

Roll No.: _____

Enrolment No. _____

PARUL UNIVERSITY

PARUL INSTITUTE OF PHARMACY & RESEARCH

PHARM.D. 5th YEAR · FIRST INTERNAL EXAMINATION: 2021-2022

Subject Name: Clinical Research

Subject Code: 08207501

Time: 10.00am-11.30am

Date: 29/07/2021

Total Marks: 30

Instructions:

1. Make suitable assumptions wherever necessary.
2. You are trained to be a PHARM.D not a story writer, answer to the point.
3. If you have not attended my classes and haven't prepared, don't waste your time, instead pray to GOD.
4. Don't Unnecessarily smile at the person sitting next to you in exam hall, they may also not know answer, moreover exam hall is not a right place for networking.
5. Exams are like EXES, try to get over it as early as possible.
6. It's good to have a beautiful option in life, but here question 3 are compulsory.
7. May you know more than what Hippocrates Knows, Good Luck!!!

I Long Essay. (Answer Any One)

10 X 1 = 10M

1. Interpret Protocol. Enlist the various steps of protocol designing. Explain in detail about the same.
2. Elucidate drug development process. Illustrate in detail about IND application to drug discovery.

II Short Essay. (Answer Any Two)

5 X 2 = 10M

1. What steps can be taken to help ensure privacy, security and confidentiality of the eIC information?
2. Interpret ICF. Under what conditions can informed consent be altered or waived for minimal risk research?
3. What is drug characterization and write about Toxicological approach of Drug Discovery.

III Short Answers. (Answer All)

2 X 5 = 10M

1. Some research ethics committees operate within research institutions (where they may be known by different names, including "institutional review board" (IRB)), while others operate on a regional or national basis.
 - (a) True
 - (b) False
2. One approach to ethical analysis is to identify a set of governing principles and then apply those principles to evaluate the appropriateness of particular behaviour. In bioethics, Which of the following is NOT commonly identified principles:

(P.T.O.)