**Name:**

**Enrolment No:**

**UNIVERSITY OF PETROLEUM AND ENERGY STUDIES**

**End Semester Examination, December 2022**

**Course: Ethics in Clinical Research** **Semester : III**

**Program: Integrated (B. Sc.) - (M. Sc.) Clinical Research** **Duration: 3 Hours**

**Course Code: HSCR2016** **Max. Marks: 100**

**Instructions:**

| S. No. | Section A<br>Short answer questions/ MCQ/T&F<br>(20Qx1.5M= 30 Marks) | Marks | COs |
|---|---|---|---|
| Q 1 | What is an "investigational new drug"? | 1.5 | CO1 |
| Q 2 | Application for permission to import of drugs comes under the rule<br>a) 122A<br>b) 122B<br>c) 122DA<br>d) 122E | 1.5 | CO2 |
| Q 3 | What should a narrative of ADR consist of? | 1.5 | CO1 |
| Q 4 | What are the objectives of obtaining IEC/IRB review of the protocol? | 1.5 | CO3 |
| Q 5 | Define orphan drugs? | 1.5 | CO1 |
| Q 6 | Which document created in 1964 forms the basis of ethical considerations in clinical research?<br>a) Declaration of Geneva<br>b) Declaration of Helsinki<br>c) Declaration of Belfast<br>d) All of the above | 1.5 | CO1 |
| Q 7 | What is pharmacovigilance? | 1.5 | CO1 |
| Q 8 | Define cohort study? | 1.5 | CO1 |
| Q 9 | What is the difference between monitoring and auditing? | 1.5 | CO3 |
| Q 10 | Define the term "placebo"? | 1.5 | CO1 |
| Q 11 | What do you understand by "confidentiality" in clinical research? | 1.5 | CO3 |
| Q 12 | What is the purpose of Good Clinical Practice (GCP) | 1.5 | CO3 |
| Q 13 | What is a protocol? | 1.5 | CO1 |
| Q 14 | What is observational research? Give an example. | 1.5 | CO1 |
| Q 15 | How the quality systems are implemented within GCP? | 1.5 | CO3 |
| Q 16 | 122DA rule of Drug and cosmetic acts, 1945 deals with<br>a) Permission to import/manufacture Fixed Dose Concentration | 1.5 | CO2 |

| | | | |
|---|---|---|---|
| | b) Permission to conduct Clinical Trials<br>c) Clinical Trial Definition<br>d) New Drug Definition | | |
| **Q 17** | Enlist three cardinal principles of Belmont report? | **1.5** | **CO3** |
| **Q 18** | What is a AE and how is it different from ADR? | **1.5** | **CO1** |
| **Q 19** | What is source document? | **1.5** | **CO1** |
| **Q 20** | Define double blinding? | **1.5** | **CO1** |
| **Section B<br>(4Qx5M=20 Marks)** | | | |
| **Q 1** | Discuss the toxicity study data required to be submitted for conduct of clinical trial of new drug or investigational new drug? | **5** | **CO5** |
| **Q 2** | Brefily describle the EMA guidance for pharmacoepidemiologic assessment ? | **5** | **CO4** |
| **Q 3** | Highlight the ICMR Ethical guidelines for biomedical research. | **5** | **CO2** |
| **Q 4** | Discuss the ethical aspects of conducting drug trials in pregnant women. | **5** | **CO5** |
| **Section C<br>(2Qx15M=30 Marks)** | | | |
| **Q 1** | Write a short note on following:<br>a) Legal and ethical components of informed consent<br>**b)** Tuskegee Syphilis Study<br>**c)** NDA 505(b) (2) of the FD&C Act | **15** | **CO1,<br>CO3<br>CO4** |
| **Q 2** | Describe the schedule Y for clinical trial regulation in India? | **15** | **CO2** |
| **Section D<br>(2Qx10M=20 Marks)** | | | |
| **Q 1** | What is CDSCO? Explain the structure, role and responsibilities of CDSCO. | **10** | **CO2** |
| **Q 2** | Discuss the FDA Safety Reporting Requirements for INDs and BA/BE Studies? | **10** | **CO4** |