Q. Code:970052

Reg. No. | | | | | | | | | | | | | |

M.E / M.TECH. DEGREE EXAMINATIONS, MAY 2024

Second Semester

BY22020 – CLINICAL TRIALS, BIOETHICS AND BIOSAFETY

(Biotechnology)

(Regulation 2022)

TIME: 3 HOURS **MAX. MARKS: 100**

COURSE OUTCOMES	STATEMENT	RBT LEVEL
CO 1	Understand about phases of clinical trials and regulatory issues related to clinical trials.	**2**
CO 2	Describe the various ways in which clinical trials can be designed and the advantages and disadvantages of each approach.	**3**
CO 3	Apply relevant ethical principles and provide a rational justification for ethical decisions.	**3**
CO 4	Apply various biosafety levels required for performing biological experiments.	**3**
CO 5	Describe the biosafety guidelines to be followed and the regulatory authorities responsible for biosafety guidelines.	**4**

PART- A (20 x 2 = 40 Marks)

(Answer all Questions)

		CO	RBT LEVEL
1.	Outline the protocols involved in clinical trials phase III & IV.	**1**	**2**
2.	Discuss on importance of preclinical trials.	**1**	**2**
3.	Detail the ICMR policy on research integrity.	**1**	**2**
4.	Explain the process of multicenter trials.	**1**	**2**
5.	Explain the significance of patient selection in a clinical trial study protocol.	**2**	**2**
6.	Outline the process of randomization in a clinical trial and its role in minimizing bias.	**2**	**2**
7.	Discuss the role of data and safety monitoring in ensuring the ethical conduct of clinical trials.	**2**	**3**
8.	Interpret the data analysis and report preparation in clinical research.	**2**	**3**
9.	Assess the moral theory in bioethics.	**3**	**3**
10.	Describe the informed consent in clinical trials.	**3**	**2**
11.	Explain the right to refuse treatment.	**3**	**2**
12.	Analyse the ethical issues in human reproduction research.	**3**	**3**

13.	Discuss the importance of biosafety cabinets in biological research labs.	**4**	**2**
14.	Outline the different biosafety levels.	**4**	**2**
15.	Interpret the biosafety levels followed for infectious agents and infected animals.	**4**	**3**
16.	Assess the hazards associated with animal works.	**4**	**3**
17.	What is Living Modified organism?	**5**	**2**
18.	Infer the role of RCGM in GMOs research.	**5**	**3**
19.	Differentiate risk analysis and risk assessment.	**5**	**3**
20.	List few international agreements pertaining to LMOs.	**5**	**2**

PART- B (5 x 10 = 50 Marks)

			Marks	CO	RBT LEVEL
21. (a)		Elaborate the four different phases of clinical trials and their impact on the approval of drugs by FDA.	**(10)**	**1**	**2**
		(OR)			
(b)		Discuss the process of registering clinical trials in CTRI and its impact on the research community.	**(10)**	**1**	**2**
22. (a)		Interpret the selection, consent process, choice of interventions for the patients involved in the clinical research.	**(10)**	**2**	**3**
		(OR)			
(b)		How data maintenance and monitoring strategies followed during any clinical trials are analysed?Give suitable examples.	**(10)**	**2**	**3**
23. (a)	**(i)**	Assess the importance of considering bioethics in clinical researches to maintain the justice and rights to the patients.	**(6)**	**3**	**3**
	(ii)	Describe the process of informed consent and refusal during the trials.	**(4)**	**3**	**3**
		(OR)			
(b)	**(i)**	Discuss the ethical considerations and regulatory aspects followed in transplantation.	**(6)**	**3**	**3**
	(ii)	Infer the ethical issues considered for IVF treatment.	**(4)**	**3**	**3**
24. (a)		Analyse the different biosafety levels with their specific utilization protocols and identify the potential hazards associated with each level.	**(10)**	**4**	**3**

(OR)

		Marks	CO	RBT LEVEL
(b)	Discuss on the issues relevant to utilization of animals and hazards associated within the animal house in consideration with Institutional Bio Safety Committee (IBSC) protocols.	**(10)**	**4**	**3**
25. (a)	Elaborate the overall advisory, approval and monitoring committees involved in GMOs research and commercialization.	**(10)**	**5**	**4**

(OR)

(b)	Analyse the protocol followed for the risk analysis and assessment followed in the process of GMOs approval for public usage with suitable example. Examine the processes involved in risk analysis, risk assessment, and risk management and communication within this context.	**(10)**	**5**	**4**

PART- C (1 x 10 = 10 Marks)

(Q.No.26 is compulsory)

		Marks	CO	RBT LEVEL
26.	Discuss the complex interplay between environmental release of genetically modified organisms (GMOs) and biosafety guidelines for genetic engineering/recombinant DNA technology.	**(10)**	**5**	**4**