



Department of Biotechnology	LP: BY22020 Rev. No: 00 Date: 06.12.2023
B.E/B.Tech/M.E/M.Tech : <b>Biotechnology</b> PG Specialisation : Biotechnology Sub. Code / Sub. Name : BY22020/CLINICAL TRIALS, BIOETHICS AND BIOSAFETY Unit : I	Regulation: 2022

**Unit Syllabus: Fundamentals of Clinical Trials**

9

Introduction to clinical trials; History of clinical research; Clinical trial phases - Phase I, II, III & IV; CPCSEA guideline & pre-clinical trials; Clinical Trial Registry-India; ICMR policy on research integrity and publication ethics; Multicenter Trials; Regulatory Issues; Case studies.

**OBJECTIVE:** To impart knowledge on clinical trials and regulatory issues related to clinical trials.

Session No *	Topics to be covered	Ref	Teaching Aids
1.	Introduction to clinical trials; History of clinical research	TB4 Pg No. 1-18 RB1 Pg. No. 1-17	LCD & BB
2.	Clinical trial phases - Phase I, II, III & IV	TB1 Pg No.23-25 TB4 Pg No.5-9 IS7	LCD, Blended Learning & BB
3.	CPCSEA guideline & pre-clinical trials	IS3	LCD
4.	Clinical Trial Registry-India	TB1 Pg.No.134-135 IS 5	LCD, ICT Tools & BB
5.	ICMR policy on research integrity and publication ethics	IS 2	LCD
6.	Multicenter Trials	TB4 Pg No. 501-515	LCD, ICT Tools & BB
7.	Regulatory Issues	TB4 Pg No. 519-538	LCD, ICT Tools & BB
8.	Case studies- Clinical Trails	IS1	LCD
9.	Case studies- Clinical Trails	IS1	LCD
<b>Content beyond syllabus covered (if any):</b>			

\* Session duration: 50 minutes



## SRI VENKATESWARA COLLEGE OF ENGINEERING

## COURSE DELIVERY PLAN - THEORY

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Sub. Code / Sub. Name : BY22020/CLINICAL TRIALS, BIOETHICS AND BIOSAFETY  
Unit : II

**Unit Syllabus: CLINICAL TRIAL DESIGN AND METHODOLOGY**

9

Clinical trial study protocol; Patient selection; The consent process; Choice of interventions; Choice of design; Assigning the interventions; Statistical considerations; Randomization; Recruitment of Study Participants; Data Collection and Quality Control; Data and Safety Monitoring; Analysis and reporting

**OBJECTIVE:** To provide insights into clinical trial protocol development and data collection.

Session No *	Topics to be covered	Ref	Teaching Aids
10.	Clinical trial study protocol; Patient selection	TB1 Pg.No.27-32 TB4 Pg. No.74-81	LCD & BB
11.	Clinical trial study protocol; The consent process	TB1 Pg.No.30-32	LCD & BB
12.	Choice of interventions; Choice of design	TB1 Pg. No. 33-37	LCD & BB
13.	Assigning the interventions	TB1 Pg. No. 38-43	LCD & BB
14.	Statistical considerations; Randomization	TB1 Pg. No. 49-74 TB4 Pg. No. 121-143 IS8	LCD, Blended Learning & BB
15.	Recruitment of Study Participants	TB4 Pg. No. 215-230	LCD & BB
16.	Data Collection and Quality Control	TB4 Pg. No. 233-248	LCD & BB
17.	Data and Safety Monitoring	TB4 Pg. No. 244-250	LCD & BB
18.	Analysis and reporting	TB4 Pg. No. 255-274	LCD & BB
<b>Content beyond syllabus covered (if any):</b>			

\* Session duration: 50 mins



Sub. Code / Sub. Name : BY22020/CLINICAL TRIALS, BIOETHICS AND BIOSAFETY  
Unit : III

**Unit Syllabus: BIOETHICS**

9

Moral theory in bioethics; Basic law bioethics; Justice and the right to care; Autonomy and individual responsibility; Informed consent; Informed refusal and the right to refuse treatment; Issues in human reproduction; Medical research-clinical trials; Transplantation ethics.

**OBJECTIVE:** To impart knowledge on ethical theories, ethical issues in medicine, health care and life sciences.

Session No *	Topics to be covered	Ref	Teaching Aids
19.	Moral theory in bioethics	TB3 Pg. No. 25-64	LCD & BB
20.	Basic law bioethics	TB3 Pg. No. 73-81	LCD & BB
21.	Justice and the right to care	TB3 Pg. No. 85-125 RB2 Pg. No. 1-24	LCD & BB
22.	Autonomy and individual responsibility	TB3 Pg. No. 131-146	LCD & BB
23.	Informed consent	TB3 Pg. No. 158-207 IS9	LCD, Blended Learning & BB
24.	Informed refusal and the right to refuse treatment	TB3 Pg. No. 221-259	LCD & BB
25.	Medical research- clinical trials	TB3 Pg. No. 433-451	LCD & BB
26.	Transplantation ethics	TB3 Pg. No. 457-486	LCD & BB
27.	Case studies	TB3 Pg. No. 457-465	LCD & BB
<b>Content beyond syllabus covered (if any):</b>			

\* Session duration: 50 mins



Sub. Code / Sub. Name :BY22020/CLINICAL TRIALS, BIOETHICS AND BIOSAFETY  
Unit : IV

**Unit Syllabus: BIOSAFETY**

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Introduction; Historical Background; Introduction to Biological Safety Cabinets; Primary Containment for Biohazards; Biosafety Levels; Biosafety Levels of Specific Microorganisms; Recommended Biosafety Levels for Infectious Agents and Infected Animals; Research principles for Biosafety; Animal biosafety issues: Hazards associated with animal work - Housing and caging systems - PPE.

**OBJECTIVE:** To provide insights about Biosafety and various levels of biosafety.

Session No *	Topics to be covered	Ref	Teaching Aids
28.	BIOSAFETY-Introduction; Historical Background	RB4 Pg. No. 1-12	LCD & BB
29.	Introduction to Biological Safety Cabinets	RB4 Pg. No. 1-12 TB2 Pg. No. 81-102	LCD & BB
30.	Primary Containment for Biohazards	RB4 Pg. No. 487-508	LCD & BB
31.	Biosafety Levels	RB4 Pg. No. 303-323	LCD, Experiential learning (Lab visit) & BB
32.	Biosafety Levels of Specific Microorganisms	RB4 Pg. No. 90-116	LCD & BB
33.	Recommended Biosafety Levels for Infectious Agents and Infected Animals	RB4 Pg. No. 579-586	LCD & BB
34.	Research principles for Biosafety	RB4 Pg. No. 303-323	LCD & BB
35.	Animal biosafety issues: Hazards associated with animal work	TB5 Pg. No. 327-340 IS3	LCD Experiential Learning (Animal House visit) & BB
36.	Animal biosafety issues: Housing and caging systems - PPE	TB5 Pg. No. 679-683 IS3	LCD & BB
<b>Content beyond syllabus covered (if any):</b>			

\* Session duration: 50 mins



Sub. Code / Sub. Name : BY22020/CLINICAL TRIALS, BIOETHICS AND BIOSAFETY  
Unit : V

**Unit Syllabus: BIOSAFETY GUIDELINES**

9

Government of India; Definition of GMOs & LMOs; Roles of Institutional Biosafety Committee, RCGM, GEAC, BRAI, CRNBio etc. for GMO applications in food and agriculture; Environmental release of GMOs; Biosafety guidelines for genetic engineering/recombinant DNA technology; Risk Analysis; Risk Assessment; Risk management and communication; Overview of National Regulations and relevant International Agreements.

**OBJECTIVE:** To impart knowledge on various biosafety guidelines and monitoring/governing committees, its composition and roles

Session No *	Topics to be covered	Ref	Teaching Aids
37.	BIOSAFETY GUIDELINES - Government of India	RB4 Pg. No. 587-593	LCD & BB
38.	Definition of GMOs & LMOs	RB4 Pg. No. 8-10 IS6	LCD, ICT tools & BB
39.	Roles of Institutional Biosafety Committee, RCGM, GEAC, BRAI, CRNBio etc. for GMO applications in food and agriculture	IS4 Pg. No. 3-8	LCD & BB
40.	Environmental release of GMOs	RB4 Pg. No. 431-435	LCD & BB
41.	Biosafety guidelines for genetic engineering/recombinant DNA technology	IS4 Pg. No. 27-50	LCD & BB
42.	Risk Analysis	RB4 Pg. No. 437-440 TB2 Pg. No. 13-14	LCD & BB
43.	Risk Assessment	RB4 Pg. No. 437-440 TB2 Pg. No. 13-14 RB3 Pg. No. 5-25	LCD & BB
44.	Risk management and communication	RB4 Pg. No. 441-445	LCD & BB
45.	Overview of National Regulations and relevant International Agreements	RB3 Pg. No. 91-94 IS4 Pg. No. 99-101	LCD & BB
<b>Content beyond syllabus covered (if any):</b>			

\* Session duration: 50 mins



Sub. Code / Sub. Name :BY22020/CLINICAL TRIALS, BIOETHICS AND BIOSAFETY

**TEXTBOOKS:**

1. David Machin, Peter M. Fayers, Bee Choo Tai, Randomised Clinical Trials - Design, Practice and Reporting, 2nd Edition, John Wiley & Sons Ltd, 2021.
2. NIH guidelines for research involving recombinant or synthetic nucleic acid molecules, 2019.
3. Gary E Jones, Joseph P DeMarco, Bioethics in Context: Moral, Legal, and Social Perspectives, Broadview Press, 2016, Sixth Edition.
4. Lawrence M Friedman, Curt D Furberg, David L DeMets, David M Reboussin, Fundamentals of Clinical Trials, 5th Edition, Springer International Publishing, 2015
5. Dawn P. Wooley, Karen B. Byers, Biological Safety: Principles and Practices, 5th Edition, ASM Press, 2017.

**REFERENCE BOOKS:**

1. Timothy M. Pawlik, Julie A. Sosa, Clinical Trials, 2nd Edition, Springer, 2020, Second Edition.
2. Carl Elliott, A Philosophical Disease Bioethics, Culture, and Identity, Routledge Press, 1999, First Edition
3. Laboratory biosafety manual, 4th edition, WHO, 2020.
4. Fleming D.O, and Hunt D.L, "Biological Safety: Principles and Practices", 4th Edition, American Society for Microbiology, 2006, Fourth Edition.

**INTERNET SOURCES:**

1. <https://www.fda.gov/media/102332/download>
2. ICMR policy on research integrity and publication ethics, 2019
3. <https://ccsea.gov.in/WriteReadData/userfiles/file/Compendium%20of%20CPCSEA.pdf>
4. [https://dbtindia.gov.in/sites/default/files/uploadfiles/Regulations\\_%26\\_Guidelines\\_for\\_Reocminant\\_DNA\\_Research\\_and\\_Biocontainment%2C2017.pdf](https://dbtindia.gov.in/sites/default/files/uploadfiles/Regulations_%26_Guidelines_for_Reocminant_DNA_Research_and_Biocontainment%2C2017.pdf)
5. <https://ctri.nic.in/Clinicaltrials/faq.php#1a>
6. <https://www.youtube.com/watch?v=0OdQVB-akww>
7. <https://www.youtube.com/watch?v=dsfPOpE-GEs>
8. [https://www.youtube.com/watch?v=Dy\\_NXWjyh44](https://www.youtube.com/watch?v=Dy_NXWjyh44)
9. <https://www.youtube.com/watch?v=Y7uI3sM9wtc>

	Prepared by	Approved by
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Date	13.2.2024	13.2.2024
Remarks *: If the same lesson plan is followed in the subsequent semester/year it should be mentioned and signed by the Faculty and the HOD.		