**SPH 534: ETHICS IN HEALTH CARE AND RESEARCH: -- NOVEMBER 2013**
**MPH 1**

**Candidate Number …… Date …….**

***Please hand in ALL your question paper pages at the end of this test.**

**SECTION A:**

**Answer ALL the questions in this section.**

**Circle the correct answer**

1. What documents must the participant or participant's legally acceptable representatives receive prior to participation in a study? (**5**)
    a. A copy of the signed and dated written Informed Consent. True / False
    b. A copy of the clinical trial protocol. True / False
    c. Certificate of Insurance from the Study Product's manufacturers. True / False
    d. A copy of the IRB approval / clearance of the study True / False
    e. A copy of the investigator's curriculum vitae. True / False

2. The reason why informed consent has to be written down is: (**5**)
    a. It is a test of literacy for the participant True / False
    b. It offers a permanent record. True / False
    c. In cases of dispute it can be referred to. True / False
    d. Commitment can be demonstrated through signing. True / False
    e. It is a requirement in the laws of Zimbabwe True / False
3. In a randomized trial: (**5**)
    a. Participants should not be informed that they may not be receiving any actual treatment. True / False.
    b. The foreseeable risks presented in the informed consent do not require review and approval by an Ethics Review Committee. True / False.
    c. Informed consent must be obtained by a third party without interest in the research. T True / False
    d. Research participants have to be informed of alternative treatments that are available. T True / False

e. The DSMB (Data & Safety Monitoring Board) protects participants from unnecessarily prolonged exposure to inferior therapy. True / False

4. Indicate if true or false. In research: **(5)**
   a. Informed consent is mostly a legal requirement, rather than an ethical obligation. True / False
   b. Written documentation of informed consent is usually required. True / False
   c. The information in informed consent must be presented in a manner that is comprehensible to the potential participant. True / False
   d. Informed consent must be obtained by a third party without direct interest in the research. True / False
   e. The researcher's special cultural or intellectual status should not play a role in inducing the potential research participant's decision. True / False

5. The following documents require IRB approval: (**5**)
   a. Study protocol. True / False
   b. Informed consent. True / False
   c. Investigator's brochure. True / False
   d. Information pamphlets intended for prospective participants. True / False
   e. The research clinic's registration certificate True / False

6. According to the Nuremberg Code: (**5**)
   a. Military doctors should never conduct medical research. True / False
   b. Voluntary consent of the study participant is absolutely essential. True / False
   c. Research must not be conducted in times of war. True / False
   d. Research must be regulated by an international agency. True / False
   e. Research should be guided by results of animal experiments. True / False

7. The ethical principles that govern the conduct of research involving human participants, were developed in response to: (**5**)
   a. Nazi experiments on prisoners on concentration camps. True / False
   b. Placebo-controlled AZT studies in Africa. True / False
   c. Research conducted on pregnant women. True / False
   d. The Tuskegee syphilis study. True / False

e. Failing HIV vaccine trials True / False

8. Indicate if true or false: **(5)**
   a. A prisoner is not autonomous and cannot give informed consent True / False
   b. A community leader's consent to participate in research is more important than an individual's consent. True / False
   c. Written consent should be obtained in **all** research studies True / False
   d. Testing safety of a drug in monkeys is a Phase I study True / False
   e. Beneficence is about fair distribution of risks and benefits True / False

9. Research should not be conducted with vulnerable groups if: **(5)**
   a. It is aimed at benefiting them directly as a group True / False
   b. If it can be conducted using other non vulnerable groups True / False
   c. If non vulnerable groups refuse to participate True / False
   d. Ethic committee approval has been granted True / False
   e. It is studying a problem peculiar to vulnerable populations True / False

10. The following are clear examples of scientific misconduct **(5)**
    a. Misrepresentation of facts True / False
    b. Falsification of credentials True / False
    c. Unintentional breaches of confidentiality True / False
    d. Honest error in interpretation or judgment True / False
    e. Undertaking research without Ethics Committee clearance True / False

11. Disclosing a patient's information without their consent may be justified under the following circumstances: (**5**)
    a. If they have a highly infectious disease True / False
    b. To protect the health worker from contracting HIV. True / False
    c. In cases of child abuse or injury True / False
    d. If failure to do so may expose the patient or others to risk, death or serious harm. T True / False
    e. If the patient is a criminal. True / False

**SECTION B:**

**Answer ALL THREE questions in this section. Each question carries 15 marks.**

1. One half of a class of students argues in favor of the moral permissibility of early abortions. The other half argue against the moral permissibility of abortions of (healthy) fetuses at any stage of pregnancy. Explain what you would expect to be the main ideas of their arguments, highlighting the possible strengths and weaknesses of each argument. Conclude by explaining which side, in your judgment, has the stronger case overall, and why.

2. You have been requested by the Government to advise on compulsory screening of pregnant women for HIV. Write an essay in which you present your opinion, justifying your position.

3. Describe the qualities of a good research ethics committee, outlining what measures you think should be taken to achieve and maintain those qualities for a university institutional research ethics committee.

**END OF QUESTION PAPER**