic review and start drafting the background section for a trial protocol. Students can then use this as a basis for developing a draft protocol for assessment.

*Assessment: one two-hour unseen written paper and written assignment(s), weighted on the scale 20:80.*

### **CT202 Trial designs [9160CTC202]**

*Students are advised to study the four core modules of the Postgraduate Diploma/MSc degree in Clinical Trials or have already studied similar syllabuses, as deemed acceptable by the Course Director, before studying this module.*

By the end of this module students should be able to appreciate the use of different trial designs such as non-inferiority and equivalence, cross-over, factorial, multi-armed trials and cluster randomised trials in assessing interventions and therapies, including complex interventions. The strengths and weaknesses of each design will be discussed, together with their implications for sample size requirements, analytic methods, interpretation and reporting.

*Assessment: one two-hour unseen written paper and written assignment(s), weighted on the scale 80:20.*

### **CT203 Project management and research co-ordination [9160CT203]**

*Students are advised either to study CT101 and CT103 or have already studied similar syllabuses, as deemed acceptable by the Course Director, before studying this module.*

This module will provide students with a full understanding of project and business management theory in the context of a clinical trial. Students will learn how to develop a project management plan, identify key milestones and develop delivery

<sup>2</sup> Modules CT202 to CT205 may also be useful but are not prerequisites.

plans. The module will explore implementation and co-ordination of the project plan with an emphasis on communication and project promotion and monitoring. It will also consider the major challenge of identifying barriers to implementation and creating deliverable solutions.

*Assessment: one two-hour unseen written paper and written assignment(s), weighted on the scale 80:20.*

### **CT204 Regulatory affairs, good clinical practice and ethics [9160CT204]**

*Students are advised either to study CT101 and CT103 or have already studied similar syllabuses, as deemed acceptable by the Course Director, before studying this module.*

The module will cover the regulatory legislation and associated approvals and permissions required to conduct high quality single-centre, national and international clinical trials. Integral to the legislation is Good Clinical Practice (GCP). Students will gain a solid understanding of GCP and will explore ways of implementing GCP, including risk assessment and trial monitoring. Although the focus will be on trials of medicinal products, a variety of clinical and geographical settings will be examined. Ethical issues will be considered throughout the module.

*Assessment: one two-hour unseen written paper and written assignment(s). Assessment: one two-hour unseen written paper and written assignment(s), weighted on the scale 80:20.*

### **CT205 Data management [9160CTC205]**

**The phrasing of this syllabus has changed. However, this is a change in wording only; the content of the module remains the same as previous years.**

*Students are advised either to study CT101 and CT103 or have already studied similar syllabuses, as deemed acceptable by the Course Director, before studying this module.*

This module covers the principles and practices required to ensure that the patient data collected as part of a clinical trial are of high quality prior to analysis. Compliance with regulatory requirements and International Conference on Harmonisation (ICH) Good Clinical Practice (GCP) is emphasised. Students will learn how to establish the necessary infrastructure (the computing environment and its controls), and how to obtain the necessary skills and resources required to manage a successful data management project.

*Assessment: one two-hour unseen written paper and written assignment(s), weighted on the scale 80:20.*

### **CT206 Data monitoring and interim analyses [9160CT206]**

This module will cover issues relating to the on-going monitoring of the data in a study in order that sufficient data are available to answer the trial's question reliably without recruiting more patients than necessary, or exposing them to unacceptable risks. The module will therefore focus on the ethical context of decisions about whether or not to continue entering patients into trials. A number of different statistical approaches will be explored, and the role and conduct of data monitoring committees in this process will be examined.

*Assessment: one two-hour unseen written paper and written assignment(s), weighted on the scale 80:20.*

### **CT207 Design and analysis of epidemiological studies [9160CT207]**

*Students are advised either to study CT101 and CT102 or have already studied similar syllabuses, as deemed acceptable by the Course Director, before studying this module.*

Epidemiological studies often provide important background information prior to initiating a trial. Additionally, trial datasets may prove to be the basis for further epidemiological research. In this module students will be introduced to the key considerations in planning and designing epidemiological studies. This will include descriptions and interpretations of epidemiological measures, including disease frequency and effect, and the relative merits of different study designs. Strategies for addressing sampling error, bias and confounding in epidemiological studies will be demonstrated. Students will consider a range of analytic methods including stratified and multivariable approaches, and be able to critically appraise the design, analysis and interpretation of published epidemiological studies. Students studying this module will be able to register for additional advanced epidemiology modules.

*Assessment: one two-hour unseen written paper and written assignment(s).*

### **CT208 Further statistical methods in clinical trials [9160CT208]**

*Students are advised either to study CT101 and CT102 or have already studied similar syllabuses, as deemed acceptable by the Course Director, before studying this module.*

This module will build on module CT102 **Fundamentals of clinical trials** to cover more advanced statistical methods used in clinical trials. Topics covered will include the concept of likelihood and regression analyses including logistic, Poisson and Cox regression. The module will also cover adjustment for covariates, analyses of repeated measures and other correlated data, missing data, sub-group analyses and sensitivity analyses. Data analyses will be carried out using Stata.

*Assessment: one two-hour unseen written paper and written assignment(s).*

### **CT209 Cluster randomised trials [9160CT209]**

*Except with the special permission of the Course Director, students must study CT208 Further statistical methods in clinical trials or EP304 Advanced statistical methods in epidemiology before studying this module. Module CT202 may also be useful but is not a prerequisite.*

Trials in which individuals are randomised in groups (clusters) are being increasingly utilised, especially in the fields of infectious diseases, implementation research, and public health and complex interventions. This module will consider the advantages and disadvantages of the use of cluster trials, with particular emphasis on statistical considerations for their design and analysis, as well as the implications for informed consent and reporting.

Please note: students studying this module should have access to Microsoft Excel 97 or later.

*Assessment: one two-hour unseen written paper and written assignment(s).*

# Short Course General Regulations: Masters Level Programmes

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## 1. The Regulations

1.1 The University offers a number of short course programmes to External students. These short course programmes include credit bearing and non-credit bearing short courses.

1.2 The provision of credit bearing and non-credit bearing short course programmes at Masters level, and the registration of External students for credit and non-credit bearing short courses, is regulated by both these General Regulations and the Short Course Programme Regulations.

1.3 Registered External students are required to comply with these General Regulations and the appropriate Short Course Programme Regulations. They must also comply with the procedures, deadlines and instructions issued by the University in, for example, the relevant Student handbook and in the Notice to Candidates, which is sent to students prior to an examination. The University is not responsible for any consequences arising from failure to comply with these Regulations, procedures, deadlines or instructions.

1.4 The rules relating to credit bearing and non-credit bearing short courses in any given year are those included in the General Regulations and the relevant Short Course Programme Regulations for that current year and not in the year in which the student initially registered.

1.5 To register for a short course programme as an External student, an applicant must satisfy any entrance requirements for the programme concerned. In addition, an applicant who was either previously registered as an External student or who was previously enrolled at a constituent College or Institute of the University of London must have made satisfactory payment to the University or College/Institute of all due fees and accounts. An applicant who fails to satisfy this condition will **not** be permitted to register, or to register again, as an External student.

1.6 On all matters concerning the interpretation of these Regulations and the Short Course Programme Regulations, or on which they are silent, the decision of the University shall be final.

### Changes to the short course provision

1.7 Short course programmes are reviewed annually and are subject to change. Two years' notice will normally be given to registered students of any major amendment to a programme, particularly where courses are to be withdrawn.

### Terminology and definitions

1.8 A 'short course programme' is a collection of short courses in a particular field of study, as defined in the Short Course Programme Regulations.

1.9 'Credit bearing' short courses are short courses that may be taken into account for admission, and for credit, to a related or unrelated Postgraduate degree, diploma or certificate provided the formal assessment of that short course has been successfully completed.

1.10 'Non-credit bearing' short courses are short courses that may **not** be taken into account for admission to a related or unrelated Postgraduate degree, diploma or certificate. No credit or exemption for the related or unrelated degree, diploma or certificate will be given.

1.11 Credit bearing and non-credit bearing short courses are collectively known as 'short courses' in these Regulations.

1.12 These Short Course General Regulations describe the individual elements of a short course programme as 'subjects'. In the Short Course Programme Regulations these may be called 'courses', 'units', 'modules' or 'sections'.

1.13 'Formal assessment' is the means by which credit bearing short courses are examined. The forms of assessment associated with the appropriate level of postgraduate study are used.

1.14 The term 'examination' used in these Regulations refers to the **entire** assessment for a credit bearing short course, and includes not only the written paper for that short course but also any coursework, project, dissertation or online requirements that count towards the final assessment.

1.15 Where short courses are associated with a particular Postgraduate degree, diploma and/or certificate, these are referred to as '**related**' degrees, diplomas and certificates.

1.16 The 'Admission Notice' is provided to each student who has made an entry to an examination. The Admission Notice contains the student's candidate number and confirmation of the dates and time of the examination(s) for which he/she has entered.

1.17 The 'Notice to Candidates' contains prescribed rules for the examinations. The Notice to Candidates is provided to students together with their Admission Notice.

### Student complaints procedure

1.18 The University has a *Procedure for External student complaints* which can be found on the External System web site.

## 2. Short courses

2.1 The short courses available are given in the relevant Short Course Programme Regulations for the current year.

2.2 The maximum number of credit bearing and non-credit bearing short courses that may be taken is indicated in the relevant Short Course Programme Regulations.

2.3 All credit bearing short courses will accommodate no less than 50 notional study hours.

2.4 Notional hours for non-credit bearing short courses are indicated in the relevant Short Course Programme Regulations.

2.5 Students may apply to take any short course available in that year unless they have already been awarded a related degree/diploma/certificate, in which case they may not normally

offer a short course which is the same as, or equivalent to, a subject previously taken.

2.6 All students registering for any short course will receive a certificate of registration. A certificate of achievement will be presented to students who have satisfactorily completed any study requirements indicated in the relevant Short Course Programme Regulations and who successfully complete the assessment of a short course.

2.7 To be eligible for a certificate of registration and a certificate of achievement, a student must have been registered for that short course as an External student and must have complied with the Regulations in all respects, and have made satisfactory payment to the University of all due fees. The University reserves the right not to present a certificate to students who fail to satisfy any of these conditions.

2.8 A mark or grade awarded for a short course will not replace any mark or grade for a degree, diploma or certificate already awarded.

2.9 Unless the relevant Short Course Programme Regulations state otherwise, a student whose registration for a short course has been terminated because he or she has exhausted the permitted number of attempts at an examination may apply to register again as an External student for a short course or award in the same or different subject or field of study. All applications will be considered on an individual basis. Permission to register in these circumstances will be given at the discretion of the University and will be subject to any further conditions specified in these Short Course General Regulations or in the relevant Short Course Programme Regulations, or by the University.

### **3. Progression to a degree, diploma or certificate**

#### **Credit bearing short courses**

3.1 Successful completion by formal assessment of a credit bearing short course or courses may be taken into account for admission to a related or unrelated Postgraduate degree, diploma or certificate.

3.2 Successful completion by formal assessment of a credit bearing short course or courses may be taken into account for credit towards the related Postgraduate degree, diploma or certificate, provided that the application is made within **three** years of the completion of the relevant course or courses.

3.3 Where indicated in the relevant Short Course Programme Regulations, a student who has successfully completed the formal assessment of the relevant credit bearing short courses may apply to receive any related awards provided they satisfy the requirements for those awards and the application is made within **three** years of the completion of the relevant short courses.

3.4 Successful completion of a credit bearing short course or courses does not in itself automatically satisfy entry requirements for any Postgraduate degree, diploma or certificate, or ensure credit.

3.5 All applications for progression from a credit bearing short course to a Postgraduate degree, diploma or certificate will be considered on an individual basis and permission to progress,

and, where appropriate, to receive credit, will be at the discretion of the University.

3.6 A student who does not successfully complete the assessment for a credit bearing short course may be permitted to proceed to a degree, diploma or certificate **provided** he or she satisfies the entrance requirements for the degree, diploma or certificate concerned. Such students may be required to cancel their existing registration and to submit a fresh application for registration and comply with the Regulations for that degree, diploma or certificate.

#### **Non-credit bearing short courses**

3.7 The completion of a non-credit bearing short course or courses will not be taken into account for admission, or for credit, to a related or unrelated Postgraduate degree, diploma or certificate.

3.8 A student who is registered for a non-credit bearing short course or courses may apply to register for a degree, diploma or certificate provided he or she satisfies the entrance requirements for the degree, diploma or certificate concerned. Such students may be required to cancel their existing registration and to submit a fresh application for registration and comply with the Regulations for that degree, diploma or certificate.

### **4. Period of registration**

4.1 Students registering for a short course will be registered for a maximum period of two years. There is no minimum period of registration, unless indicated otherwise in the relevant Short Course Programme Regulations.

4.2 Applications for a renewal of registration for a further two years, or for an extension of registration of one year beyond the prescribed maximum period, may be made by students who have not completed all the requirements for a short course for which they are registered. A fee may be payable.

4.3 Renewal of registration and extension of registration are approved only at the discretion of the University and will be subject to the General Regulations and Short Course Programme Regulations that are current at the time of renewal or extension.

4.4 Students who are permitted to proceed from a credit bearing short course to a Postgraduate degree, diploma or certificate will be given a new period of registration as an External student, effective from the date of registration for the degree, diploma or certificate concerned. The maximum period of registration permitted will be the same as for all other degree, diploma or certificate students registered for that programme, as indicated in paragraph 5 of the relevant Programme Regulations.

4.5 The University reserves the right to apply the Disciplinary Procedure and The Suspension and Termination of Registration of Students in Debt process as described in the University of London Ordinances (Ordinances 26 and 28 respectively).

### **5. Assessment**

5.1 The assessment of a short course or courses is governed by the Short Course General Regulations and the relevant Short Course Programme Regulations that is applicable at the time of the examination and **not** at the time that a student was initially

registered or first attempted the examination/assessment concerned.

### **Credit bearing short courses**

5.2 The assessment for credit bearing short courses varies and is as described in the Short Course Programme Regulations.

5.3 Credit bearing short courses will be formally assessed using the forms of assessment associated with the appropriate level of postgraduate study.

5.4 Students may choose whether or not to be formally assessed in the credit bearing short course for which they are registered. Students who choose to be formally assessed will be examined to the same standard as that required by students registered for the related degree, diploma or certificate. All students must comply with the rules given in the Short Course Programme Regulations for those examinations, and may not make more than the number of attempts permitted.

5.5 In order to sit an examination, a student must:

- have completed the relevant application and registration/enrolment procedures with the University by the appropriate deadlines and be registered as an External student for the short course concerned **and**
- have made an examination entry in accordance with both the University's and the appropriate examination centre/Overseas Examination Centre's instructions and deadlines.

5.6 Except in the circumstances of paragraph 5.7, all examinations by written paper for the same short course, wherever held, will take place on the same date and at the same time. The University reserves the right to set different papers in the same subject in separate countries and in different time zones.

5.7 In the event of any unavoidable delay in the arrangement of examinations in a country other than the United Kingdom, the Overseas Examination Centre will arrange for the relevant papers to be taken with as little deviation as possible from the original dates assigned to them. Students are required to abide by any such revised arrangements. The University reserves the right not to mark a paper taken at a different time from that prescribed.

5.8 Where it is deemed necessary, Examiners may change the format or rubric of a written paper, from that of a previous year, without prior notice to students.

5.9 Except where the syllabus/course outline or rubric for a written paper for a particular short course indicates otherwise, all answers to examinations must be written in English.

### **Examination centres**

5.10 Examinations by written paper are held at established examination centres worldwide.

5.11 Outside the United Kingdom and Republic of Ireland, examinations are conducted by independent bodies known as Overseas Examination Centres.

5.12 In countries where an established Overseas Examination Centre exists, students must use the facilities provided by that Centre. The University will not establish an alternative centre in those countries.

5.13 All examinations are held at the discretion of the examination centre/Overseas Examination Centre and are subject to any conditions they may impose.

5.14 Students are required to apply to the relevant examination centre/Overseas Examination Centre for permission to sit an examination. The University can accept no responsibility for making examination arrangements on behalf of a student. It is entirely at the discretion of the examination centre or Overseas Examination Centre to accept or refuse an entry to an examination.

5.15 A fee is normally levied by all examination centres (other than London) and Overseas Examination Centres. This fee is payable by students each time they make an examination entry. The University cannot be responsible for this fee nor can it influence the level of fee charged.

### **Non-credit bearing short courses**

5.16 The assessment for non-credit bearing short courses varies and is as described in the Short Course Programme Regulations. There is **no** formal assessment for non-credit bearing courses.

5.17 Students may choose whether or not to be assessed in the non-credit bearing short course for which they are registered. All students who choose to be assessed must comply with the rules and deadlines given in the Short Course Programme Regulations for the assessment.

5.18 All forms of assessment must be written in English, unless the Short Course Programme Regulations state otherwise.

5.19 In addition to paragraph 5, students are required to comply with the rules on the conduct of examinations given in paragraph 8 of these Regulations.

## **6. Number of attempts permitted**

6.1 A student who fails to satisfy the Examiners in an examination at the first attempt will be permitted to make one further attempt at that examination. The maximum number of attempts permitted at any examination is **two**.

6.2 A student who enters an examination hall to attempt a written paper will be considered to have made an examination attempt. Unless otherwise stated in the Programme Regulations, absence from an examination will not count as an attempt

6.3 The mark or grade awarded for a second attempt at an examination will supersede any previously awarded mark or grade for that examination, unless otherwise indicated in the relevant Short Course Programme Regulations.

6.4 If a student fails to satisfy the Examiners at a second attempt at any examination his or her registration for the short course concerned will cease.

6.5 Except as otherwise provided for by the University, students may not make a further attempt at the examination for a short course that has been passed.

## 7. Students with a disability and/or special needs

7.1 The University has a policy for External students with a disability and/or special needs and a statement explaining this policy is given on the External System web site.

7.2 As part of its policy, the University will make every reasonable effort to accommodate the requirements of a student with a disability and/or special needs by, wherever possible, providing any study materials in a different format (e.g. large print) or another medium, and/or by making special examination arrangements. If the University is unable to provide the study materials in the format which has been requested, the University will endeavour to make an alternative suggestion.

### Special examination arrangements

7.3 The University has a Panel which considers special examination arrangements for students with a disability and/or special needs. The aim of the Panel is to make sure that a student with a disability and/or special needs is neither disadvantaged nor advantaged when compared to other students. The University cannot guarantee that special examination arrangements will be possible in every case.

7.4 Applications from students with a disability and/or special needs may be considered for the use of special aids or for extra time in the examinations.

7.5 Special arrangements for examinations at an ad hoc centre may be made in very exceptional circumstances and then only in the United Kingdom. Arrangements cannot be made for oral or practical examinations to be held at an ad hoc centre, although in exceptional cases it may be possible to permit the use of special aids. Arrangements for examinations in a student's home are not made. Additional fees may be payable for arrangements at an ad hoc centre.

7.6 A student who finds handwriting difficult due to medical or learning difficulties must apply to the University for special arrangements to be made. The University will not transcribe illegible scripts. Any script deemed illegible by the Board of Examiners will be assigned a mark of zero and a fail result will be given. This will count as an attempt at the examination.

## 8. Conduct of examinations

8.1 All students are required to comply with the rules governing the conduct of examinations given below, and for credit bearing short course students, in the Notice to Candidates accompanying the Admissions Notice.

### Representations about examinations

8.2 Students who wish the Board of Examiners to know of any illness or other adequate cause which they think may have affected their performance must immediately inform the Examinations Office and furnish a supporting medical certificate or other supporting certification obtained at the time of illness. Notification received more than three weeks after the date of the last examination will not be taken into account by the Examiners.

8.3 Appeals against the results of examinations may not be made on academic grounds. The University will consider representations concerning examination results made on the grounds of administrative error or where there is concern that the

examination may not have been conducted in accordance with the relevant Instructions and/or Regulations. An administration fee (currently £50 per paper) is payable for the consideration of such representations (refundable in the event that an error is found). Any representation must be made within one month of the publication of the decision of the Board of Examiners to which it relates and should be addressed to the Head of Special Examination Services and be accompanied by payment of the administration fee. Representations must state the grounds on which the appeal is made and provide evidence to support it. Further information on the procedure may be obtained from the Head of Special Examination Services.

### Permitted materials

8.4 A student may use in the examination only such books, notes, statutes, statistical tables, instruments, or other materials as are specifically permitted in the Admission Notice/timetable. No other books, notes, instruments, or other materials or aids whatsoever may be introduced into an examination room or be handled or consulted during an examination. Any such materials or aids in the possession of a student on entry to the examination room must be deposited immediately with the Invigilator before the examination starts. It is an examination offence to introduce unauthorised materials into the examination room.

8.5 The use of calculators in the examinations is strictly controlled. Students may use their own electronic calculators in the examinations provided that:

- the Short Course Programme Regulations permit this
- the calculator complies with the specification given in paragraph 8.6
- Where no such permission is given in the Short Course Programme Regulations, calculators may **not** be used.

8.6 Where calculators are permitted, the following specification will apply, unless the Short Course Programme Regulations state otherwise:

- Non-programmable. The use of a calculator or other electronic device that communicates, stores textual or numerical information, or displays textual (except error) messages, graphical or algebraic information is strictly forbidden. The use of a calculator with alphabet and/or symbol keys not listed below is strictly forbidden.
- PDAs, mobile phones or other devices are forbidden
- Hand held
- Compact
- Portable
- Solar and/or battery powered
- Quiet in operation
- The use of calculators with the following symbols and functions **only** are permitted:
  - Digit keys 0 to 9 and decimal point;
  - Keys for basic arithmetical functions of addition, subtraction, multiplication, division and equals;
  - Percentage key;
  - Square root key;
  - Basic 3 key memory (MRC, M-, M+);
  - Clear keys (C, AC);
  - On/off key.

8.7 The use of any calculator other than the type specified in the paragraph 8.6 of the Short Course General Regulations, or in paragraph 6 of the Short Course Programme Regulations, will constitute an examination offence and will be subject to the provisions in paragraph 8.16 of these regulations. Students are responsible for ensuring that their calculators are in working order for the examination. Students must ensure that they have alternative means of calculation in the event of the calculator

failing during the examination, either through the use of a second calculator, which complies with the specification given in the Short Course Programme Regulations, or to continue the examination without the use of a calculator. If students use electronic calculators in examinations they must indicate on their examination scripts the name and type of machine used. Calculators will **not** be provided by the University.

### **Examination offences**

8.8 It is an examination offence to introduce into, or use in the examination room, unauthorised materials or aids. Any unauthorised materials or aids brought into an examination room and not deposited with the Invigilator (see paragraph 8.4) must be surrendered to the Invigilator on request. Any materials or aids so surrendered may be handed over by the Invigilator to the University which may make copies of them. The original materials or aids (together with all such copies) may be retained by the University at its absolute discretion.

8.9 Students must not pass any information from one to another during an examination of a written paper. A student may not act in collusion with another student or any other person, nor copy from another student, nor engage in any similar activity. Any of these activities constitutes an examination offence.

8.10 Plagiarism is the presentation of another person's thoughts or words as if they were the student's own: for example, copying from text books and other sources (including the Internet) without due acknowledgement that the passages quoted are copied and without giving the source of those passages (see paragraph 8.12). Plagiarism is an examination offence.

8.11 All work submitted as part of the requirements for any examination must therefore be expressed in the student's own words and incorporate his or her own ideas and judgements.

8.12 Direct quotations from the published or unpublished work of another person must always be clearly identified as such and a full reference to the source must be provided in the proper form. A series of short quotations from several different sources, if not clearly identified as such, constitutes plagiarism in the same way as an unacknowledged quotation from a single source. Equally, if another person's ideas or judgements are summarised, the student must refer to that person in the text, and give details of the work to which reference is made. Further instructions on acknowledging other people's work and the extent to which other sources may be quoted is given in student handbook.

8.13 It is an examination offence to submit work which has been written jointly by two or more persons, unless expressly permitted in the Short Course Programme Regulations or student handbook.

8.14 Assignments, essays, projects, reports, dissertations and other similar work must therefore be the student's own work and must be written without the assistance of other people, except where expressly permitted in the Short Course Programme Regulations or student handbook. Students will be required to submit a signed declaration for all such work submitted, stating that they understand what is meant by plagiarism, and confirming that the work submitted is entirely their own and that the use of published or unpublished works of other people has been acknowledged in accordance with the University's requirements.

8.15 It is the responsibility of the student to safeguard his or her assignments, essays, projects, reports, dissertations and other

similar work and to prevent them from being copied by other students.

8.16 The examination offences listed in the foregoing paragraphs will be treated as cheating or irregularities of a similar character under the provisions of the Regulations for Proceedings in respect of Examination Offences by Candidates for University Awards, except as otherwise provided for in the Short Course Programme Regulations or student handbook. Under the Regulations for Proceedings in respect of Examination Offences by Candidates for University Awards students found to have committed an offence may have the results of their examinations withheld, and may be excluded from all future examinations of the University. A copy of these Regulations may be obtained from the Head of Special Examination Services.

### **Other matters**

8.17 The University reserves the right to require students sitting an examination for a written paper to remain within the examination hall or its precincts for the duration of the relevant paper.

8.18 All examination scripts are the property of the University and will not be returned to students. Answers to assignments, essays, course projects and other similar work written in the student's own time will only be returned to the student as described in the relevant short course programme manual. Final reports on research projects or dissertations will not be returned to students, unless indicated otherwise in the Short Course Programme Regulations.

8.19 All question papers will be retained by the University.

## **9. Fees**

9.1 Students are required to pay the fees that are due in any particular year in full at the time when they fall due. Fees must be paid in accordance with the University's procedures and deadlines given in the prospectus and the relevant Short Course Programme Regulations.

9.2 The University reserves the right to amend previously announced fees. The University also reserves the right to make additional charges.

9.3 Students who are permitted to proceed from a short course to a Postgraduate diploma, degree or certificate (see paragraph 3) will be required to pay the registration fee for the diploma, degree or certificate and the fee for the remaining subjects.

9.4 Students who are permitted to renew their registration at the expiry of the initial period of registration (see paragraph 4.2) will, as applicable, be required to pay a further fee for the relevant short course concerned.

### **Refunds**

9.5 Fees will only be refunded in exceptional circumstances and at the discretion of the University. All refunds will be subject to an administrative charge determined by the University.

9.6 Examination re-entry fees, where applicable, are not refundable nor can they be transferred from one examination to a later one. A student is liable for the full fee at any subsequent entry, in accordance with the Regulations then in force.









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