B.Sc. (Hons-Research) Clinical Research Semester II (2024)

PAPERCODE: BCR MIC 301

Paper Title: Ethics in Clinical Research

Time: 2.5 Hrs **Maximum Marks: 60**

Write the roll number at the top immediately on receipt of this question paper. Attempt all questions. All parts of a question must be attempted in continuation. Start answer of a fresh question on a new page. Cite examples whenever necessary.

Q1. Define the following **2x6=12**

i. Meta-analysis
ii. Good Clinical Practices
iii. Bias
iv. Effect Size
v. Intention-to-treat Analysis
vi. Translational Research

Q2. Discuss Off-label use of drugs and legal aspect for physician in India. **12**

OR

Discuss key points in the rational use of medicines with special emphasis on challenges faced in India.

Q3. Describe different methods for screening of New Molecules (NCE) in drug developmentProcess. **12**

OR

Discuss various methods of randomization in clinical trials and its significance.

Q4. Give an outline about calculation of compensation if a subject experiences serious adverse event during clinical trial. Discuss recommended timeline for paying compensation by the sponsor after a trial related serious adverse event. **12**

OR

Discuss the principles of research among vulnerable population according to recent Ethical guidelines in India. What are the protective mechanisms to safeguard their interests.

Q5. Enumerate Essential and additional elements of Informed consent document. Discuss the conditions in which Ethics committee can grant waiver of consent. **12**

OR

Discuss various regulatory drug approval pathways.