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

**CLASS: M.PHARM** **SEMESTER: II**
**BRANCH: PHARMACY** **SESSION:SP/24**

**SUBJECT: MPL204T CLINICAL RESEARCH & PHARMACOVIGILANCE**

**TIME: 3.00 Hours** **FULL MARK: 75**

**INSTRUCTIONS:**

**1. The missing data, if any, may be assumed suitably.**
**2. Before attempting the question paper, be sure that you have got the correct question paper.**
**3. Tables/Data hand book/Graph paper etc. to be supplied to the candidates in the examination hall.**
**5. Answer any five questions.**

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| 1a. | Describe different phases of clinical trials and different regulatory bodies required for conducting clinical trials. | [7] CO I |
| 1b. | Explain different types of interventional study design require for clinical trial study . | [8] CO I&II |
| 2a. | What is Contract research Organization and Clinical Outsourcing? Explain role and responsibilities of CRO | [7] CO I |
| 2b. | Explain Monitoring and Auditing of clinical trial ? | [8] CO I &II |
| 3a. | What is CRF and Explain general principle of CRF design construction? | [7] CO II&III |
| 3b. | Illustrate different types of observational study design require for clinical trial study | [8] COII &III |
| 4a | Differentiate among adverse drug reaction , Side effects and toxic effects and explain different classes of adverse reactions with suitable examples | [7] CO I |
| 4b | Depending on risks involved, IEC review falls under how many categories. | [8] COII |
| 5a | Enumerate different partners in Pharmacovigilance.How National centres & Health professionals act as important partners. | [7] CO I |
| 5b. | How Erice declaration of 1997 provides a framework in drug safety issues. | [8] CO III |
| 6a | Discuss compensation for participants& selection of special groups as research participants. | [7] CO II |
| 6b | What general principles to be followed with regards to research using human beings. | [8] CO III |
| 7a | Discuss compensation for participants& selection of special groups as research participants. | [7] CO II |
| 7b. | Give objectives of ICH-GCP guidelines. Define ADR, GCP & Informed consent as per GCP. | [8] CO I&II |

**:::::26/04/2024 E:::::**