THE TAMIL NADU Dr. M.G.R. MEDICAL UNIVERSITY, CHENNAI -600 032

REGULATIONS FOR THE POST GRADUATE DIPLOMA IN CLINICAL RESEARCH (ONE YEAR)

1. SHORT TITLE AND COMMENCEMENT : These regulations shall be called **THE REGULATIONS FOR THE POST - GRADUATE DIPLOMA COURSE IN "CLINICAL RESEARCH".**

2. REGISTRATION: A candidate admitted into Post-Graduate Diploma Courses in any of the affiliated Institutions of the Tamil Nadu Dr. M.G.R. Medical University, Chennai shall register with the University by remitting the prescribed fees along with the application form for registration duly filled in and forwarded to the Controller of Examinations of t his University through the Head of the affiliated institution within the stipulated date. The candidate's name must be registered in the University within 3 months from the date of his/her admission.

3. ELIGIBILITY: Candidates for admission to the **One year Post-Graduate Diploma in Clinical Research Course** shall be required to possess the Bachelor of Science in Life sciences from a recognised University acquired as a full-time student.

4. . AGE LIMIT:

No upper age limit for Admission

5. ELIGIBILITY CERTIFICATE:

Candidates who have passed any qualifying examination as stated in (1) other than the Tamil Nadu Dr. M.G.R. Medical University shall obtain an "Eligibility Certificate" from this University by remitting the prescribed fees along with the application form and required documents before seeking admission to any one of the affiliated institutions. The application form is available in the University website :web.tnmgrmu.ac.in.

6. DURATION OF THE COURSE : The period of certified study and training for the Post - Graduate Diploma course shall be **ONE YEAR**.

7. COMMENCEMENT OF THE COURSE:

The course shall commence from **1st September** of the academic year. Cut off date for Admission is **30th September every year**.

8. .MEDIUM OF INSTRUCTION:

English shall be the Medium of Instruction for all the Subjects of study and for examinations for the POST-GRADUATE DIPLOMA COURSE IN **"CLINICAL RESEARCH".**

9. CURRICULUM:

The Curriculum and the syllabus for the course shall be as prescribed in these regulations and are subject to modifications by the Standing Academic Board from time to time.

10. CUT-OFF DATE OF THE COURSE:

i) 30th September of the year concerned

ii) The candidates admitted upto **30th September** of the Academic Year shall be registered to take up the **1st year examination during October of the next year**.

11. COMMENCEMENT OF THE EXAMINATION:

15th October / 15 May

If the date of commencement of Examination falls on Saturdays, Sundays or declared Public Holidays, the examination shall begin on the next working day.

12. WORKING DAYS IN AN ACADEMIC YEAR. : The academic year shall consist of not less than **270 working days.**

13. ATTENDANCE REQUIREMENTS FOR ADMISSION TO EXAMINATIONS:

No candidate shall be permitted to appear for the Examination unless he/she put in 85% attendance during his/her period of study and training in the affiliated institution recognized by this University and produces the necessary certificate of study, attendance and progress from the Head of the Institution by maintaining log book.

14. MAINTAINENCE OF LOG BOOK:

- Every Post-graduate Diploma candidate shall maintain a record of skills he has acquired during the one year training period certified by the various Heads of Departments he has undergone training.
- The candidates should also be required to participate in the teaching and training programme of the institute.
- In addition, the Head of the Department shall involve their post-graduate candidates in Seminars, Journal Clubs, Group discussions and conferences.
- The Head of the Department shall scrutinize the Log Book once in every three

months.

- At the end of the course, the candidate should summaries the contents and get the Log Book certified by the Head of the Department.

- The Log Book should be submitted at the time of practical examination for the scrutiny of the Board of Examiners.

15. MIGRATION/TRANSFER OF CANDIDATES:

- A student studying in **POST-GRADUATE DIPLOMA COURSE IN "CLINICAL RESEARCH"** can be allowed to migrate/transfer to another institution of Allied Health Science under the same or another University.

- Under extraordinary circumstances, the Vice Chancellor shall have the powers to place any migration/transfer he/she deems fit before the Governing Council and get its approval for grant of permission/ratification for Migration/Transfer to the candidates undergoing the course of study in affiliated institutions of this University.

16. RE-ADMISSION AFTER BREAK OF STUDY: The regulations for re-admission are as per the University Common Regulation for Re-admission after break of study for all courses**.**

17. VACATION:

There is no vacation

18. Scheme of Examination

Paper	Title	Theory		I.A		Total	
		Max.	Min.	Max.	Min.	Max.	Min.
1	Clinical Research concepts and Study designs	100	50	50	25	150	75
2	Pharmacology and drug development	100	50	50	25	150	75
3	Ethical, Regulatory and Legal issues	100	50	50	25	150	75
4	Clinical data management	100	50	50	25	150	75
5	Clinical Trial project Management	100	50	50	25	150	75

DISTRIBUTION OF THE THEORY MARKS

Type of Questions	Distribution of Marks	Total Marks
Long Essays	2 x 20	40
Short Notes	10 x 6	60

Total 100 mark and Minimum pass mark 50

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- **SYLLABUS OVERVIEW FOR P.G DIPLOMA IN CLINICAL RESEARCH**

Suggested duration: 1 year (including internship)

Module - 1 : Clinical Research concepts and Study designs
Module - 2 : Pharmacology and drug development
Module - 3 : Ethical, Regulatory and Legal issues
Module - 4 : Clinical data management
Module – 5 : Clinical Trial project Management

Module – 1
Clinical Research concepts and Study designs

Units

Definition and scope of clinical research
Historical perspectives on clinical research
Fundamentals and components of clinical research
Basic terminology used in clinical research
Development of Research Question
Writing a protocol
Clinical Research -Study Designs
Recruitment and allocation
Randomization and blinding
Hypotheses testing
Power and sample size calculations
Case Studies - Various clinical Trials in India
Principles of planning and implementing clinical research

Module – 2
Pharmacology and drug development

Units

- Basic pharmacology and clinical research
- Drug nomenclature and dosage forms
- Routes of drug administration
- Overview and phases of drug Development
- Pharmacokinetics
- Pharmacodynamics
- Drug Interactions
- Pharmacogenomics
- Introduction to Pharmacoeconomics
- Principles of Clinical and systemic toxicology

Module - 3

Ethical, Regulatory and Legal issues

Units

- History clinical Research
- Ethical Principles in Clinical Research
- Good Clinical Practices
- Ethical guidelines for biomedical research on Human subjects Schedule-ICMR Guidelines
- Institutional Review Board/Independent Ethics Committee (IRB/IEC)
- Informed consent in research
- Safety monitoring in clinical trials -Termination of Trial
- Contents of the Investigator’s Brochure
- Compliance with Protocol and Informed Consent of Trial Subjects
- Notification/Submission to Regulatory Authority(ies)
- Essential Documents for the conduct of clinical trial
- Legal Issues in Clinical Research
- Clinical Research in International Settings

Module 4
Clinical data management

Units

- Characteristics of data
- Data Representation
- Types of Data and Data Standards
- Data Capture, Storage, and Retrieval
- Data Auditing and Safety data management
- Adverse Event Monitoring and Reporting
- Legal and Regulatory Issues Related to Data Reporting
- Follow-Up and Analysis in clinical research

Module 5
Clinical Trial project Management

Units

- Introduction to Project management
- Feasibility studies and risk assessment
- Budget
- Project planning
- Roles and responsibilities
- Implementing and controlling the project
- Tracking process
- Task network
- Creating schedule
- Risk analysis
- Project closing
- Post-project evaluation

OVER ALL REFERENCE BOOK

S.NO	MODULE	REFERENCE BOOK	Author
1	Clinical research concepts and study designs	1. Design and Analysis of Clinical Trials: Concepts and Methodologies 2. Designing Clinical Research 3. Principles and Practice of Clinical Research 4. Clinical Trials: Study Design, Endpoints and Biomarkers, Drug Safety, and FDA and ICH guidelines 5. .Strategy and Statistics in Clinical Trials: A Non-Statisticians Guide to thinking, designing and executing	1. Shein-Chung Chow, Jen-Pei Liu 2. Stephen B. Hulley, Steven R. Cummings, Warren S. Browner, Deborah G. Grady, Thomas B. Newman 3. John I. Gallin, Frederick P Ognibene, Laura Lee Johnson 4. Tom Brody 5. Joseph Tal
2	Pharmacology and Drug development	1. Pharmaceutical Medicine and Translational Clinical Research 2. Drug Discovery and Clinical Research 3. Stockley's Drug Interactions 4. Clinical Toxicology: Principles and Mechanisms, Second Edition 5. Principles of Pharmacoeconomics	1. Divya Vohora, Gursharan Singh 2. SK Gupta 3. Ivan H. Stockley 4. Frank A. Barile 5. J. Lyle Bootman, Raymond J. Townser
3	Ethical, Regulatory and legal issues	1. Principles and Practice of Clinical Research 2. The Oxford Textbook of Clinical Research Ethics 3. Writing Clinical Research Protocols: Ethical Considerations	1. John I. Gallin, Frederick P Ognibene, Laura Lee Johnson 2. Ezekiel J. Emanuel, Christine Grady, Franklin G. Miller, Reidar K. Lie, Robert A. Crouch 3. 1. Evan DeRenzo, Joel Moss

		4. Reviewing Clinical Trials: A Guide for the Ethics Committee 5. Principles of Good Clinical Practice	4. Johan Petter Einar Karlberg, Marjorie A. Speers 5. Michael J. McGraw, Adam N. George, Shawn P. Shearn, Thomas F. Haws, Jr., Rigel L. Hall
4	Clinical data management	1.Clinical Data Management (24 January 2002) 2. Practical Guide to clinical data management (3rd Edition) 3. The Oxford Textbook of Clinical Research Ethics 4. Clinical Trials Handbook: Design and Conduct (17 October 2012)	1. Richard K. RondelSheila A. VarleyColin F. Webb 2. Susanne Prokscha 3. Ezekiel J. Emanuel, Christine C. Grady, Robert A. Crouch, Reidar K. Lie, Franklin G. Miller, and David D. Wendle 4. Curtis L. Meinert
5	Clinical trial project management	1. Clinical Trial Project Management 2. Project Management in Clinical Trials 3. Oxford Handbook of Clinical and Healthcare Research 4. Handbook for Clinical Research: Design, Statistics, and Implementation 5. Becoming A Successful Clinical Trial Investigator 6. Clinical Trials Risk Management	1. Martin Robinson, Helena Korjonen 2. Alexey Levashov 3. Sumantra Ray, Sue Fitzpatrick, Rajna Golubic, Susan Fisher, Sarah Gibbings 4. Flora Hammond, MD 5. . P. K. Julka 6. Martin Robinson, Simon Cook

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