BIRLA INSTITUTE OF TECHNOLOGY, MESRA, RANCHI
(END SEMESTER EXAMINATION)

CLASS: M.PHARM **SEMESTER : II**
BRANCH: PHARMACY **SESSION : SP/18**

SUBJECT: MPH2037 CLINICAL RESEARCH AND PHARMACOVIGILANCE

TIME: 3 HOURS **FULL MARKS: 60**

INSTRUCTIONS:
1. The question paper contains 7 questions each of 12 marks and total 84 marks.
2. Candidates may attempt any 5 questions maximum of 60 marks.
3. The missing data, if any, may be assumed suitably.
***4*. Before attempting the question paper, be sure that you have got the correct question paper.**
5. Tables/Data hand book/Graph paper etc. to be supplied to the candidates in the examination hall.

Q.1(a)	Discuss the principles to be followed for any research carried on human beings.	[6]
Q.1(b)	In which cases expedited review is to be followed by IEC.	[6]
Q.2(a)	What all components are required in the patient information sheet?	[6]
Q.2(b)	In which cases Reconsent and waiver of consent necessary.	[6]
Q.3(a)	What are Adverse drug reactions. How to classify it. Give predisposing factors effecting ADR's?	[6]
Q.3(b)	Give basic steps in setting up of pharmacovigilance centre.	[6]
Q.4(a)	What are the Inclusion and Exclusion criteria for clinical trial and write the different types of study design in clinical trial?	[6]
Q.4(b)	Classify experimental study design and observational study design in clinical study with suitable examples.	[6]
Q.5(a)	Explain detail about different types of Randomized Controlled Trials.	[6]
Q.5(b)	Define cohort study and what are the advantages and disadvantages of cohort study.	[6]
Q.6(a)	Explain prospective and retrospective cohort study and explain the indications and elements of a cohort study.	[6]
Q.6(b)	What are the general consideration while selection of study subject and selection of comparison group?	[6]
Q.7(a)	Define case –control study with suitable examples and Write advantages and disadvantages of case-control study.	[6]
Q.7(b)	Explain roles and responsibilities of Investigator, Study Coordinator and Sponsor for conducting clinical trial.	[6]

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