Reg.No. \_\_\_\_\_\_\_\_\_\_\_\_



**UNIVERSITY**

(Karunya Institute of Technology & Sciences)

(Declared as Deemed-to-be University under Sec.3 of the UGC Act, 1956)

**End Semester Examination-April/May-2017**

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| **Sub. Code :** | **14BI2035** | **Duration :** | **3hrs** |
| **Sub. Name :** | **CLINICAL PRACTICES AND REGULATIONS** | **Max. marks :** | **100** |

**ANSWER ALL QUESTIONS (5 x 20 = 100 Marks)**

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| Q. No. | Sub Div | Questions | Course  Outcome | Marks |
| 1. | For each of the following summaries of studies, write a single sentence that specifies the design and research question; the latter should include the main predictor and outcome variables, and the population sampled. Think about the main inference that can be drawn from the study: To what phenomena and which populations can the findings be generalized? What are the potential errors in drawing and applying these inferences? | | CO1 |  |
|  | a. | Giving vitamin D to patients with vitamin D deficiency can improve strength, but little is known about any influence it may have on the ordinary weakness of aging. We selected 38 men 70 years of age and greater from a hypertension treatment clinic and randomly assigned them to receive either vitamin D3oridentical placebo. Muscle strength of the quadriceps, measured with an isokinetic dynamometer after 6 months of treatment, was similar in the two groups. | **5** |
|  | b. | A random sample of high school students was surveyed in the fall aboutthe frequencyof watching wrestling on television and fighting at school and on dates. The same subjects were surveyed again in the spring. The adjusted odds of reporting fighting witha date in the spring survey increased by 14% (OR = 1.14, 95% CI 1.06− 1. 22)for each episode of wrestling the students reported having watched in the 2-weekperiod before the fall survey. | **5** |
|  | c. | To assess whether the sedative effects of psychotropic drugs might cause hip fractures, we studied 1,021 women with hip fractures and an equal number without hip fracture among elderly Medicaid enrollees. Women who had taken short-acting tranquilizers had no increased risk of hip fracture, but those who had taken tranquilizers with half-lives exceeding 24 hours did have an increased risk(odds ratio, 1.8; 95% CI 1.3 to 2.4). | **5** |
|  | d. | Knowledge about AIDS was studied among 1,526 teen-aged boys and girls in12 secondary schools in Zimbabwe. Ninety-three percent of the children thought that it was an infection caused by having sexual relations, and 10% believed that it could be contracted from toilet seats. | **5** |
| **(OR)** | | | | |
| 2. | Consider the following research questions. First, write each question in a singlesentence that specifies a study design, predictor, outcome, and population. Thendiscuss whether this research question and the design you have chosen meet theFINER (Feasible, Interesting, Novel, Ethical, Relevant) criteria. Rewrite the questionand design until you have overcome any problems in meeting these criteria. | | CO1 |  |
|  | a. | What is the relationship between depression and health? | **5** |
|  | b. | Does eating red meat cause cancer? | **5** |
|  | c. | Can relaxation exercises decrease anxiety during a mammogram? | **5** |
|  | d. | Are there proteomic markers for coronary atherosclerosis? | **5** |
| 3. | The research question is, ‘‘Does maternal height or weight predict infant birthweight?’’ During a 12-month period, an investigator assembles data on consecutive newborns in a large maternity hospital. The study is limited to term newbornsas defined by delivery 38 to 42 weeks after the mother’s last menstrual period.In the maternity ward, the investigator measures each infant’s birth weight andthe mother’s height and weight. Based on the data obtained, the investigatorconcludes that birth weight is strongly dependent on both maternal height andweight. | | CO2 |  |
|  | a. | What kind of study is this? | **6** |
|  | b. | Explain why you agree or disagree with the investigator’s conclusions? | **14** |
| **(OR)** | | | | |
| 4. |  | The research question is, ‘‘What is the prevalence of alcohol and drug use amongpersons who attend rock concerts?’’ Classify the following sampling schemes forselecting individuals to fill out a brief questionnaire, commenting on feasibility andwhether the results will be generalizable to all people who attend rock concerts. | CO2 |  |
|  | a. | As each patron entered the theater, she is asked to throw a die. All patrons whothrow a 6 are selected. | **3** |
|  | b. | As each patron entered the theater, she is asked to throw a die. Men who throwa 1 and women who throw an even number are selected. | **3** |
|  | c. | Tickets to the concert are known to be numbered serially. Each patron whose ticket number ends in 1 is selected. | **3** |
|  | d. | After all the patrons are seated, five rows are chosen at random by drawing from a shuffled set of cards that has one card for each theater row. All patrons in those five rows are selected. | **3** |
|  | e. | The first 27 patrons who enter the theater are selected. | **2** |
|  | f. | Some tickets were sold by mail and some were sold at the box office just beforethe performance. Whenever there were three or more people waiting in line tobuy tickets at the box office, the last person in line (who had the most timeavailable) was selected. | **3** |
|  | g. | When patrons began to leave after the performance, those who seemed willingand able to answer questions were selected. | **3** |
| 5. |  | Classify the following variables as dichotomous, nominal, ordinal, continuous, or ordered discrete. Could any of them be modified to increase power, and how? | CO2 |  |
|  | a. | Sex | **2** |
|  | b. | Age | **2** |
|  | c. | Education (high school degree/no degree) | **2** |
|  | d. | Education (highest year of schooling) | **2** |
|  | e. | History of heart attack (present/absent) | **2** |
|  | f. | Number of alcohol drinks per day | **2** |
|  | g. | Depression (none, mild, moderate, severe) | **2** |
|  | h. | Percent occlusion of coronary arteries | **2** |
|  | i. | Hair color | **2** |
|  | j. | Body weight (obese/not obese) | **2** |
| **(OR)** | | | | |
| 6. | The research question is, ‘‘How much does a family history of ovarian cancer increase the risk for ovarian cancer?’’ The investigator plans a case–control studyto answer this question. | | CO2 |  |
|  | a. | How should she pick the cases? | **3** |
|  | b. | How should she pick the controls? | **3** |
|  | c. | Comment on potential sources of bias in the sampling of cases and controls. | **2** |
|  | d. | How would she measure ‘‘family history of ovarian cancer’’ as the predictor variable of interest? Comment on the sources of bias in this measurement. | **4** |
|  | e. | What measure of association would she use, and what test of statistical significance? | **4** |
|  | f. | Do you think the case–control method is an appropriate approach to thisresearch question? Discuss the advantages and disadvantages of the case–controldesign relative to other possibilities for this research question. |  | **4** |
| 7. |  | The investigator undertakes a case–control study to address the research question, ‘Does eating more fruits and vegetables reduce the risk of coronary heart disease(CHD) in the elderly?’’ Suppose that her study shows that people in the controlgroup report a higher intake of fruits and vegetables than people with CHD.What are the possible explanations for this inverse association between intakeof fruits and vegetables and CHD? How could each of these possibilities be alteredin the design phase of the study? How could they be addressed in the analysis phase?Give special attention to the possibility that the association between eatingfruits and vegetables and CHD may be confounded by exercise (if people who eat more fruits and vegetables also exercise more and this are the cause of their lowerCHD rates). What approaches could you use to cope with exercise as a possibleconfounder, and what are the advantages and disadvantages of each plan? | CO3 | **20** |
| **(OR)** | | | | |
| 8. | A large (> 200 person per arm) trial of hyperfine is being planned. The primary aim is to test whether this herbal extract decreases the incidence of a clinical diagnosis of dementia among elderly men and women who have mild cognitive impairment. | | CO3 |  |
|  | a. | Hyperfine is expected to occasionally cause gastrointestinal symptoms, including diarrhea, nausea, and vomiting. Describe a plan for assessing adverse effects of this new treatment on symptoms or diseases besides cognitive impairment. | **10** |
|  | b. | Describe a general plan for baseline data collection: what types of information should be collected? | **10** |
| **Compulsory:** | | |  |  |
| 9. | The research question is, ‘‘Does vitamin B12deficiency cause hip fractures in the elderly?’’ | | CO3 |  |
|  | a. | Briefly, outline a study plan to address this s research question with a prospective cohort study. |  | **6** |
|  | b. | An alternative approach would be to compare evidence of vitamin B12deficiencyin women who have hadprevious hip fracture with that in women who have-not. Compared with this ‘‘case–control’’ approach, list at least one advantage and one disadvantage of your prospective cohort study. |  | **7** |
|  | c. | Could the cohort study be designed as a retrospective study, and how would this affect these advantages or disadvantages? |  | **7** |

ALL THE BEST