

2022

Your Roll Number.....

SCHOOL OF CHEMICAL AND LIFE SCIENCES
B.Sc. Hons. PROGRAM IN CLINICAL RESEARCH
SEMESTER-I, EXAMINATION April-2023

PAPERCODE: BCR DSC 101

PAPERTITLE: Introduction to CR

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

Q 1. Define the following [1.5 X 10=15]

- a. Open label studies.
- b. Sulfanilamide Disaster
- c. Belmont report
- d. Power of the study
- e. Sample Size
- f. Non-Inferiority trial
- g. Case control study
- h. Blinding
- i. CRF
- j. Impartial witness

Q2. Attempt ANY THREE questions from the following [5*3=15]

- a. Write a short note on randomized trials
- b. Write about the matched pair.
- c. Discuss various documents that need to be submitted to ethics committee for approval of protocol
- d. What are the different sources of bias?
- e. Discuss the method by which we can control the biasness in the clinical study.

Q 3. Discuss the quorum, role, and responsibilities of ethics committee.

OR

Discuss various endpoints that need to be considered for planning the clinical study. [15]

Q 4. Discuss the historical evolution that becomes the basis of the clinical research and regulatory guidelines.

OR

Enumerate the various components of the informed consent form. [15]