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JAYPEE UNIVERSITY OF INFORMATION TECHNOLOGY, WAKNAGHAT

MID SEMESTER EXAMINATION- March 2015

B.Tech Biotechnology 8th Semester, BTDD 11th Semester and MTech 4th Semester

COURSE CODE:11B1WBT837 MAX. MARKS: 30

COURSE NAME: Clinical Trials and Database Management

COURSE CREDITS: 3 MAX. TIME: 2 Hrs

*Note: All questions are compulsory. Attempt all questions of a particular section at one place.*



SECTION A (Marks: 6)

**Briefly describe followings (each question carry 1 mark):**

**(1) Write the role of office for human research protection in clinical trials.**

**(2) Why the blinded study is important in research work.**

**(3) How can we locate the presence of particular kind of protein in cells?**

**(4) Why shRNA method is considered to be better compared to siRNA in gene knockdown approach.**

**(5) Differentiate between Placebo and LADME.**

**(6) Explain one to one and one to many relationships with an example each.**

SECTION B (each question carry 3 marks = 9)

1. **Define database. Differentiate between DBMS and RDBMS. Justify your answer with an example.**
2. **Design an information sheet for the patients consent form for the research purpose.**
3. **What is ICH and write the various guidelines of ICH.**

SECTION C (each question carry 5 marks = 15)

1. **Why clinical trials are important for us? Describe in details about the various phases of clinical trials.**
2. **What is an Institutional review board? Write the purpose and role of institutional review board.**
3. **Discuss human rights and ethical challenges in clinical trials. Also write about the ethical problems in clinical trials.**

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