

MHA
THIRD SEMESTER
BASIC AND TRANSLATIONAL RESEARCH PROJECTS
MHA – 303
[USE OMR FOR OBJECTIVE PART]

SET
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Duration: 3 hrs.

Full Marks: 70

Time: 20 min.

(Objective)

Marks: 20

Choose the correct answer from the following:

1×20=20

1. Which of the following events is known for raising awareness about ethical issues in clinical research?
 - a. The Tuskegee Syphilis Study
 - b. The Framingham Heart Study
 - c. The Diabetes Control and Complications Trial
 - d. The Women's Health Initiative
2. The Declaration of Helsinki, adopted by the World Medical Association in 1964, primarily addresses:
 - a. The design of clinical trials.
 - b. The ethical principles for medical research.
 - c. The safety of pharmaceutical products.
 - d. The role of placebos in research.
3. The Belmont Report, published in 1979, is important because it:
 - a. Outlines the history of clinical trials.
 - b. Provides ethical principles and guidelines for research.
 - c. Discusses statistical methods in clinical research.
 - d. Reviews the impact of clinical research on public health.
4. What is the primary purpose of the preclinical stage of clinical research?
 - a. To evaluate the drug's effectiveness in humans.
 - b. To assess the safety and biological activity in animal models
 - c. To conduct large-scale trials for efficacy.
 - d. To gather post-marketing data.
5. In a cohort study, researchers:
 - a. Compare patients with a specific condition to those without it.
 - b. Follow a group of people over time to assess outcomes based on exposures.
 - c. Conduct randomized controlled trials.
 - d. Perform a detailed analysis of a single case.

6. GCP Stands for
 - a. Good Community Practice
 - b. Good Clinical Practice
 - c. Good Clinical Participation
 - d. Good Clinical Participation
7. FDA stands for
 - a. Food Delivery Administration
 - b. Food and Drug Administration
 - c. First Drug Administration
 - d. None
8. In a case-control study, participants are selected based on:
 - a. Randomization.
 - b. Their outcome status.
 - c. Their treatment assignment.
 - d. Their exposure status.
9. Randomized controlled trials (RCTs) are primarily used to:
 - a. Generate hypotheses.
 - b. Establish efficacy and safety of interventions through random assignment.
 - c. Observe outcomes in observational studies.
 - d. Analyze single case reports.
10. Which phase of clinical trials is primarily focused on assessing the safety of a new drug or treatment?
 - a. Phase I
 - b. Phase II
 - c. Phase III
 - d. Phase IV
11. Which study design is most suitable for rare diseases?
 - a. Cohort study
 - b. Cross-sectional study
 - c. Case-control study
 - d. RCT
12. What was the main outcome of the Nuremberg Trials after World War II in relation to clinical research?
 - a. Development of new medical guidelines.
 - b. Establishment of the Nuremberg Code, emphasizing informed consent.
 - c. Implementation of rigorous drug approval processes.
 - d. Creation of the FDA.
13. A key advantage of cohort studies is:
 - a. They can establish a temporal relationship between exposure and outcome.
 - b. They are less time-consuming than case-control studies.
 - c. They require fewer participants than RCTs.
 - d. They eliminate selection bias completely.

14. What distinguishes an observational study from an experimental study?
- a. The use of control groups.
 - b. The absence of intervention by the researcher.
 - c. The focus on hypothesis testing.
 - d. The collection of qualitative data.
15. In a clinical trial, if participants know which treatment they are receiving, this can lead to:
- a. Selection bias
 - b. Observer bias
 - c. Performance bias
 - d. Attrition bias
16. In which phase of clinical research are randomized controlled trials most commonly used?
- a. Phase I
 - b. Phase II
 - c. Phase III
 - d. Phase IV
17. What is the primary way to reduce observer bias in clinical trials?
- a. Blinding participants and researchers
 - b. Increasing sample size
 - c. Standardizing data collection methods
 - d. Using multiple outcome measures
18. What is the primary purpose of a clinical trial?
- a. To determine the safety and efficacy of a treatment
 - b. To test a new drug for marketing purposes
 - c. To compare different marketing strategies
 - d. To gather patient testimonials
19. In a case-control study, what type of bias is most commonly encountered?
- a. Information bias.
 - b. Confounding bias
 - c. Selection bias
 - d. All of the above
20. During which stage do researchers typically design the study protocol and seek regulatory approval?
- a. Preclinical stage
 - b. Phase I
 - c. Phase II
 - d. Phase III

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(Descriptive)

Time: 2 hr. 40 mins.

Marks: 50

[Answer question no.1 & any four (4) from the rest]

1. How many phases are there in clinical trial? Write briefly about the different phases. 10
2. Write briefly the concepts of Open Label study, Single Blind study and Double-Blind study. Compare their advantages and disadvantages. 10
3. On the basis of which study Belmont Report came into existence? What are the fundamental ethical principles established through the report? 10
4. What is the Significance of RCT in Phase-III clinical trials. How it reduces the bias. 10
5. Define basic and translational research. How they are related to each other? 10
6. Write in detail about the WMA declaration of Helsinki. 10
7. Describe about the Nuremberg Code and its guidelines. 10
8. Describe about Public Health Service Syphilis Study. What was the impact of the study? 10

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