

Maharashtra University of Health Sciences,

Nashik

SYLLABUS

**“Basic Training Programme in Clinical
Research”**

Basic Training Programme on Clinical Research

1. Proper name of the course :-

Basic Training Programme on Clinical Research

2. Duration of the Course :

Total 9 weeks, (60 hrs)

3. Eligibility criteria for admission

Undergraduate students in **Health Sciences**

Selection Criteria for candidates:

Fellows should be selected in a fair and non-discriminatory manner in accordance with the Equal Opportunities. The selection process will be according to MUHS guidelines.

The candidate is expected to appear for the multichoice(MCQ) written examination of 100 marks. Selected candidates will be called for the interview. Ultimately, selection of a candidate for a fellowship will be done by an interview with panel of faculties constituted by the MUHS.

Examination paper for selection of candidates for Fellowship:

Three sets of MCQ paper will be set by the committee of the faculties approved by MUHS & only one paper will be selected by random process on the day of examination.

Evaluation of the examination conducted will be done by a committee of faculties

Merit list & Successful candidates name will appear on the WEB site of MUHS

4. Curriculum of the course

Week 1

Introduction to Clinical Research

- What is Clinical Research?
- Why do we need Clinical Research?
- Formulating a Research Question
- The Process of Drug Development
- Getting Started : Literature Search/Searching Pubmed

Week 2

Ethics

- History of Ethics in Clinical Research & Belmont Report
- Good Clinical Practice- ICH and Indian guidelines
- Role of Research Ethics committee

Week 3

Study Related Process

- Study designs, Randomization
- Informed Consent form, Patient/Volunteer Information Sheet
- Designing a protocol

Week 4

Statistics -1

- Why Statistics
- Data types
- Distribution
- Confidence Intervals
- Sample size calculation

Week 5

Statistics – 2

- P Value
- Parametric and non parametric tests
- Odds ratio and relative risk + problem solving
- Demo on Microsoft Excel, PS software

Week 6

Regulatory Module /GLP

- ICMR Guidelines on Biomedical Research
- Figures and Graphs
- Presentations by students – 90 mins (3 students)

Week 7

Report Writing

- Critical appraisal of published papers
- How to write a research paper
- Case Reports

Week 8

Miscellaneous

- Careers in Clinical Research
- Pharmacoeconomics & Pharmacogenomics

Week 9

- Communication Skills

5. Teaching Scheme : Total periods and periods allotted to each topic

- No. of Modules : 9
- Total Duration : 27 hours
- Timings : Every Friday, 15 :00 – 18:00 hrs

- Attendance : 100% is ideal. Attendance is a must for 8 out of 9 modules. Those who attend less than 8 modules will not be allowed to appear for the examination and will not be eligible for the award of the certificate.

6. Text books and reference books :

Books

- Guide to clinical trials – Bert Spilker
- Methodology of clinical drug trials – Spriet and Simon
- Designing clinical research – Hulley and Cummings
- Intuitive Biostatistics – Harvey Motulsky
- Statistics at square one – Swinscow
- How to write a research paper – George M Hall

Journals

- Lancet
- New England Journal of Medicine
- British Journal of Clinical Pharmacology
- Drug
- Drug Safety
- British Medical Journal
- Indian Journal of Medical Research

7. Infrastructure required for conduction the course and its availability in your college.

Seminar Hall (capacity for 50 students), LCD projection, laptop, black board, air-conditioning and software for teaching. The Course does not require clinical facilities. Clinicians from the institute will be teachers for the course.

8. Faculty required with their qualification and experience :

Those with MD in Internal Medicine, Paediatrics, Pharmacology, Preventive and Social Medicine with 5 years teaching/training and **research** experience in academia or pharmaceutical industry are eligible as faculty. **Renowned researchers may be invited as visiting faculty.**

General Information

9. Advertisement

- On the MUHS website and the intranet
- On the notice boards of the medical colleges
- Basic qualification : Undergraduate Medical students

10. Intake capacity

As prescribed rules by the University

11. Selection

Merit based and as per MUHS rules/guidelines

12. Pattern of Evaluation

The entire course is Credit System based. For each Module, the candidates will be assigned credits for their work by respective Faculty/Institute.

Total Credits: 150

Minimum Number of Credits for successful completion of programme:-120 credits

Transfer of Credit to and from other Universities: Not at present but will be informed once broad consensus among other universities is established.

Breakup of credits

■ **For each Module (or week) 10 credit points (Total of 90 credits)**

Throughout the course student will be evaluated through questions, observing the understanding, etc. Credits will be allotted at the end of each modules.

■ **Project work (25 credit point)**

Preparation of a research/study project on a research question under faculty guidance and presentation of it.

■ **Practicals (35 credit points)**

1. Open book exam for Statistics module. **(15 credit points)**
2. Discussion on journal article **(10 credit points)**
3. Viva **(10 credit points)**

15. Announcement of results

Results will be announced on the website and notice board within one week of the conclusion of the examination.

16. Award of Fellowship

Certificates will be awarded by the MUHS after the results will be sent to the MUHS.