

Name of Block	Block 1
Name of Elective	Clinical Research Methodology
Location of hospital Lab or research facility	Department of Pharmacology
Name of internal preceptor(s)	Dr Sandeep Kaushal
Name of external preceptor (if applicable)	NA
Learning objectives of elective	1. To design a research question 2. To do literature search for the research question 3. To write a research protocol 4. To design a case record form 5. To design Patient information sheet 6. To design a consent form
Number of students that can be accommodated in this elective	4
Prerequisites for elective	Microsoft word
Learning resources for students	1. GCP guidelines (Indian and ICH GCP) 2. New Drugs and Clinical trial rules 3. Pub Med User Guide 4. The medical Research Handbooks
List of activities of student participation	1. To design a research question in a therapeutic area 2. To do literature search for the research question designed 3. Make A&O for the research question 4. Prepare Material and methods to fulfill A&O of study 5. To design a case record form 6. To design Patient information sheet 7. To design a consent form 8. To plan statistical methods to evaluate the results expected from the study 9. Prepare for Ethics committee review 10. Evaluate a protocol for its strength and weakness
Portfolio entries required	Complete protocol with CRF, ICF and PIS
Log book entry required	Satisfactory completion of protocol with “Meets the expectations (M)” grade

Logbook- *cum*- Portfolio
Elective Module: Clinical Research Methodolgy

Assessment	• Attendance • Completion of research protocol with log book entry • Evaluation of protocol developed • Appear in Mock ethics committee review • Critical evaluation of sample protocols (including CRF, PIS, ICF) for its strengths and weakness
Other comments	

Logbook- *cum*- Portfolio

Elective Module: Clinical Research Methodolgy

Clinical Research Methodology

Research is essential for generation of evidence. In order to validate the results, the methodology needs to be robust as per current international and national guidelines. One needs to plan the study by doing good background search of all aspects. The most important thing in research is to have a wide range of information on topic of research. Based on the information collected, one needs to formulate the hypothesis and then design a research question. Once the research question has been framed, we need to plan aims and objectives to answer the research question. Later on the methods to achieve the desired objectives need to be defined as per current sensitivity and specificity of evaluation method, technology and standards defined.

A case record form needs to be designed to capture all this information and results in a structured performa. The candidate must be able to present his thoughts and ideas to his peers and experts. He should be able to defend his proposed plan and get peer and expert validation of the study designed. This elective will help the student to understand good clinical practices, Indian guidelines for research and enable him to plan a research study and get exposure to review of project by mock ethics committee.