

As Per NEP 2020

University of Mumbai



Syllabus for Basket of OE Life Sciences	
Board of Studies in Life Sciences	
UG First Year Programme	
Semester II	
Title of Paper	Credits 2/ 4
I) Clinical Research	2
From the Academic Year	2024 – 2025

I. Name of the course: Life Sciences - Clinical Research

Sr.No.	Heading	Particulars	
1	Description the course : Including but Not limited to:		
2	Vertical :	Open Elective	
3	Type :	Theory	
4	Credits :	2 credits (1 credit = 15 Hours for Theory)	
5	Hours Allotted :	30 hours	
6	Marks Allotted:	50 Marks	
7	Course Objectives(CO): The course aims to: CO1 To explain the concepts in clinical research CO2 To understand the importance of phases of clinical trials CO3 To discuss about the ethics involved in clinical research clinical trials		

8	Course Outcomes (OC): The learner would be able to: OC 1. Know about history and importance clinical research OC 2. Know about phases 1, 2, 3 4 of clinical trials OC 3. Know about the ethics and its background in clinical research	
9	Module 1:-Introduction to clinical research	Lectures 15
	1. Definition of Clinical Research 2.History of Clinical Research 3. CPCSEA Guidelines & Pre-clinical Trials 4.Different Phases of Clinical Research 5.Subtypes of Phase 1,2 and 3 of clinical trials 6.Phase 4 of clinical trials	1 2 3 4 3 2
	Module 2: Ethics in Clinical Research	15
	Ethics committees, constitution and practices Codes in Ethics -The Belmont report The declaration of Helsinki etc. Informed consent in clinical trials a. Misconduct and Fraud in clinical research b. Ethics in clinical research publication; publication policy, Canadian guidelines.	2 3 1? 2 2

10 and 11.	Text and Reference Books: 1. Textbook of Clinical Research by Vikash Dhikav 2. Clinical Research made easy by Mohit Bhandari 3. Essentials of Clinical Research by Dr. Rabindra B. Ghooi 4. Practical Guide to Clinical Data Management by Susanne Prokscha - Taylor & Francis		
12	Internal Continuous Assessment: 40%	Semester End Examination: 60%	
13	Continuous Evaluation through: Quizzes, class test, presentation, project, role play, creative writing, assignment etc.: 15 marks Attendance and Participation: 05 marks. Total 20 marks.	Theory evaluation: 30 marks.	
14	Format of Question Paper: Details given at the end of the document.		

Evaluation for Open Elective Course: 50 Marks

The evaluation of these courses would include continuous evaluation (internal assessment) and Semester end examinations (External assessment). The evaluation pattern would be as follows:

Internal Assessment: 20 marks.

Quizzes, class test, presentation, project, role play, creative writing, assignment etc: 15 marks.

Attendance and Participation: 05 marks

External Assessment: 30 marks.

Theory Component: 30 marks.

- Duration: **1 Hour**
- Theory question paper pattern:

Question No.	Unit	Question	Marks
Q1.	I	Any 1 out of 2 (1 or 1a, b)	12
Q2	II	Any 1 out of 2 (2 or 2a, b)	12
Q3.	I and II	Any 2 out of 4 (3: a, b, c, d)	06
		Total	30

**Sign of the
Offg. Dean
Prof. Shivram S. Garje
Faculty of Science &
Technology**

**Sign of the
Offg. Associate Dean
Dr. Madhav R. Rajwade
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