INVESTIGATOR 101 TEST QUESTIONS

Circle the one correct answer.

Part 1

Ethical Making Session

1. What are the potential benefits for investigators to have knowledge of research ethics?
   A. The knowledge provides a structure for analysis and decision making;
   B. Investigators may make better decisions regarding how they conduct their research;
   C. The knowledge may help investigators to avoid snap decisions;
   D. All of the above.

The Belmont Principles Session

2. What are the three principles of The Belmont Report that underlie the conduct of human research?
   A. Respect for persons, beneficence, and justice;
   B. Do no harm, fair sharing of research benefits and burdens, and equitable selection of subjects;
   C. Respect for persons, voluntary informed consent, and voluntary withdrawal of subjects from research.
   D. Good research design, voluntary participation, and respect for privacy.

3. Assuring privacy of the subjects and the research data and the requirement to obtain informed consent from subjects best reflects which ethical principle.
   A. Beneficence;
   B. Respect for Persons;
   C. Justice;
   D. Do no harm.

History of Research Ethics Session

4. An example of evidence that the Declaration of Helsinki, in contrast to the Nuremberg Code, was taken seriously by American scientists is:
   A. The Tuskegee trial was immediately stopped;
   B. Scientists began, for the first time, to obtain informed consent from research subjects;
   C. Many scientific journal editors began to request that if a human research study were to be published it must have been performed within ethical standards;
   D. All of the above.
5. Which of the following principles is NOT part of the Nuremberg Code?
   A. Voluntary informed consent is essential, there should be no expectation of death or disabling injury, and the research subject may withdraw from the study at any time;
   B. The Investigator must be ready to withdraw a subject from the study, only qualified scientists must conduct research, and the risks of the study must be outweighed by the importance of the research study;
   C. All research study designs must be based on prior animal work, the study designs should avoid unnecessary physical and mental suffering, and the research should yield useful results;
   D. Consent should be in writing, except where the physician deems it necessary to rely upon consent in other than the written form, in the case of legal incompetence informed consent should be obtained from the legal guardian, and for the enrollment of minors, the assent of the minor must be obtained in addition to the parent.

6. What was the significance of the Beecher article, "Ethics and Clinical Research" published in the New England Journal of Medicine in 1966? The article:
   A. Clarified that all research must be peer reviewed;
   B. Exemplified the requirement for written informed consent to be obtained from all subjects participating in research;
   C. Resulted in all Public Health Service (PHS) funded research requiring ethical board review;
   D. Documented to the research community the unethical human research that had been performed.

7. What was the first set of ethical guidelines and standards that were written by researchers and physicians?
   A. Nuremberg Code (1949);
   B. Declaration of Helsinki (1964)
   C. Belmont Report (1979);

8. The Public Health Service (PHS) policy governing human research promulgated in 1966:
   A. Provided the first formal code outlining the rights of human research subjects;
   B. Required prior ethics review of all human subject research by the PHS;
   C. Established and documented the rights of investigators conducting human research;
   D. Established a data safety monitoring board (DSMB) requirement for all PHS-funded research.
**Applying Research Ethics Session**

9. In applying research ethics principles to protocol design, what issues should be considered by the investigator?
   A. Is the research designed so that it will result in valid information?
   B. What are the risks and how can they be minimized?
   C. What are the benefits and how can they be maximized?
   D. All of the above.

10. Which statement is NOT applicable when applying the principle of "respect for persons" in protocol design?
    A. All research populations are equal and should be treated uniformly;
    B. Subject privacy must be maximally protected;
    C. The consent process must maximize autonomy;
    D. Additional protections must be put in place for vulnerable populations.

11. What processes must be present to assure that the research involving human subjects is ethical?
    A. There is appropriate initial and continuing informed consent of subjects;
    B. There is a scientifically valid hypothesis with a favorable risk/benefit ratio;
    C. There are appropriate inclusion and exclusion criteria for recruitment of research subjects;
    D. All of the above.

12. What is a method of maximizing a prospective subject's autonomy in the research setting?
    A. Using trained personnel in the research setting and allowing them sufficient time to communicate with subjects;
    B. Designing the study to maximally protect subject privacy;
    C. Collecting only appropriate and study-specific information;
    D. All of the above.

**Key Issues in Research Session**

13. In addition to physical risks, research subjects may be exposed to what types of risks:
    A. Social and psychological risks;
    B. Legal risks such as incriminating behavior;
    C. Economic risks, such as costs of a device not covered by insurance;
    D. All of the above.
14. When designing a research protocol, the Investigator must consider the ratio, best defined as:
   A. Benefits to subjects must always outweigh the risks;
   B. The potential for risk and potential for benefit must always be equal;
   C. The probability of a bad outcome for the subject versus the probability of something good happening to either the subject or the larger society;
   D. Risks and benefits may be balanced by monetary payment for participation in the study.

15. What benefits of participating in a research study need be considered when evaluating the risk/benefit ratio of a research protocol?
   A. The benefits to the research subject only;
   B. The benefits to the research subject, his/her family, and society;
   C. The money paid to participants in exchange for their taking part in a research study;
   D. None of the above.

16. Investigators must be aware that authority relationships may affect the ethical decision-making process in a research study regarding the conduct, subject selection process, and reporting of data. Examples of such relationships include:
   A. Investigator over staff and Investigator over Subject;
   B. Investigator over staff, Sponsor over Investigator, and Investigator over Subject;
   C. Institutional Official over Investigator, Sponsor over Investigator and Protocol over Investigator;
   D. All of the above.

17. The Milgram Study that used fake electric shock administration demonstrated:
   A. The potential problem of authority relationships;
   B. The importance of learning under stress;
   C. The need for Investigators to maintain authoritative control over the research process;
   D. The need for strict protocol adherence.

18. Under the fiduciary relationship in the research setting, which of the following is TRUE:
   A. The researcher may assume the responsibility of making informed consent decisions for the research subject;
   B. The researcher conducting the study should not also be the research subject's physician;
   C. The researcher must place his or her obligation to protect the subject ahead of all other conflicting interests or else not conduct the research;
   D. The researcher may be compensated directly by the sponsor.
Part 2

Designing Ethical Research Session

1. What are the ethical differences between a physician (health care provider) conducting clinical research and a physician (health care provider) providing clinical care?
   A. In the clinical care setting, the health provider suggests interventions solely for the purpose of benefiting the patient;
   B. In the research setting, the benefit is directed solely to the patient/research subject and the decisions about medical procedures and interventions are made by the health care provider;
   C. In the research setting, the patient/research subject must consent to participate, but the researcher makes all the procedural and interventional decisions;
   D. There are no differences.

Complying with Federal Regulations Session

2. When conducting clinical research in the United States or abroad, the Investigator may be held accountable to comply with which of the following applicable research regulations:
   A. Department of Health and Human Services (DHHS) regulations, including all subparts when applicable;
   B. FDA regulations for all investigational drugs, devices, and biologics;
   C. International Conference on Harmonization Guidelines;
   D. All of the above.

3. What is a Federalwide Assurance?
   A. An agreement between the investigator/researcher and the Department of Health and Human Services (DHHS) regarding the conduct of human research within the investigator’s institution;
   B. An agreement between an institution and the DHHS regarding the conduct of human research at that institution;
   C. A registration system for investigators/researchers with the federal government;
   D. An assurance with the federal government regarding an institution's educational program in human research.

4. Research, which requires IRB review, is as follows:
   A. A systematic investigation designed to develop or contribute to generalizable knowledge about human subjects, whether living or dead;
   B. A systematic investigation designed to develop or contribute to generalizable knowledge about living human subjects;
   C. A systematic investigation on human subjects when the data is identifiable but is from publicly available data sources;
   D. All of the above.
**Obtaining Prior Approval Session**

5. Criteria for IRB approval of a research protocol includes:
   A. There must be an appropriate risk versus benefit ratio and the risks must be minimized where applicable;
   B. When applicable, there is an informed consent process and the consent is documented;
   C. The privacy and confidentiality of the research subjects are safeguarded, and additional safeguards are added for vulnerable subjects, if included in the research;
   D. All of the above.

**Implementing Protocol as Approved Session**

6. Which of the following is an example of a change in protocol that does NOT need prior approval?
   A. Expanding recruitment procedures from printed media to electronic media;
   B. Reallocating of financial support to conduct and complete a research project;
   C. Implementing a procedural change that is less painful, more cost effective and yielding the same outcome;
   D. Changing the informed consent text one Institution's letterhead to a second Institution's letterhead in order to recruit additional subjects.

**Obtaining Informed Consent/Assent Session**

7. Which of the following is/are included in the federal requirements for basic elements of informed consent?
   A. Purpose and duration of the study;
   B. Risks and benefits of study procedures;
   C. Alternative procedures or treatments, if appropriate;
   D. All of the above.

**Documentation of Informed Consent/Assent Session**

8. Each of the following statements about the documentation of the written informed consent is true EXCEPT:
   A. The research subject must sign the consent form and date it;
   B. The investigator must use only the current IRB-approved consent form when enrolling subjects;
   C. When written informed consent is delayed, verbal telephone consent should be documented in the research record by two study personnel, and written consent obtained as soon as possible;
   D. The research subject or legally authorized representative must be provided with a copy of the consent form.
9. Which of the following scenarios is in compliance with federal regulations regarding the consenting procedure for enrollment of subjects in research?

A. The Investigator identifies a hospitalized patient who is eligible for enrollment in a research study. The patient, because of his illness, is not competent to give informed consent and there is no legal guardian, or next of kin/family to approach. Because the research has the potential for direct benefit to the patient, and standard care of the patient will be continued during the study, the Investigator approaches two physicians who are not affiliated with the study who concur with the medical opinion of the Investigator about enrollment of the patient and who sign the research consent form for the enrollment of the patient into the study;

B. The Principal Investigator is away at a conference. A Co-Investigator identifies a potential research subject and is unable to find the approved and validated consent form. The Co-Investigator documents the subject's consent with an available expired consent form with the understanding that he will have the subject sign the approved consent form once the up-to-date consent form is located. The Co-Investigator documents in the research record this variance in consent procedure;

C. At the conclusion of the research study, at the time of final data audit by the sponsor, the Investigator discovers that a number of the signed consent forms are missing. The Investigator, with agreement of the sponsor, contacts those specific research subjects and has them sign and date a new consent form;

D. The Investigator identifies a research subject who is eligible for a research study and approaches regarding participation. The Investigator begins the presentation of the study and gives the consent form to the potential subject. The Investigator notes that the validation stamp on the consent form is out of date. The Investigator completes a brief discussion of the study and reschedules a meeting with the research subject to execute the full consent procedure after contacting the IRB to determine the requirements to obtain an updated consent form.

**Submitting Progress Reports Session**

10. What are the requirements for the Investigator regarding the submission of a progress report on a research study for continuing review by the IRB?

A. An investigator needs to submit a progress report with adequate information about the research study only when the notifies the Investigator that the study is due for continuing review;

B. The investigator is responsible for developing a system to know when the research study is due for continuing review and submitting adequate information so that review can be conducted within one year from the original approval;

C. An investigator needs to submit a summary of the past experience on the research study with adequate information for continuing review at a time determined by the sponsor;
D. An investigator needs to submit a summary of the past experience on the research study with substantive information in the format established by the federal government and in a timely manner determined by the federal government.

11. Which statement reflects the correct procedures regarding the conduct of the research study that is undergoing continuing review?
   A. If the IRB approval of the study has expired but the study is on the IRB's next agenda, the Investigator may continue subject enrollment with the expired consent form until the study and consent form are re-approved at the next meeting;
   B. If the IRB approval of the study has expired but the study is on the IRB's next agenda, the Investigator may obtain an expedited approval from the IRB Chairman for the interim period until the meets and re-approves the study;
   C. If the IRB approval of the study has expired but the study is on the IRB’s next agenda, the Investigator must cease enrollment until the study is re-approved;
   D. If the IRB approval of the study has expired, the approval of the study will be extended an additional month to allow the study to continue until the study undergoes its continuing review.

**Reporting Unanticipated Problems Session**

12. What are an Investigator's responsibilities for reporting injuries, adverse events, or unanticipated problems involving subjects in the research study?
   A. Comply with all local IRB policies;
   B. When appropriate, comply with all federal regulatory reporting requirements;
   C. Comply with sponsor/funding agency requirements when appropriate;
   D. All of the above.

**Retaining Records Session**

13. An Investigator is required to retain all research records for what specific period of time?
   A. 3 years from the last continuing review date of the protocol;
   B. 3 years the last amendment review date;
   C. 3 years from the completion of the study;
   D. 3 years after the date that the last research subject is enrolled in the study.

**Please complete:**

The amount of time that it took me to review the CD-ROM and complete this test was ______ hours.