



MASINDE MULIRO UNIVERSITY OF SCIENCE AND TECHNOLOGY

(MMUST)

MAIN CAMPUS

UNIVERSITY EXAMINATIONS

MAIN EXAM

2021/2022 ACADEMIC YEAR

THIRD YEAR SECOND SEMESTER EXAMINATION

**FOR THE DEGREE OF BACHELOR OF SCIENCE IN EPIDEMIOLOGY AND
BIOSTATISTICS**

COURSE CODE: HEM 322

COURSE TITLE: PRINCIPLES OF CLINICAL TRIALS

DATE: 20/04/2022

TIME: 8.00-10.00 AM

**INSTRUCTIONS TO CANDIDATES: ANSWER ALL QUESTIONS IN SECTION A AND
ONLY TWO QUESTIONS IN SECTION B.**

TIME: 2 HOURS

MARKS: 70

MMUST observes ZERO tolerance to examination cheating

Paper Consists of 3 Printed Pages. Please Turn Over



SECTION A

SHORT ANSWERS – ANSWER ALL QUESTIONS IN THIS SECTION (EACH QUESTION IS 4 MARKS. TOTAL MARKS = 40)

1. Explain the significance of the following terms in Clinical trials
 - a. Randomization
 - b. Blinding
 - c. Confounding
 - d. Clinical equipoise
 - e. Clinical Trial Design
 - f. Control Group
 - g. Adverse event
 - h. Translational Research
2.
 - a. Define a Placebo treatment.
 - b. Explain when a placebo treatment is acceptable in a Clinical Trial.
3. Describe all the phases of a clinical trial for a new biomedical intervention.
4. A good research proposal must be of sound scientific quality and must have clarity of presentations. What do the two criteria mean?
5. Distinguish between the objectives of a superiority trial and non-inferiority trial.

6. Define a clinical trial outcome or endpoint and explain three commonly used examples of such endpoints.
7. Outline the aspects that are covered by GCP.
8. How do you calculate the following?
 - a. Odds ratio (OR)
 - b. Absolute risk (AR)
 - c. Absolute risk reduction (ARR)
 - d. Number needed to treat (NNT)
9. Outline the four possible interpretations at the end of a Clinical Trial?
10. a. Define Close out
 - b. Explain what happens during this period

SECTION B

ESSAY QUESTIONS. ANSWER ANY TWO QUESTIONS. (EACH QUESTION IS 15 MARKS / TOTAL MARKS = 30)

1. Discuss the Ethical Considerations involved Clinical Trials.
2. Discuss
 - a. Commonly used designs in Clinical Trials
 - b. Commonly used controls in Clinical Trials
3. Discuss the use of protocols in Clinical Trials.

END

