

Post-Graduate Diploma in
“Clinical Trial and Clinical Data
Management”

SHORT TITLE AND COMMENCEMENT:-

These regulations shall be called as **THE REGULATIONS FOR THE COURSE OF POST GRADUATE DIPLOMA IN “CLINICAL TRIAL AND CLINICAL DATA MANAGEMENT”**.

They shall come into force from the academic year 2020-2021

The Regulations and the Syllabus framed are subject to modification by the Standing Academic Board from time to time.

1. ELIGIBILITY

Candidates for admission to the **Post Graduate Diploma in “Clinical Trial and Clinical Data Management”** should have passed:

- (a) Degree with Clinical Trial and Clinical Data Management
- (b) Degree with Statistics (OR)
- (c) Any Degree with an additional diploma in Statistics / Health Statistics / Biostatistics

2. REGISTRATION:

A candidate admitted in the **Post Graduate Diploma in “Clinical Trial and Clinical Data Management”** 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 this 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 CERTIFICATE

Candidates who have passed any qualifying examination as stated in Regulation No.1 above 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 medical institutions. The application form is available in the University website: <https://www.tnmgrmu.ac.in>.

4. AGE LIMIT:

No upper age limit for Admission

5. DURATION OF THE COURSE:

Total duration of the course is one year (12 months) – beginning with 1st September every year.

6. 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.

7. COMMENCEMENT OF THE EXAMINATIONS:

15th October / 15th May

Theory examinations not to be held on Saturdays and Sundays. If the date of commencement of examination falls on Saturdays / Sundays or declared Public Holidays, the examination shall begin on the next working day.

8. CUT- OFF DATE FOR ADMISSION TO EXAMINATIONS:

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

9. CURRICULUM:

The Curriculum and the syllabus for the course shall be as prescribed by the Standing Academic Board from time to time.

10. MEDIUM OF INSTRUCTION:

English shall be the Medium of Instruction for entire course of the Post Graduate Diploma in Health Promotion and Education.

11. WORKING DAYS IN THE ACADEMIC YEAR:

Each academic year shall consist of not less than 270 working days.

12. ATTENDANCE REQUIRED FOR ADMISSION TO EXAMINATIONS:

- a) No candidate shall be permitted to appear in any one of the parts of **Post Graduate Diploma in “Clinical Trial and Clinical Data Management”** course in Examinations unless he/she has attended the course in the subjects for the prescribed period in an affiliated institution recognized by this University and produce the necessary certificate of study, attendance and satisfactory conduct, progress from the Head of the institution.
- b) A candidate is required to put in minimum of 85% of attendance in both theory and practical separately in each subject before admission to the examinations.

13. MAINTAINENCE OF LOG BOOK:

- a) 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.
- b) The candidates should also be required to participate in the teaching and training programme of the institute.
- c) In addition, the Head of the Department shall involve their post-graduate candidates in Seminars, Journal Clubs, Group discussions and conferences.

- d) The Head of the Department shall scrutinize the Log Book once in every three months.
- e) At the end of the course, the candidate should summaries the contents and get the Log Book certified by the Head of the Department.
- f) The Log Book should be submitted at the time of practical examination for the scrutiny of the Board of Examiners.

14. CONDONATION OF LACK OF ATTENDANCE:

There shall be no condonation of lack of attendance.

15. MIGRATION/TRANSFER OF CANDIDATES:

- A student studying in **Post Graduate Diploma in “Clinical Trial and Clinical Data Management”** 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.

14. SCHEME OF EXAMINATIONS

Post Graduate Diploma in “Clinical Trial and Clinical Data Management” (ONE YEAR)

First Year	Theory Paper	Internal Assessment		Theory		Total		Hours Per Week
		Max	Min	Max	Min	Max	Min	
Paper I	Clinical Research concepts and Study	50	25	100	50	100	50	4

	designs and advanced study designs (sequential Trials and Stopping rules)							
Paper II	Ethics in Clinical Trials and Drug Development	50	25	100	50	100	50	4
Paper III	Applications of Clinical data management System (CDMS) and statistical packages	50	25	100	50	100	50	4
Paper IV	Biostatistics and Statistical Programming	50	25	100	50	100	50	5

INTERNAL ASSESSMENT MARKS:

For making Internal Assessment

- a. At least 3 class test or assignment are to be conducted for such subject during the duration of course.
- b. Internal Assessment will be made on the basis of
 - i) Field seminar performance of the candidate and
 - ii) Record of activity on the field by the candidate.

16. QUESTION PATTERN

No of questions			Total Marks
Essays	2	20	40
Short Notes	10	6	60
Total			100

17. MARKS QUALIFYING FOR A PASS:

A candidate shall be declared to have passed the examination if he/she obtains the following qualifying marks:-

50% of marks in University theory examination

50% of marks in University oral examination and

50% of aggregate marks in Theory, Internal Assessment & oral Examination.

18. REVALUATION/ RETOTALLING OF ANSWER PAPERS:

Retotaling - Revaluation of answer papers is not permitted.

19. CARRY- OVER OF FAILED SUBJECTS:

A candidate who has not passed in a paper / papers can take the examination for that paper / papers again in the Supplementary examination.

20. RE-ADMISSION AFTER BREAK OF STUDY:

The regulations for readmission are as per the University Common Regulation for Re-admission after break of study for all courses.

21. DUR ATION FOR COMPLETION OF THE COURSE OF STUDY:

The duration for the completion of the course shall be fixed as double the duration of the course and the students have to pass within the said period otherwise they have to get fresh admission.

22. AUTHORITY TO ISSUE TRANSCRIPT:

The University shall be the Authority for issuing Transcript after remitting the prescribed fee or as may be prescribed from time to time.

23. MIGRATION/TRANSFER OF CANDIDATES:

Migration/Transfer of candidates from one recognized college to another recognized college of this University or from another University shall not be granted.

24. VACATION:

There is no vacation.

25. AWARD OF MEDALS AND PRIZES:

The University shall award at its Convocation, Medals and prizes to outstanding candidates as and when instituted by the donors as per the schedule prescribed for the award.

PROJECT & VIVA

Project		Viva Voce		Total	
Max.	Min.	Max.	Min.	Max.	Min.
100	50	50	25	150	75