AMREF INTERNATIONAL UNIVERSITY

SCHOOL OF PUBLIC HEALTH

DEPARTMENT OF HEALTH SYSTEMS MANAGEMENT AND DEVELOPMENT

MASTER OF SCIENCE IN BIOETHICS / MASTER OF SCIENCE IN HEALTH

END OF SEMESTER EXAMINATION NOVEMBER – DECEMBER 2024

UNIT CODE: MBE 719 Research Ethics
DATE: DEC 2024
TIME: Three Hours **Start:** 5:30 PM **Finish** 8: 30 PM

INSTRUCTIONS

1. This exam is marked out of 100 marks
2. This Examination comprises TWO Sections
   Section A: Compulsory Question (25 marks)
   Section B: Long Answer Questions (75 marks)

SECTION A: COMPULSORY (25 Marks)

Short Answer Questions

Conflict of Interest

BN is a researcher at Utafiti Institute and is implementing a proposal on the genetic diversity of the COVID-19 virus circulating in Kenya. Her study population will include individuals who have been quarantined in quarantine centers. One particular center was televised on national television, showing the very poor conditions in which the participants were living. This center not only had the highest number of COVID-19 cases but also the greatest genetic diversity.

All participants received masks during the study. BN realizes that at the rate they are enrolling, she will get to the sample size faster than she expected and will have excess supplies including masks. One of the study staff suggested that they donate the leftover gloves and masks to the center for everyone else, even though this was not budgeted for in the study. BN

declines to do so, as this might interfere with the infection rates. BN is aware that the new infections at the quarantine are much higher than the national figures but does not share this information with the authorities.

During a study team meeting, the study coordinator raises the issue of re-consenting the participants and informing them of the high infection rate. BN rationalizes that since she has no more than two weeks of enrolment left and that there are rumors that a vaccine will be available soon, there is no need to re-consent the participants, as this will require writing an amendment. By the time the amendment is approved, the study will have stopped enrolling.

Critically analyze the ethical dilemmas related to conflict of interest in the case study involving BN and her research on the genetic diversity of the COVID-19 virus. In your response, address the following components:

1. Evaluate the conflict-of-interest issues presented in this case. (6 marks)
2. Discuss the ethical implications of BN's decision not to donate the leftover supplies and not to report the high infection rates to authorities. (6 marks)
3. Analyze BN's rationale for not re-consenting participants, in light of the principles of informed consent and participant safety. (6 marks)
4. Propose ways in which BN could have addressed these conflicts of interest ethically and professionally while maintaining the integrity of the research and the welfare of the participants. (7 marks)

Support your analysis with relevant ethical guidelines, such as those related to conflict of interest, informed consent, and participant protection.

SECTION B (Set 5 Questions)

ANSWER ANY THREE (3) QUESTIONS (75 Marks)

Long Answer Questions

QUESTION 1 : In 2023, the Global Health Initiative (GHI) launched a multi-country research project aimed at evaluating the efficacy of a new vaccine in diverse populations. The project involved collaboration between several international research institutions and local health authorities. As the research progressed, researchers faced challenges related to ethical and regulatory compliance, both internationally and locally. The researchers referenced the Declaration of Helsinki and the Belmont Report as foundational documents for ethical standards in human research. However, they encountered difficulties in aligning these guidelines with local regulations that differed significantly in terms of informed consent and risk assessment. In one participating country, local ethics committees raised concerns about the

recruitment process, particularly regarding the inclusion of vulnerable populations. They questioned whether adequate protections were in place to ensure informed consent and to minimize risks associated with participation. Researchers also faced challenges related to cultural differences in perceptions of medical research and consent, which affected participant recruitment and retention.

Critically analyze the ethical and regulatory challenges faced by the GHI in conducting human research across different jurisdictions. In your response, address the following components:

A. Evaluate the importance of harmonizing international ethical guidelines with local regulations. ~~What~~ Identify strategies that researchers can employ to navigate these differences effectively? (9marks)

B. Discuss the ethical implications of recruiting vulnerable populations in research. ~~How~~ Discuss how researchers can ensure that informed consent is obtained ethically while respecting local customs and practices. (8 marks)

C. Analyze the ways in which ~~how~~ cultural factors influence ethical considerations in human research. What role does cultural competence play in ensuring ethical compliance and participant engagement? (8 marks)

2. **QUESTION 2:** Evaluate the historical scandals and tragedies associated with research involving human subjects, focusing on their ethical implications and the lessons learned. In your response, address the following components:

1. Select two significant historical scandals and analyze the ethical violations that occurred. ~~What~~ Identify the consequences for the participants involved. (12 marks)

2. Discuss ~~ho.~~ ways in which these scandals have influenced contemporary ethical standards in research involving human subjects. What Identify and list key regulations or guidelines that have emerged as a direct response to these events(13marks)

~~**QUESTION 3:** Informed consent is a foundational ethical and legal principle in research and healthcare. Its development is rooted in historical events, legal precedents, and moral imperatives that emphasize respect for patient autonomy and the right to make informed decisions. However, achieving valid informed consent presents various challenges, including the complexity of information disclosure, comprehension, and voluntariness, especially in vulnerable populations.~~

QUESTION 3: In 2024, a research team aims to investigate the mental health challenges faced by refugees resettling in a new country. The team seeks to understand not only the prevalence of mental health issues but also the personal experiences and coping strategies of these individuals. Given the sensitive nature of the topic, the researchers are considering two study design options: A Mixed-Methods Design and a purely Qualitative Design.

Critically choose one study design and analyze the research design options available to the team in this case study. (10 marks)

In your response, justify your choice based on the ethical considerations associated with each design option and provide a scientific argument supporting your chosen research design, highlighting how it will enhance understanding of the mental health challenges faced by refugees. (15 marks)

QUESTION 4 : Critically analyze the historical, moral, and legal foundations of informed consent in research and healthcare. In your response, address the following components:

1. Provide an overview of the historical events and legal cases that shaped the development of informed consent. (6 marks)
2. Discuss the moral basis of informed consent, focusing on the principles of autonomy, beneficence, and justice. (6 marks)
3. Outline the key components of a valid informed consent process. (6 marks)
4. Analyze the challenges that may arise in obtaining informed consent in practice, including issues related to comprehension, voluntariness, and cultural sensitivity. (7 marks)

Support your analysis with examples and relevant ethical or legal frameworks.

QUESTION 5: Critically analyze the ethical implications of conducting research that involves the interconnectedness of humans, animals, and the environment within the One Health framework. In your response, consider the following aspects:

1. Discuss the importance of collaboration among various disciplines (e.g., veterinary science, human medicine, environmental science) in addressing health issues (9 marks)
2. Evaluate the challenges of obtaining informed consent in studies that involve both human and animal subjects. (8 marks)

3. Assess the adequacy of existing ethical guidelines and regulatory frameworks in governing One Health research. (8 marks)