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(University of Choice)

MASINDE MULIRO UNIVERSITY OF SCIENCE AND TECHNOLOGY (MMUST)

UNIVERSITY EXAMINATIONS

2021/2022 ACADEMIC YEAR

MAIN EXAMINATIONS

MAIN CAMPUS

FIRST YEARSECOND SEMESTER EXAMINATIONS

FOR THE DEGREE

OF

MASTER OF SCIENCE IN MEDICAL DIETETICS/ PUBLIC HEALTH NUTRITION

COURSE CODE: **HMD 806/ PHN 922**

COURSE TITLE: **BIOETHICS AND BIOSAFETY IN HUMAN SUBJECT RESEARCH**

DATE : 26TH APRIL 2022 **TIME : 2:00PM – 5:00PM**

INSTRUCTIONS TO CANDIDATES

ANSWER QUESTION ONE AND ANY OTHER TWO QUESTIONS (60 MARKS)

TIME: 3 HOURS

MMUST observes ZERO tolerance to examination cheating

SECTION A: CASE ANALYSES (TOTAL 40 MARKS)

Case Study 1. Principles of Research Ethics in the Developing a Vaccine for Malaria (20 Marks)

A North American university is planning to test a multistage, DNA malaria vaccine. Preliminary studies in North America have been encouraging; immunization of human subjects shows evidence of a strong immune response. Experimental challenge studies in North American volunteers will begin soon. Larger field studies, both Phase II and III, are being planned. A country in sub-Saharan Africa where malaria is endemic has expressed interest in participating in the vaccine research effort. The African and North American researchers begin working together to design a study protocol to assess the vaccine's efficacy in reducing deaths due to malaria in children under five years of age, particularly infants.

A district in the country with a population of approximately 150,000 has developed an effective epidemiologic surveillance system. Trained community health workers (CHWs) visit all homes in each village in the district every three months to record all births, deaths, major illnesses, marriages, and migrations. A centralized, computerized record keeping system was created and is regularly updated with data from the CHWs reports. Nevertheless, most of the villages are remote, and there are only four health posts to serve the entire population. Furthermore, in addition to the high malaria burden (18 percent of annual income lost due to the disease), trained health care workers, laboratory facilities, and medicines are in short supply. Children under five years of age in the study area suffer an average of six bouts of malaria a year. Fatally afflicted children and infants often die less than seventy-two hours after developing symptoms.

The researchers will randomly select potential participants (infants) for the vaccine trial from the database gathered by the CHWs. A study vaccination team will visit each home, explain the study, and obtain informed consent from the appropriate caregiver. Researchers will administer the vaccine or placebo in double-blind fashion to those who agree to participate. Although many children will experience some soreness at the injection site, the risks of vaccination are minor. Once all participants receive the vaccine, the team will leave the village without implementing any other interventions. Using the system already in place – that is, monitoring patients who come to the clinic or hospital with symptoms of malaria, as well as the active surveillance regularly conducted by the CHWs – researchers can collect data on subsequent illness and death due to malaria. If the vaccine is found to be effective, the benefit is prevention of morbidity or mortality due to malaria.

There is no clearly defined immunological marker to measure protective immunity against malaria. As mortality is the most important outcome variable that can be measured, the researchers will look at deaths as a study endpoint. To the extent that health records and verbal autopsies allow, the researchers are specifically interested in those deaths known to be caused by malaria. If all cases of malaria in the study population were identified and treated, researchers could not measure the efficacy of the vaccine in preventing deaths. In the absence of a surrogate marker for mortality, the study researchers do not want to interfere with the "natural" consequences of malaria transmission in the study villages.

Questions:

1. Is the use of a placebo appropriate in this context?
2. Is the study design appropriate to demonstrate the efficacy of the vaccine?
3. Should the researchers provide treatment for malaria cases in the community?
4. Should the researchers provide information on how to prevent illness?
5. The case study does not indicate that any provision has been made for an ethical review by the country where the research is being conducted. If the North American partners insist that the review conducted in North America is adequate, what should the host country do? If the host country does not have the capacity to provide ethical oversight, what options are available?

Case Study 2. Individual versus Community Consent: The Impact of Vitamin A on Diarrhea in Children (20 Marks)

A U.S. university gives a grant to conduct a study to evaluate the impact of periodic doses of high-dose vitamin A on the incidence of diarrhea and acute respiratory infection (ARI) in children less than five years of age. High-dose vitamin A capsules or placebo would be administered in a double-blind fashion every four months for one year to children from six months to five years of age. A record of morbidity (diarrhea and ARI) and mortality data would be measured weekly, and blood samples for vitamin A status would be drawn at zero, six, and 12 months.

To inform the community of the impending study, the local chief and council of elders called the villagers together. In a festive environment, the researchers described the study and answered questions from community members and the council. Later, the village chief and council met briefly and gave their approval. Shortly thereafter, in accordance with the guidelines of the funding university's Institutional Review Board (IRB), the field staff began going house to house to obtain signed parental informed consent for children to participate in the study. The mothers (usually the parent at home during the visit) said that they did not need to sign anything as the chief had already approved the study and they could not sign anything because they could not read what they would be signing.

On the second day, the field staff were summoned to the chief's house and politely informed that since the chief and council had given approval for the study, it was both unnecessary and unacceptable to seek individual signatures. The staff said the grant agreement required them to obtain signed informed consent forms. They were told that if they insisted on doing so, they would have to leave the community.

Questions

1. How should the researcher handle this problem?
2. How critical is signed informed consent in this setting?
3. Is it acceptable to obtain consent from the village chief or is individual consent necessary?
4. Is informed consent culturally bound or is it a universal principle?
5. Are there circumstances when informed consent is unnecessary?
6. Does it protect the researcher or the participant?
7. Can the IRB waive informed consent in such instances?

SECTION B: ESSAY QUESTIONS (TOTAL 30 MARKS)

Question One: 10 marks
With regards to responsible use of animals in experimentation and research. Ethical considerations in the use of animals to advance good and benefits for humans, animals or the environment, demands a demonstration of an appreciation that animals have moral status. Such views are reflected in the following positions: 1) that animals have an intrinsic value which must be respected, 2) that animals are sentient creatures with the capacity to feel pain, and the interests of animals must therefore be taken into consideration. 3) that our treatment of animals, including the use of animals in research, is an expression of our attitudes and influences us as moral actors. Based on the foregone these positions, attempt a comprehensive discussion of the ethical guidelines and principles that should be applied as tools when balancing between harm and benefit during animal research and experimentation.

Question Two: 10 marks
The Cartagena Protocol on Biosafety to the Convention on Biological Diversity is an international agreement which aims to ensure the safe handling, transport and use of living modified organisms (LMOs) resulting from modern biotechnology that may have adverse effects on biological diversity, taking also into account risks to human health. The protocol was adopted in 2000 and entered into force 2003. Attempt a comprehensive discussion on the KEY ELELMENTS of the Cartagena Protocol on Biosafety.

Question Three: 10 marks
The UNESCO's Universal Declaration on Bioethics and Human Rights provides a universal normative framework of principles and procedures to guide the actions of States, individuals, groups, communities, institutions and corporations, public and private. A key element of the declaration is that that it connects bioethics and human rights, addressing ethical issues related to medicine, life sciences and associated technologies as applied to human beings, taking into account their social, legal and environmental dimensions. Attempt a brief analysis of the advantages and challenges of conflating bioethics and human rights as advanced by the declaration.

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INTERNAL EXAMINER

GOODLUCK