2/17

0906E551

Candidate's Seat No :_____

PG Dip. ACR Examination
PGD in Clinical Research
June 2022

Time : 2-00 Hours] **[Max. Marks : 50**

Instructions: All Questions in **Section I** carry equal marks.
Attempt any **THREE** questions in Section I
Question IX in **Section II is COMPULSORY**

SECTION I

Que. 1 Answer in Detail

(i) Write a brief note on Essential Document for conduct in clinical Trail. 07

(ii) Explain in brief: The Belmont Report. 07

Que. 2 Answer in Detail

(i) Describe: Role and Responsibilities of Sponsor. 07

(ii) Describe: Role and Responsibilities of Investigator. 07

Que. 3 Answer in Detail

(i) Describe about different method of trial designing. 07

(ii) Describe: Cross-over design and replicate design 07

Que. 4 Answer in Detail

(i) Explain in brief IPR (Intellectual property Rights) 07

(ii) Describe: Role of QA-QC. 07

Que. 5 Answer in Detail

(i) Differentiate between IND and ANDA. 07

(ii) Discussion about Factors affecting bioavailability. 07

Que. 6 Answer in Detail

(i) Describe: Thalidomide Tragedy. 07

(ii) Explain General Principle of WMA Declarations of Helsinki 07

Que. 7 Answer in Detail

(i) Explain Phases of Clinical Trail. 07

(ii) Write a short note on NDA (New Drug Application) 07

Que. 8 Answer in Detail

(i) Write a short note on Importance of GCP in clinical research 07

(ii) Describe: Role & Responsibilities of Business development person. 07

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SECTION II

Que.9 Answer in short (Any Eight) 08

A. Name the drug regulatory agency of Canada

B. For drug with short half-life, _____ study design is preferred.

C. Give full form of: ICF

D. What is BABE study?

E. RMP means _____.

F. What do you mean by causality?

G. Post-study documents list includes _____.

H. Phase-II is known as _____.

I. What is unblinding?

J. W What is the difference between an ADE and ADR?