CIP EXAM PREP-ANSWER KEY

Social Behavioral Research Modules:

Students in Research

1. Nuremburg Code

2. Studies collecting data about the individual

3. Expedited Review

4. Not Human Subjects

5. Exempt

6. IRB Office, Student Advisor

7. Reviewing recruitment materials and strategies, Protecting the rights and welfare of human subjects, Assuring that all applicable institutional policies and Federal regulations are followed

8. Avoid using their own students in their research

9. All of the above

10. Exempt Review

History and Ethical Principles

1. Respect for persons

2. IRB review and approval

3. Respect for Persons, Beneficence, Justice

4. Nazi medical experiments

5. It heightened awareness of problems with unethical research

Defining Research with Human Subjects

1. A study of twenty 4^{th} grade classrooms in which researchers ask the schools to systematically vary the time of day reading is taught and collect weekly assessments of reading comprehension for each child over a three-month period.

2. A study is proposed about the effects of evoking stereotypes about gender-related differences in math ability on female subjects' performance of mathematical tests.

3. A cognitive psychologist proposes recruiting undergraduate students for a computer-based study about the effect of activating mood states on problem solving behaviors.

4. A developmental psychologist proposes videotaping interactions between groups of toddlers and their care givers to determine which intervention methods most effectively manage aggression.

5. Identifiable private information

The Regulations and the Social-Behavioral Sciences

1. The basic criteria for IRB review of proposed research, The composition of the IRB, Continuing review of approved protocols

2. No more than minimal risk and the research activities fall within regulatory categories identified as eligible

3. Must occur within 12 months of the approval date

4. The research falls into one of six categories of research activity described in the regulations

5. Protect the rights and welfare of research subjects

6. Prisoners

Assessing Risk in Social and Behavioral Sciences

1. Obtain a waiver of documentation of informed consent

2. Experience emotional or psychological distress

3. Risk may be culturally determined

4. Protect identifiable research information from forced disclosure

5. False

Informed Consent

1. The only record linking the subject and the research is the consent document and the principal risk is a breach of confidentiality

2. Require that potential subjects talk over their decisions with family members

3. All of the above

4. The children might feel pressure to participate due to the nature of their relationship with the therapist

5. False

Privacy and Confidentiality

1. Conducting the interview in a private room

2. Securing a Certificate of Confidentiality

3. They allow investigators to refuse to disclose information about individual research subjects

Research with Prisoners

1. Not an excessive incentive

2. Not approve this project because the prisoners are merely a population of convenience

3. Confidentiality of the prisoner's health status is maintained

4. Researchers may study the effects of privilege upgrades awarded by the prison

Research with Children

1. Recruiting m idle school students in the presence of their parents

2. The assent process for the children should vary depending upon their age and maturity

3. When it falls into an eligible category of research activity

4. The children are emancipated minors

5. False

Research in Public Elementary and Secondary Schools

1. False

2. Provide parents certain rights over their children's educational records

3. The research was pilot tested with no adverse events

4. An IRB has approved a waiver of the requirement for parental permission

5. Educational testing

International Research

1. True

2. Laws, customs, and norms in the area in which the research will be conducted

3. Assessing local transportation conditions

4. Obtaining informed consent and conducting research interviews

Internet Research

1. Designing the survey so that subjects are not forced to answer one question before going to the next

2. Screening out minors

3. True

4. False

Biomedical Research Modules:

Belmont Report and CITI Course Introduction Quiz

1. The Belmont Report indicates that it is necessary to rigorously avoid conflicts of interest as an example of the Principle of Justice

2. Determining that the study has a maximally favorable risk vs benefit ratio

3. Respect for Person, Beneficence, Justice

History and ethical Principles

1. Respect for Person, Beneficence, Justice

2. Respect for persons

3. IRB review and approval

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5. Nazi medical experiments

Basic Institutional Review Board (IRB) Regulations and Review Process

1. Occur at least annually

2. For a minimum of three years after completion of the study

3. The changes must be immediately implemented for the health and well-being of the subject

4. The study involved no more than minimal risk and meets one of the allowable categories of expedited review specified in federal regulations

5. Report the adverse drug experience immediately to the IRB using the forms or the mechanism provided by the institution

Informed Consent

1. Give the subject comprehensive information about the new drug, including its side effects. Discuss the pros and cons of both the investigational drug and the commercially available drug and then allow the subjects to decide whether to withdraw from the research to take the new drug

2. The investigator and another physician agree that the situation necessitates the use of the test article. An exception or waiver for informed consent can be made under these circumstances. The IRB will be notified later.

3. Send a copy of the informed consent via facsimile to the subject's wife. After she has the opportunity to speak to the investigator and her husband, she can sign the informed consent and fax it back.

4. You must provide blood samples that will be kept in a "bank" for future research. Once you have provided these blood samples, you cannot change your mind about being in the research and have the sample removed from the "bank".

Social and Behavioral Research for Biomedical Researchers

1. Breach of confidentiality from the focus group participants

2. Less predictable, more variable and less treatable than physical harms

3. Physical exams

4. Confidentiality of the individual subject's response

Records Based Research

1. Determination of exemption

2. Review by the convened IRB (Full Review)

Genetic Research in Human Populations

1. Ownership of biological specimens

2. Original signed consent documents include provisions for recontacting subjects

Research with Protected Populations-Vulnerable Subjects Overview Quiz

1. Undue influence of the subjects

2. Potential undue influence or coercion of subjects

3. The patients are institutionalized

4. Students taking one of his courses

Vulnerable Subjects-Research with Prisoners

1. Research that is relevant to prisoners and their conditions or situations

2. Since this research involves individual subjects who would be considered prisoners and examines an alternative to incarceration, the IRB should ensure that the additional requirements for prisoner research are met

3. One member who is a prisoner or prisoner representative

4. Prisoners

Vulnerable Subjects-Research Involving Minors

1. Honor the child's decision

2. No more than minimal risk to the child

3. Assent of the child and permission for both parents are required

Vulnerable Subjects-Research Involving Pregnant woman and Fetus in Utero

1. The pregnant woman and the father of the fetus

2. There is compelling evidence that inclusion would be inappropriate with respect to the health of the subjects

3. The pregnant woman only

International Research (no quiz)

Group Harms: Research with Culturally or Medically Vulnerable Groups

1. All of the above

2. An anonymous survey of state high school teachers, athletic directors, and administrators that, among other things, asks for perceptions about the sexual preferences of their high school coaches

3. A study designed to investigate genetic links between DNA samples found at a prehistoric central Asian archeological site and west coast American Indian tribes

FDA Regulated Research

1. The medical center to replace the use of paper records with electronic records for its research

2. Allow the use of electronic documents and signatures in the regulatory process for drugs and devices

3. Submit the research protocol to the IRB for review and submit an IND application to the FDA before conducting the research

4. Treat the patient with the drug based on physician's best medical judgment

5. Significant risk device

Workers as Research Subjects

1. All of the above

2. True

3. Workers

4. All of the above

IRB Member Module-"What Every IRB Member Needs to Know"

1. Table the protocol and ask the investigator to provide the needed information for review by the full board at the next convened meeting

2. The non-scientist member.

3. Evaluate the study risks and study benefits and to determine if approve procedures are in place to minimize study risk to participants

4. 8

5. Defer the proposal to the next meeting because of a loss of quorum

6. The research must be re-reviewed by the Full IRB Committee on or before February 14, 2008