MAASAI MARA UNIVERSITY

REGULAR UNIVERSITY EXAMINATIONS

2022/2023 ACADEMIC YEAR

***FOURTH YEAR SECOND* SEMESTER**

SCHOOL OF SCIENCE
BACHELOR OF SCIENCE IN APPLIED STATISTICS WITH COMPUTING

COURSE CODE: STA 4242
COURSE TITLE: BIOMETRY METHODS
DATE: TIME:

INSTRUCTIONS TO CANDIDATES

1. Answer **ALL** questions from section A and any **TWO** from section B.
2. Use of sketch diagrams where necessary and brief illustrations are encouraged.
3. Read the instructions on the answer booklet keenly and adhere to them.

*This paper consists of **four** printed pages. Please turn over.*

SECTION A (30 MARKS)

Answer all questions

QUESTION ONE (30 MARKS)

(a) Distinguish the following terms as used in design and analysis of clinical trials

(i) Type I error and Type II error. [2 Mks]

(ii) Single Masking and Double Masking. [2 Mks]

(iii) Level of significance and p-value. [2 Mks]

(iv) the prevalence and incidence rate. [2 Mks]

(b) In a case-control study that described an alleged relationship between reserpine and breast cancer, the data were as follows:

	Breast Cancer cases	**Patients without Breast Cancer (Control)**	**Total**
Users of Reserpine	11	26	37
Nonusers of Reserpine	139	1174	1313
Total	150	1200	1350

(i) Compute and compare the proportions of breast cancer for the group that uses reserpine versus the group of nonusers of reserpine. What would be your conclusion? [4 Mks]

(ii) Calculate the odds ratio associated with not using reserpine. Does this result support your conclusion in part (i)? [4 Mks]

(c) The table below compares the levels of carboxyhemoglobin for a group of non-smokers and a group of cigarette smokers. Sample means and standard deviations are shown. It is believed that the mean carboxyhemoglobin level of the smokers must be higher than the mean level of the nonsmokers. There is no reason to assume that the underlying population variances are identical.

Group	**Sample Size (n)**	**Caroxyhemoglobin (%)**	
Nonsmokers	121	$\overline{x} = 1.3$	$s = 1.5$
Smokers	75	$\overline{x} = 1.3$	$s = 1.5$

(i) Identify the response variable. [2 Mks]

(ii) Is the assumption of identical variance justified? Explain. [4 Mks]

(iii) Write the null and alternative hypotheses in the context of the problem. [2 Mks]

(iv) Conduct the test at the 0.05 level of significance. What do you conclude? [6 Mks]

SECTION B (40 MARKS)

Answer any TWO Questions

QUESTION TWO (20 MARKS)

(a) A randomize clinical trial is used to compare the two unequally sized treatment groups using the t-test

(i) Determine the number of patients required to detect a difference of 0.5 standard deviations using $\alpha = .05$ and $\beta = 0.2$. [5 Mks]

(ii) How does the sample size change if twice as many patients are assigned to one treatment group? [4 Mks]

(b) An investigator conducted a small safety and efficacy study comparing the treatment to the placebo with respect to adverse reactions. The data are as follows:

	Treatment	Placebo
Adverse Reaction	12	4
No Adverse reaction	32	40

(i) Estimate the risk difference, relative risk and the odds ratio for the treatment and Placebo groups. [3 Mks]

(ii) Compute and compare the proportions of adverse reaction for the two groups. What would be your conclusion? [4 Mks]

(iii) Calculate the odds ratio associated with adverse reaction. Does this result support your conclusion in part (i)? [4 Mks]

QUESTION THREE (20 MARKS)

(a) Describe briefly each of the four phases of clinical trials. [8Mks]

(b) A group of children five years of age and younger who were free of respiratory problems were enrolled in a cohort study examining the relationship between parental smoking and the subsequent development of asthma. The association between maternal cigarette smoking status and a diagnosis of asthma before the age of twelve was examined separately for boys and for girls.

Gender	**Smoking Status**	**Asthma Diagnosis**	
		Yes	**No**
Boys	**$\geq 1/2$ pkt/day**	17	63

	$< 1/2$ pkt/day	41	274
Girls	**$\geq 1/2$ pkt/day**	8	55
	$< 1/2$ pkt/day	28	316

(i) Obtain estimate of odds ratio using the crude method. [3 Mks]

(ii) Obtain estimate of odds ratio using the Cochran-Mantel-Haenszel procedure. [5 Mks]

(iii) Compare the estimates obtained in (i) and (ii) above. [4 Mks]

QUESTION FOUR (20 MARKS)

(a) Discuss the main ethical issues in clinical trials. [6 Mks]

(b) What is an informed consent? [4 Mks]

(c) What is a clinical trial protocol? [4 Mks]

(d) Discuss the ethical principles and guidelines as provided in the Belmont report (1976) [6 Mks]

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