

**CIP Preparation Course  
Summer 2008**

Project Lead: Susan Rose, Ph.D.  
Office for the Protection of Research Subjects

Instructors: Darcy Spicer, Frances Richmond, Kathy Hurtado, Sandy Jean, Kristin Craun, Susan Rose, Peter Mestaz, Gordon Olacsi, Marlene Krammer

Location: HRA 7<sup>th</sup> Floor, Conference Room

When: Weekly on Mondays from 4:30pm – 6:00pm  
From June 16, 2008 – August 18, 2008.

Attendees: Genora Baker, John Revilla, RoseAnn Fleming, Nasairah Carter, Marie Reyes, Scott Maul

**Course Objectives:**

The objective of this course is to provide IRB staff with the necessary tools, information, training, and support needed to prepare for and successfully pass the Certified IRB Professional (CIP) examination.

**Course Content**

**Lecture Content and Speaker(s)**

Week 1 (6/16/08)	Introduction, Overview, History, Common Terminology (Susan, Gordon, Peter)
Week 2 (6/23/08)	HHS/OHRP regulations, definitions, guidances (Kristin)
Week 3 (6/30/08)	FDA regulations & definitions, FDA/HHS similarities & differences, applicability (Kathy & Sandy)
Week 4 (7/7/08)	Reportables: Adverse Events, Unanticipated Problems Involving Risks to Subjects or Others (Darcy)
Week 5 (7/14/08)	HSPP/IRB Organizational & Administration International Research (Kristin, Sandy)
Week 6 (7/21/08)	Vulnerable Populations (Frances Richmond)

Week 7 (7/28/08)	Revisit FDA & OHRP ICH & GCP (Kathy & Kristin or Sandy)
Week 8 (8/4/08)	HIPAA, COI, State Law (Marlene)
Week 9 (8/11/08)	*Pre-post practice test, Q&A, CIP Discussion, Test Strategies (Sandy Jean)

\*Pre-post practice test (Sandy) TBD

**Notes:**

We want to have people teach their expertise and don't want to overburden anyone.

The OPRS office will confirm attendance, handle logistics, etc...

Course materials will be provided by OPRS: IRB Management and Function (Bankert & Amdur), Protecting Study Volunteers in Research (Dunn & Chadwick), speaker handouts, CIP exam outline.

At least one person from the OPRS office will attend each session.

## Terms List: CIP Exam Preparation

1. Declaration of Helsinki
2. Significant/Non-significant Risk Devices
3. Belmont Report
4. Risk-Benefit Analysis
5. Respect for Persons
6. Informed Consent
7. Beneficence
8. Waiver of Consent
9. Justice
10. Waiver of Documentation
11. Nuremberg Code
12. Vulnerable Subjects
13. Council for International Organizations of Medical Sciences
14. Emergency Uses
15. International Conference on Harmonisation
16. Advertisements
17. Study Designs
18. Inclusion/Exclusion Criteria
19. Risk
20. Fetuses
21. DMC
22. Pregnant Women,
23. Monitoring
24. IVF Prisoners
25. Privacy
26. Children Emergency-setting
27. Confidentiality
28. Research Data,
29. Deception
30. Documents, Records, Specimens, Repositories
31. HHS Regulations
32. International Research
33. Common Rule
34. Auditing
35. FDA Regulations
36. Protocol Deviations
37. Drugs
38. Federalwide Assurance of Protection for Human Subjects (FWA)
39. Biologics
40. IRB Registration
41. Devices
42. Noncompliance
43. Health Insurance Portability and Accountability Act (HIPAA)
44. Terminations/Suspension
45. Research
46. Accreditation

## Terms List: CIP Exam Preparation

- |  |  |
|--|--|
| 47. Human Subjects                                 | 48. Quorum                                       |
| 49. Minimal Risk                                   | 50. Records                                      |
| 51. Vulnerable Populations                         | 52. Investigators                                |
| 53. Engaged in Research                            | 54. Institutional Officials                      |
| 55. Approve/Disapprove/Modify<br>Suspend/Terminate | 56. Certificates of Confidentiality              |
| 57. Exempt   | 58. Final Reports/Study Closure                  |
| 59. Expedited Review                               | 60. Minor Increase                               |
| 61. Convened Meeting Review                        | 62. Greater than Minimal                         |
| 63. Initial Review                                 | 64. Amendment Review                             |
| 65. Continuing Review                              | 66. Adverse Event/ Unanticipated Problems Review |

# CIP Exam Prep—Practice Test Questions

Summer 2008

## Social Behavioral Research Modules

### STUDENTS IN RESEARCH

Question 1 Multiple Choice/Single Answer - select only one answer (1 point)

The history of ethical regulations in human subjects research began with the

- Declaration of Helsinki
- Nuremburg Code
- Common Rule
- Belmont Report

Question 2 Multiple Choice/Single Answer - select only one answer (1 point)

Which of the following studies **need** IRB approval?

- Studies that use census data.
- Studies collecting data about the individual.
- Studies that use data collected for internal department use only.
- Studies that involve cadavers.

Question 3 Multiple Choice/Single Answer - select only one answer (1 point)

A student working on his dissertation plans on interviewing 15 principals in neighboring high schools. The student plans to collect data about the personal experiences the principals have had with disruptive students and what types of disciplinary actions were taken. Identifiers will be collected. This study would be categorized as which type of review?

- Expedited Review
- Full Board Review
- Exempt Review
- Not Human Subjects

Question 4 Multiple Choice/Single Answer - select only one answer (1 point)

A Masters degree candidate needs to conduct a research project for her Masters thesis. She is interested in the types of junk food available to the public. She plans on going to the local convenience stores and asking the owners what types of junk food they normally stock and what are their biggest sellers. Identifiers will not be collected. This study would be categorized as which type of review?

- Expedited Review
- Exempt Review
- Full Board Review
- Not Human Subjects

Question 5 Multiple Choice/Single Answer - select only one answer (1 point)

Which type of IRB review does not require an IRB approval but **does** require a *determination* by the IRB or an IRB designee?

- Full Board
- Expedited
- Exempt
- All of the above

Question 6 Multiple Choice/Multiple Answer - select all correct answers (1 point)

Where can student researchers and/or student subjects find reliable additional resources regarding the IRB approval process?

- IRB Office.
- Student Advisor.
- The Student Union.
- "Gray's Anatomy"
- Compliance Office.

Question 7 Multiple Choice/Multiple Answer - select all correct answers (1 point)

What is the Institutional Review Board (IRB) charged with?

- Conducting inquiries into research misconduct.
- Reviewing recruitment materials and strategies.
- Protecting the rights and welfare of human subjects.
- Assuring that all applicable institutional policies and Federal regulations are followed.
- Reviewing manuscripts prior to submission for publication.

Question 8 Multiple Choice/Single Answer - select only one answer (1 point)

How can faculty researchers avoid coercion of student subjects?

- Provide extra credit to those who participate
- Conduct research for less than 10 minutes during class so as to not take up much class time

- Avoid using their own students in their research
- Offer more monetary compensation

Question 9 Multiple Choice/Single Answer - select only one answer (1 point)

Which of the following elements must be included in an informed consent?

- Procedures/methods involved in the research
- The purpose of the research
- All foreseeable risks and discomforts
- All of the above

Question 10 Multiple Choice/Single Answer - select only one answer (1 point)

A student is conducting a research project that involves using a survey. The survey asks subjects about their political affiliation and their favorite politicians. No identifiable information will be collected. This study would be categorized as which type of review?

- Expedited Review
- Full Board Review
- Exempt Review
- Not Human Subjects

## HISTORY AND ETHICAL PRINCIPLES

Question 1 Multiple Choice/Single Answer - select only one answer (1 point)

An investigator fails to inform subjects about the foreseeable risks in a study of a new drug. Which of the following best describes the ethical principle violated?

- Access to research.
- Research Integrity.
- Respect for persons.
- Justice.

Question 2 Multiple Choice/Single Answer - select only one answer (1 point)

An investigator wishes to study lifestyle and diet influences on the risk of developing a specific cancer. The investigator chooses a case-control design with paired lifestyle interviews and a few blood and urine tests and assigns a study manager to identify patients with the diagnosis from the pathology logbook that lists names. The study manager would then ask each patient's primary physician for permission to contact the patient. Which of the following is required before the investigator begins the study?

- Permission from the Oncology Department.
- Hospital accreditation.

- IRB review and approval.
- A Clinical Trials Office.

Question 3 Multiple Choice/Single Answer - select only one answer (1 point)

Which of the following lists the three principles discussed in the Belmont Report?

- Privacy, Confidentiality, Equitable selection of subjects.
- Informed Consent, Institutional Assurance, Researcher responsibility.
- IRB review, federal regulations, Declaration of Helsinki.
- Respect for Persons, Beneficence, Justice.

Question 4 Multiple Choice/Single Answer - select only one answer (1 point)

Which of the following studies led to the establishment of the National Research Act and ultimately the Belmont Report and Federal regulations for human subject protection?

- Obedience to authority study (Milgram study).
- Jewish chronic disease study.
- The Public Health Service syphilis study.
- Nazi medical experiments.

Question 5 Multiple Choice/Single Answer - select only one answer (1 point)

In what way did the Beecher article impact research in the United States?

- It resulted in the creation of the IRB.
- It heightened awareness of problems with unethical research.
- It reinterpreted the Belmont principles with a focus on therapeutic medical research.
- It prompted congress to create an ad hoc panel to provide oversight for human research.

## DEFINING RESEARCH WITH HUMAN SUBJECTS

Question 1 Multiple Choice/Single Answer - select only one answer (1 point)

Which of the following studies meets the definition of research with human subjects?

- The collection of data by a playground designer hired by the superintendent of schools about the physical dimensions of school playgrounds, presence of fencing, and the kinds of equipment currently provided.
- A study of twenty 4th 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.
- An analysis of aggregate data comparing statewide high school graduation rates, provided by the State Department of Public Instruction, with county tax bases.

- None of the above

Question 2 Multiple Choice/Single Answer - select only one answer (1 point)

Which of the following studies meets the definition of research with human subjects?

- A researcher receives anonymized data for secondary analysis from a survey about gender-related differences in stress levels conducted by a colleague at another university.
- A study is proposed about the effects of evoking stereotypes about gender-related differences in math ability on female subjects' performance of mathematical tests.
- An organization for women academics in engineering asks a federal agency to provide the number of women investigators funded by that agency to include in a report for its membership.
- A university designs an in-house study to improve the mentoring of women students in its engineering department with the proposed outcome consisting of a report of recommendations for the department.

Question 3 Multiple Choice/Single Answer - select only one answer (1 point)

Which of the following studies meets the definition of research with humans subjects.

- A researcher proposes a comparison of the comments made in a publicly available blog and the blogger's comments on a similar topic in a weekly magazine.
- A cognitive psychologist proposes recruiting undergraduate students for a computer-based study about the effect of activating mood states on problem solving behaviors.
- Undergraduate students in a field methods class are assigned a research question and asked to interview another classmate, to be followed by a class discussion on interview techniques.
- A researcher sets up a meeting with the superintendent of public schools to get data about the ethnic composition of the school system and the number of students receiving free lunches.

Question 4 Multiple Choice/Single Answer - select only one answer (1 point)

Which of the following studies meets the definition of research with human subjects?

- A researcher plans to conduct a linguistic study of comments posted on a local public blog
- A researcher proposes asking the director of a local free clinic about the number of newly diagnosed HIV cases in the last two years.
- A developmental psychologist proposes videotaping interactions between groups of toddlers and their care givers to determine which intervention methods most effectively manage aggression.
- A researcher proposes using custom office passenger lists for ships bringing immigrants to the United States between 1820 and 1845 to track the restrictions immigration laws imposed on certain ethnic groups.

Question 5 Multiple Choice/Multiple Answer - select all correct answers (1 point)

According to the federal regulations for protecting research subjects, a human subject is a living individual about whom an investigator obtains:

- Identifiable private information.
- Observations of public behavior.
- Identifiable public information.
- De-identified public information.

## THE REGULATIONS AND THE SOCIAL-BEHAVIORAL SCIENCES

Question 1 Multiple Choice/Multiple Answer - select all correct answers (1 point)

Which of the following are covered by the Common Rule?

- The basic criteria for IRB review of proposed research.
- Specific procedures for formatting protocols.
- The composition of the IRB.
- Continuing review of approved protocols.

Question 2 Multiple Choice/Single Answer - select only one answer (1 point)

According to federal regulations, the expedited review process may be used when the study procedures pose:

- No more than minimal risk and the research activities fall within regulatory categories identified as eligible.
- A minor increase over minimal risk and the sponsor needs approval before the next IRB meeting.
- More than minimal risk, but the study replicates previously approved research.
- Any level of risk, but all the subjects are adults.

Question 3 Multiple Choice/Single Answer - select only one answer (1 point)

Continuing review of an approved protocol

- Must occur within 12 months of the approval date.
- Is limited to review of unanticipated problems.
- Must be conducted by a convened IRB.
- Is not required unless additional risks have been identified.

Question 4 Multiple Choice/Single Answer - select only one answer (1 point)

According to the federal regulations, research is eligible for exemption, if

- All the subjects are adults and the risk is minimal.
- Participation in the research will involve 10 minutes or less of the subjects' time.

- The investigator is experienced in the field of inquiry.
- The research falls into one of six categories of research activity described in the regulations.

Question 5 Multiple Choice/Single Answer - select only one answer (1 point)

The primary purpose of the IRB is to:

- Represent the interests of the institution.
- Provide training in ethics for student researchers.
- Approve research protocols.
- Protect the rights and welfare of research subjects.

Question 6 Multiple Choice/Single Answer - select only one answer (1 point)

In addition to pregnant women, fetuses, and neonates, subparts of the DHHS regulations provide additional protections for which of the following vulnerable populations?

- Adults with decisional impairments.
- The elderly.
- Students.
- Prisoners.

## ASSESSING RISK IN SOCIAL AND BEHAVIORAL SCIENCES

Question 1 Multiple Choice/Single Answer - select only one answer (1 point)

If disclosure of a subject's involvement in a specific research study can be potentially harmful to the subject, and the consent form is the only record linking the subject to the research, which of the following would be most helpful:

- Code the subjects' responses.
- Obtain a waiver of documentation of informed consent.
- Obtain a Certificate of Confidentiality.
- Have the subject sign the consent form under an assumed name.

Question 2 Multiple Choice/Single Answer - select only one answer (1 point)

An investigator wishes to study generational differences in coping mechanisms among adults who experienced abuse as children. Adequate measures will be instituted to obtain informed consent and ensure that there is no breach of confidentiality. The most likely additional risk is that subjects may:

- Lose their legal status.
- Experience emotional or psychological distress.

- Feel that their privacy has been invaded.
- Lose their employment.

Question 3 Multiple Choice/Single Answer - select only one answer (1 point)

What statement about risks in social and behavioral sciences research is most accurate:

- Risk may be culturally determined.
- If a study offers potential benefits, it is not necessary to minimize risks.
- Anonymizing data effectively manages the risk of creating emotional distress.
- There are never any risks.

Question 4 Multiple Choice/Single Answer - select only one answer (1 point)

The primary purpose of a Certificate of Confidentiality is to:

- Prevent subjects from knowing the purpose of a study.
- Protect researchers from disclosing conflicts of interest.
- Allow law enforcement to investigate abuse cases.
- Protect identifiable research information from forced disclosure.

Question 5 True/False (1 point)

Only federally funded projects are eligible for Certificates of Confidentiality.

- True
- False

## INFORMED CONSENT

Question 1 Multiple Choice/Single Answer - select only one answer (1 point)

A waiver of the requirement for documentation of informed consent may be granted when:

- Potential subjects might find some of the research questions embarrassing.
- The only record linking the subject and the research is the consent document and the principal risk is a breach of confidentiality.
- English is not the potential subjects' primary language.
- The investigator has no place to store signed consent forms.

Question 2 Multiple Choice/Single Answer - select only one answer (1 point)

As part of the consent process a researcher is NOT required to:

- Provide consent materials in the language of the potential subjects.

- Provide potential subjects with information at the appropriate reading level.
- Require that potential subjects talk over their decisions with family members.
- Ensure that there is no undue influence on potential subjects.

Question 3 Multiple Choice/Single Answer - select only one answer (1 point)

According to the federal regulations, which of the following is a required element of consent?

- A description of expected benefits.
- An explanation of the purpose of the research.
- A description of the duration of the research.
- A statement that participation is voluntary.
- All of the above

Question 4 Multiple Choice/Single Answer - select only one answer (1 point)

A therapist at a free university clinic treats elementary school children with behavior problems who are referred by a social service agency. She is also a doctoral candidate who proposes to use data about her clients for a research project using case studies.

Which of the following statements is true?

- The children might feel pressure to participate due to the nature of their relationship with the therapist.
- If it is the best interests of the community that the children participate in the study, their assent is optional.
- The therapist already has access to her clients' records; therefore, she does not need their consent to use the files for research purposes.
- The superintendent of the school system can give permission for children to be in the study, so the therapist doesn't have to contact the subjects.

Question 5 True/False (1 point)

Informed consent is always required for research that involves human subjects.

- True
- False

## PRIVACY AND CONFIDENTIALITY

Question 1 Multiple Choice/Single Answer - select only one answer (1 point)

A researcher proposes to study the effect of erectile dysfunction on romantic relationships. He plans to recruit and interview subjects at a clinic that offers free prostate exams. He will post a flyer in the waiting room that says that he is interested in studying men's health and romantic relationships. During the consent process he will inform

potential subjects that he will be asking personal questions including questions about erectile function. Which of the following confidentiality procedures would best protect the privacy of the subjects during the interview process?

- Recording subjects' ages and income in ranges.
- Conducting the interviews in a private room.
- Asking subjects not to identify their partners by name.
- Taking notes rather than audio-taping the interviews.

Question 2 Multiple Choice/Single Answer - select only one answer (1 point)

Which of the following confidentiality procedures would provide the highest level of protection of individually identifiable information in a longitudinal study about illegal activities:

- Using data encryption for stored files.
- Securing a Certificate of Confidentiality.
- Waiving documentation of consent.
- Using pseudonyms in research reports.

Question 3 Multiple Choice/Single Answer - select only one answer (1 point)

Which of the following statements about Certificates of Confidentiality is true?

- Their use is limited to civil proceedings in the state in which the research took place.
- They allow investigators to refuse to disclose information about individual research subjects.
- They can be used to protect information about the researchers, including income.
- Their use is limited to research funded by the NIH.

## RESEARCH WITH PRISONERS

Question 1 Multiple Choice/Single Answer - select only one answer (1 point)

An investigator is examining the relationship between family contact/visitation and depression in mothers recently admitted to a state prison. The researcher will use the data to develop support programs for prison mothers. The sample will be limited to first offenders with children under the age of five years. Research subjects will be given a basket of toys to use at their children's first visit that the children can then take home. In assessing this proposal, the IRB needs to determine that the toys are:

- Age appropriate.
- Educational.
- Not an excessive incentive.
- Of high quality.

Question 2 Multiple Choice/Single Answer - select only one answer (1 point)

A graduate student wants to examine the effect of print media versus televised media on individuals' position on several social issues. Her advisor's neighbor is the superintendent of a local work release facility and will allow the graduate student access to the prison population to help her quickly accrue subjects. The subjects will be asked for 15 minutes of their time. The risks appear to be no more than minimal. The IRB would most likely?

- Approve this project since the risk appears to be no more than minimal
- Approve this project since the superintendent is the ultimate authority about what happens in his facility.
- Approve this project but submit it for federal review.
- Not approve this project because the prisoners are merely a population of convenience.

Question 3 Multiple Choice/Single Answer - select only one answer (1 point)

An investigator is examining the quality of life for prisoners who are HIV positive. The researcher plans to use standardized survey instruments followed by an interview. Neither the survey nor the interview questions are probing about the offender's past life but maintain a focus on current life situation in the prison. The IRB must ensure that:

- All prisoners receive HIV testing.
- The survey instrument is standardized.
- A medical doctor serves as co-investigator.
- Confidentiality of the prisoners' health status is maintained.

Question 4 Multiple Choice/Single Answer - select only one answer (1 point)

Which of the following statements about prison research is true?

- It is permissible for risks to be higher than those that would be accepted by non-prisoners.
- The regulations prohibit compensating prisoners.
- Researchers may study the effects of privilege upgrades awarded by the prison.
- Participation in research can be considered during parole hearings.

## RESEARCH WITH CHILDREN

Question 1 Multiple Choice/Single Answer - select only one answer (1 point)

Which of the following methods of subject recruitment presents the LEAST potential for coercion?

- Recruiting adolescents in the presence of their peers
- Recruiting college freshman on their first day on campus

- Recruiting middle school students in the presence of their parents
- Recruiting children to learn about ecology at a summer recreation program

Question 2 Multiple Choice/Single Answer - select only one answer (1 point)

A study of the effects of divorce on children proposes annual interviews of children, aged seven through sixteen, and their parents. Which of the following statements best describes the consent requirements for this study?

- Consent must be obtained and documented for all participants using the same IRB consent form.
- The assent process for the children should vary depending upon their age and maturity.
- If the teacher thinks it would be helpful for a child to talk about divorce, the child may be enrolled without parental permission.
- Parental permission is sufficient to enter a child into the study for children between the ages 7 and 14.

Question 3 Multiple Choice/Single Answer - select only one answer (1 point)

According to federal regulations, when can research with children be exempt?

- It can never be exempt
- When it falls into an eligible category of research activity
- When parents request an exemption
- When children are 12 or older

Question 4 Multiple Choice/Single Answer - select only one answer (1 point)

Parental permission for children to participate may be waived if:

- The parents are illiterate.
- The children are emancipated minors.
- The children are homeless.
- The children can read at a twelfth grade level.

Question 5 True/False (1 point)

The absence of child dissent may be considered assent to participate in research.

- True
- False

## RESEARCH IN PUBLIC ELEMENTARY AND SECONDARY SCHOOLS

### Question 1 True/False

(1 point)

A researcher completing a Master's degree in art education is interested in studying elementary school curriculum designed to help students develop visual vocabularies and visual discrimination skills. The researcher will add contemporary images to a curriculum used successfully for fifteen years and will submit the findings to the Journal of Art Education. According to federal regulations, the research must be reviewed by a convened IRB.

- True
- False

### Question 2 Multiple Choice/Single Answer - select only one answer

(1 point)

The purpose of the Family Education Rights and Privacy Act (FERPA) is to:

- Allow school counselors to access students' grades.
- Give school principals the right to discuss students' behavior problems with their parents.
- Ensure that surveys do not ask school children to provide sensitive information about their parents.
- Provide parents certain rights over their children's educational records.

### Question 3 Multiple Choice/Single Answer - select only one answer

(1 point)

According to the Common Rule, which of the following is not one of the criteria for waiving parental permission for school based research?

- The research poses no more than minimal risk of harm to the subjects.
- The waiver would not adversely affect the rights and welfare of the subjects.
- The research was pilot tested with no adverse events.
- The research would be impractical without the waiver.
- Whenever appropriate, the subjects will be provided with additional pertinent information.

Question 4 Multiple Choice/Single Answer - select only one answer (1 point)

Parental notification, in lieu of active parental permission, is allowed when:

- The superintendent of schools and the principals have approved the study.
- The researcher anticipates a low response rate.
- The researcher has conducted a similar study at another institution.
- An IRB has approved a waiver of the requirement for parental permission.

Question 5 Multiple Choice/Single Answer - select only one answer (1 point)

According to Subpart D, which of the following research activities with children would qualify for an exemption?

- Interviews
- Surveys procedures
- Participant observation
- Educational testing

## INTERNATIONAL RESEARCH

Question 1 True/False (1 point)

The only persons from whom consent should be sought are the research subjects themselves.

- True
- False

Question 2 Multiple Choice/Single Answer - select only one answer (1 point)

The age of majority in international research is determined by the

- Legal drinking age where the research will take place.
- Laws in the state where the researchers' institution resides.
- The research sponsor.
- Laws, customs, and norms in the area in which the research will be conducted.

Question 3 Multiple Choice/Single Answer - select only one answer (1 point)

Which of the following is the LEAST important activity when protecting human subjects in international research?

- Considering local customs, norms, and laws.
- Consulting with members of the community from which subjects will be recruited.
- Determining if the research might present unique risks to subjects given local socio-economic conditions.
- Assessing local transportation conditions

Question 4 Multiple Choice/Single Answer - select only one answer (1 point)

Which of the following activities constitutes engagement in research?

- Providing potential subjects with written information about a study.
- Obtaining informed consent and conducting research interviews.
- Informing prospective subjects about the availability of research.
- Obtaining subjects' permission for researchers to contact them.

## INTERNET RESEARCH

Question 1 Multiple Choice/Single Answer - select only one answer (1 point)

Consent to participate in research is an ongoing process. Which of the following Internet survey methods would ensure that participation remains voluntary throughout a study?

- Giving examples in the consent process of the kinds of questions that will be asked
- Including a privacy policy on the survey site
- Providing an e-mail link to the investigator
- Designing the survey so that subjects are not forced to answer one question before going to the next

Question 2 Multiple Choice/Single Answer - select only one answer (1 point)

A researcher is conducting an on-line survey collecting data for a study about college students' sexual behavior. Identifiers will be collected. The researcher has hired a company to help manage the study. Which of the following functions is NOT the firm's responsibility?

- Purging identifiable data from the company's servers after the research is completed
- Screening out minors
- Encryption of data transferred from the student to the company
- Protection of data during storage

Question 3 True/False (1 point)

SSL is a protocol designed to provide secure communications via the Internet.

- True
- False

Question 4 True/False (1 point)

E-mail messages are secure communications.

- True
- False

## **BIOMEDICAL RESEARCH Modules**

### BELMONT REPORT AND CITI COURSE INTRODUCTION QUIZ

Question 1 Multiple Choice/Single Answer - select only one answer (1 point)

The Belmont Report describes all of the following **EXCEPT:**

- The Belmont Report defines and delineates the differences between "Practice" and "Research".
- The Belmont Report describes the need to carefully consider how research discoveries and risks will be fairly distributed in the society.
- The Belmont Report indicates that it is necessary to rigorously avoid conflicts of interest as an example of the Principle of Justice.
- The Belmont Report describes the concept of "Respect for Person".

Question 2 Multiple Choice/Single Answer - select only one answer (1 point)

Which of the following is an example of how the Principle of Beneficence can be applied to a study employing human subjects?

- Providing detailed information about the study and obtaining the subject's consent to participate.
- Determining that the study has a maximally favorable risk vs benefit ratio.
- Insuring that confidentiality is maintained.
- Insuring that the selection of subjects includes people from all segments of the population.

Question 3 Multiple Choice/Single Answer - select only one answer (1 point)

Which of the following lists the three principles discussed in the Belmont Report?

- Respect for Person, Beneficence, Justice.

- Privacy, Confidentiality, Equitable selection of subjects.
- Informed Consent, Institutional Assurance, Researcher responsibility.
- IRB review, Federal regulations, Declaration of Helsinki

## HISTORY AND ETHICAL PRINCIPLES

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- Privacy, Confidentiality, Equitable selection of subjects.
- Informed Consent, Institutional Assurance, Researcher responsibility.

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An investigator fails to inform subjects about the foreseeable risks in a study of a new drug. Which of the following best describes the ethical principle violated?

- Research Integrity
- Access to research
- Justice
- Respect for persons

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An investigator wishes to study lifestyle and diet influences on the risk of developing a specific cancer. The investigator chooses a case-control design with paired lifestyle interviews and a few blood and urine tests and assigns a study manager to identify patients with the diagnosis from the pathology logbook that lists names. The study manager would then ask each patient's primary physician for permission to contact the patient. Which of the following is required before the investigator begins the study?

- Hospital accreditation
- IRB review and approval
- Permission from the Oncology Department
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In what way did the Beecher article impact research in the United States?

- It reinterpreted the Belmont principles with a focus on therapeutic medical research.

- It heightened awareness of problems with unethical research.
- It resulted in the creation of the IRB.
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Question 5 Multiple Choice/Single Answer - select only one answer (1 point)

Which of the following studies led to the establishment of the National Research Act and ultimately the Belmont Report and Federal regulations for human subject protection?

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- The Public Health Service (PHS) syphilis study
- Nazi medical experiments
- Obedience to authority study (Milgram study)

#### BASIC INSTITUTIONAL REVIEW BOARD (IRB) REGULATIONS AND REVIEW PROCESS

Question 1 Multiple Choice/Single Answer - select only one answer (1 point)

IRB continuing review of an approved protocol must:

- Include copies of all signed consent forms.
- Occur at least annually.
- Must be conducted by a convened IRB.
- Must occur only when the level of risk changes.

Question 2 Multiple Choice/Single Answer - select only one answer (1 point)

How long is an investigator required to keep consent documents, IRB correspondence, and research records?

- Until the IRB gives permission for them to be destroyed
- As long as the investigator is at that institution
- For a minimum of three years after completion of the study
- Until the study is closed

Question 3 Multiple Choice/Single Answer - select only one answer (1 point)

Amendments involving changes to IRB approved protocols do NOT need prior IRB approval if:

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

- They only involve changes to the consent form.
- They are eligible for review using expedited procedures.
- The investigator keeps careful records of all changes and includes them in the final report.

Question 4 Multiple Choice/Single Answer - select only one answer (1 point)

According to federal regulations, which of the following best describes when expedited review of a new, proposed study may be used by the IRB?

- The study is required for a student research project
- The study includes only research subjects that are healthy volunteers.
- The study does not require informed consent or survey instruments.
- The study involves no more than minimal risk and meets one of the allowable categories of expedited review specified in federal regulations

Question 5 Multiple Choice/Single Answer - select only one answer (1 point)

A subject in a clinical research trial experiences a serious, unanticipated adverse drug experience. How should the investigator proceed after the discovery of the adverse event occurrence?

- Do not report the adverse drug experience to the IRB since it is a common adverse experience.
- Report the adverse drug experience as part of the continuing review report.
- Report the adverse drug experience immediately to the IRB using the forms or the mechanism provided by the institution.
- Report the adverse drug experience to the IRB only if there are several other occurrences.

## INFORMED CONSENT

Question 1 Multiple Choice/Single Answer - select only one answer (1 point)

A 46-year-old man is currently enrolled in a Phase 1. study of a drug for severe diabetic neuropathy. While the study is on going, a new drug becomes commercially available that may have equal or greater benefit to the subject. The investigator should do which of the following?

- 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 subject to decide whether to withdraw from the research to take the new drug.
- Withhold this new information to avoid confusing the subject with other treatment options or alternatives

- Tell the subject about the new drug but discourage him from switching treatments until the study is completed
- Do not tell the subject about the new drug since physicians have the right to try out new treatments with their patients

Question 2 Multiple Choice/Single Answer - select only one answer (1 point)

An investigator is confronted with a life-threatening situation that necessitates using a test article in a human subject who is unable to provide informed consent and there is no time to obtain consent for the individual's legal representative. Under the FDA regulations for using test articles, which of the following describes the best course of action for the investigator:

- 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.
- Use the test article without obtaining consent from the subject or the legal representative then notify the IRB.
- Submit a research protocol to the IRB and justify an expedited review approval of the consent document so test article can be used immediately.
- Do not use the test article until either the subject or the subject's legal representative can give consent.

Question 3 Multiple Choice/Single Answer - select only one answer (1 point)

An elderly man recently diagnosed with lung cancer is screened for a clinical trial using a new investigational drug. The investigator has carefully explained all of the required information about the study to the subject and the subject's daughter. The subject demonstrates his understanding and willingness to participate, but is not able to sign the informed consent document due to paralysis from a swimming accident years before. The subject's wife is his legally authorized representative, but she is out of town on a business trip. Which of the following is the most appropriate action to take for the investigator?

- Send a copy of the informed consent via facsimile to the subject's wife. After she has had the opportunity to speak to the investigator and her husband, she can sign the informed consent and fax it back.
- Exclude the man from the study
- The investigator can go ahead and treat the man without a signed consent since he verbally agreed to participate.
- Request the IRB waive the requirement for a signed informed consent

Question 4 Multiple Choice/Single Answer - select only one answer (1 point)

A general requirement for the informed consent is that no informed consent may include any exculpatory language. Exculpatory language is that which waives or appears to waive any of the subject's legal rights or releases or appears to release those conducting the research from liability for negligence. Which of the following statements in a consent form is an example of exculpatory language?

- 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”.
- The investigator may stop you from participating in this research without your consent if you experience side effects that make your condition worse. If you become ill during the research, you may have to drop out.
- Your participation in this research is voluntary. If you choose not to participate, or change you mind later, your decision will not affect your relationship with your doctor or your right to health care or other services that you may be eligible for.
- In the event of any injury you may have related to this research, you will be given medical treatment.

## SOCIAL AND BEHAVIORAL RESEARCH FOR BIOMEDICAL RESEARCHERS

Question 1 Multiple Choice/Single Answer - select only one answer (1 point)

A researcher wants to use several small focus groups to develop a written questionnaire about relationships between ‘troubled’ teenage girls and their parents. Which of the following would be the most important issue for the researchers to consider when planning the research?

- Amount of compensation for the teen’s time
- Emotional distress from talking about their troubles
- Recruiting strategies to ensure quick enrollment and completion of the research
- Breach of confidentiality from the focus group participants

Question 2 Multiple Choice/Single Answer - select only one answer (1 point)

Which of the following most accurately describes the risks associated with SBR?

- Less serious and more frequent than physical harms
- Shorter in duration and less frequent than physical harms
- Less predictable, more variable and less treatable than physical harms
- More likely to be treatable by researchers than physical harms

Question 3 Multiple Choice/Single Answer - select only one answer (1 point)

SBR researchers may use all of the following data collections methods EXCEPT:

- surveys
- physical exams
- interviews
- participant observation

Question 4 Multiple Choice/Single Answer - select only one answer (1 point)

A researcher is conducting a written survey about people's attitudes toward walking as an exercise option at the local shopping mall that supports a walking program. The survey is anonymous (without codes, names or other information) and volunteers may complete the survey and place it in a box at the shopping mall exits. Which of the following is the most important issue that the researcher addressed in planning the research?

- Possibility of emotional distress from answering the questions themselves
- Recruitment of subjects to ensure varied characteristics of the sample size
- Confidentiality of the individual subject's responses
- Data analysis from a large sample size

## RECORDS BASED RESEARCH

Question 1 Multiple Choice/Single Answer - select only one answer (1 point)

An investigator is recording nonidentifiable information from records to study the frequency of "handedness" (left hand versus right hand) in a given population. What level of review is most appropriate?

- Expedited review by a designated IRB member
- None
- Determination of exemption
- Review by a convened quorum of the IRB

Question 2 Multiple Choice/Single Answer - select only one answer (1 point)

After beginning a records-based research project, the researcher determines that the individuals whose data is being collected need to be contacted for updated substance abuse information. This will require a change to the protocol. What level of review by the IRB is most likely?

- Expedited
- Review by the convened IRB (Full Review)
- Review for exemption
- None

## GENETIC RESEARCH IN HUMAN POPULATIONS

Question 1 Multiple Choice/Single Answer - select only one answer (1 point)

When conducting research that involves collecting biological specimens for genetic testing, which of the following issues is the most important for the IRB to consider?

- Ownership of biological specimens
- Long term financial impact of results
- Need for publication of results
- Effects of findings on other family members

Question 2 Multiple Choice/Single Answer - select only one answer (1 point)

Under which of the following conditions is it appropriate to re-contact the individuals who provided biological specimens?

- Biological specimens need to be replenished
- Discovery of related clinical information requires contacting subjects for follow-up
- Original signed consent documents include provisions for recontacting subjects
- Subjects received financial compensation for participation in the study

## RESEARCH WITH PROTECTED POPULATIONS – VULNERABLE SUBJECTS: OVERVIEW QUIZ

Question 1 Multiple Choice/Single Answer - select only one answer (1 point)

A group of elderly men, whose government disability benefits are the sole source of income, is approached to consider an experimental research study for their current colon cancer. The study involves more than minimal risk, but offers substantial financial incentives that are equal to two months of disability benefits. The IRB will be most concerned about the possibility of:

- Inadequacy of research design
- Conflict of interest
- Inaccuracy of data
- Undue influence of the subjects

Question 2 Multiple Choice/Single Answer - select only one answer (1 point)

An investigator planning to study behavioral changes during alcohol intoxication will pay subjects \$600 for 6 hours of testing that includes drinking a moderate level of alcohol and completing several written questionnaires. He plans to recruit college students taking his courses, as well as economically disadvantaged and homeless people. Which of the

following is the most important for the investigator to address before submitting the protocol to the IRB?

- Method of payment to subjects
- Literacy of homeless subjects
- Potential undue influence or coercion of subjects
- Forms of advertising for subject recruitment

Question 3 Multiple Choice/Single Answer - select only one answer (1 point)

An investigator is recruiting subjects for a study of a new antidepressant drug. The investigator has targeted a population of patients who might clearly benefit, but who are also institutionalized for a variety of psychiatric conditions. The patients are in a controlled environment and it is believed there would be little problem recruiting subjects for the study. Which of the following issues of vulnerability should be of most concern to the IRB?

- The patients are institutionalized
- The patients may be on other medications
- The patients have clinical depression, which is a difficult disease to treat
- The patients are probably illiterate

Question 4 Multiple Choice/Single Answer - select only one answer (1 point)

A faculty member wants to measure the effectiveness of a new psychological assessment instrument before including it in his new textbook. He plans to conduct a pilot test by administering both the new instrument and an established instrument to about 10 people and then compare the results. Which of the following populations would be considered potentially most vulnerable to undue influence?

- Members of his community organization who agree to take the tests
- Senior faculty in his department
- Students taking one of his courses
- Members of his professional society

## VULNERABLE SUBJECTS – RESEARCH WITH PRISONERS

Question 1 Multiple Choice/Single Answer - select only one answer (1 point)

When investigators plan to involve a prisoner population, which best describes the type of federally supported research that may be conducted?

- research that involves only minimal risk to the prisoner population
- research that has the promise of benefit to society in general, but not necessarily the prisoner population
- research that the investigator proposes and gets funded
- research that is relevant to prisoners and their conditions or situations

Question 2 Multiple Choice/Single Answer - select only one answer (1 point)

The purpose of a federally supported research protocol is to examine the characteristics and effectiveness of 'house arrest,' a program where individuals are confined to their homes under continuous surveillance. Which of the following best describes the IRB's duties when reviewing this research?

- Since this research is federally supported, the IRB does not have any duty to review this research
- Since this research does not involve individual subjects who would be considered prisoners, the IRB does not have any additional duties
- Even though this research involves individual subjects who would be considered prisoners and examines an alternative to incarceration, the IRB does not have any additional duties
- 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

Question 3 Multiple Choice/Single Answer - select only one answer (1 point)

When reviewing federally supported research involving prisoners, an IRB must have at least the following member, in addition to the standard requirements for IRBs to ensure that the prisoners' perspective is represented:

- one member who is a health care provider at the local hospital where prisoner may be treated
- two members who are currently prison guards, wardens or parole officers
- one member who is a prisoner or prisoner representative
- two members who are employed by the federal penal system

Question 4 Multiple Choice/Single Answer - select only one answer

(1 point)

Due to past abuses, which of the following groups of potential research subjects has specific Department of Health and Human Services (DHHS) regulations to ensure additional protections when this population is being considered for research.

- men
- mentally disabled persons
- the elderly
- prisoners

VULNERABLE SUBJECTS – RESEARCH INVOLVING MINORS

Question 1 Multiple Choice/Single Answer - select only one answer (1 point)

A federally funded research study involving children 8 to 12 years old involves collecting a single voided urine sample to assess the frequency of asymptomatic proteinuria (higher amounts of protein in the urine without any signs or symptoms of illness or infection). Your IRB has determined that assent of children age 8 and older is required for the study. A 10 year old does not assent to participate in the study described above. Which of the following procedures best describes the action to be taken by the investigator?

- Honor the child's decision.
- Consent both of the child's parents instead.
- Consent one of the child's parent instead.
- Request the child reconsider assenting to the study.

Question 2 Multiple Choice/Single Answer - select only one answer (1 point)

A federally funded research study involving children 8 to 12 years old involves collecting a single voided urine sample to assess the frequency of asymptomatic proteinuria (higher amounts of protein in the urine without any signs or symptoms of illness or infection). According to 45 CFR 46, an IRB's risk assessment would likely conclude that this study involves:

- No risk to the child and no further IRB review is required.
- No more than minimal risk to the child.
- More than minimal risk with prospect of direct benefit to the child.
- More than minimal risk with no prospect of direct benefit to the child.

Question 3 Multiple Choice/Single Answer - select only one answer (1 point)

An investigator proposes a study to determine the clinical relevance of a new assay technique to measure minimal residual disease (MRD) in adolescent (age 14-16) cancer patients undergoing chemotherapy. The study requires that two additional bone marrow aspirates be performed during the course of chemotherapy. The subject's chemotherapy will not be altered based on the results of the assay technique measures. However, future patients with cancer would benefit from improved interventions based on study findings. The IRB determined that the activity was a minor increase over minimal risk. Which of the following statements best describes the IRB approval requirements for involving adolescent cancer patients in the research study?

- Assent of the child and permission of both parents are required.
- Assent is not required, however, one parent must give permission for the inclusion of the adolescent in this study.
- Assent is not required, however, both parents must give permission for the inclusion of the adolescent child.
- Assent of the child only is required.

#### VULNERABLE SUBJECTS – RESEARCH INVOLVING PREGNANT WOMEN AND FETUS IN UTERO

Question 1 Multiple Choice/Single Answer - select only one answer (1 point)

A research project is designed to evaluate a new experimental type of fetal surgery to correct diaphragmatic hernia in the fetus (a potentially life-threatening condition for the baby) prior to delivery. This research is directed toward the fetus as subject to meet the health needs of the fetus. The pregnant woman is otherwise healthy. The investigator must obtain consent from whom?

- The pregnant woman only.
- The state court where the research is taking place
- The father of the fetus only.
- The pregnant woman and the father of the fetus.

Question 2 Multiple Choice/Single Answer - select only one answer (1 point)

According to current NIH Guidelines, which of the following is adequate justification for exclusion of women from NIH funded research?

- The woman is of child-bearing potential.
- Inclusion of women would complicate analysis of the results and increase the costs of conducting the clinical trial.
- There is compelling evidence that inclusion would be inappropriate with respect to the health of the subjects.

Question 3 Multiple Choice/Single Answer - select only one answer (1 point)

Investigators wish to evaluate a new treatment for eclampsia (a life threatening condition in pregnant women) in women 30 – 50 years of age. The research is intended to directly benefit the pregnant woman who is otherwise healthy and competent. The investigator must obtain consent from whom?

- The pregnant woman and the father of the fetus.
- The pregnant woman only.
- The pregnant woman and her legally authorized representative.
- The father of the fetus only.

## INTERNATIONAL RESEARCH

(no quiz)

## GROUP HARMS: RESEARCH WITH CULTURALLY OR MEDICALLY VULNERABLE GROUPS

Question 1 Multiple Choice/Single Answer - select only one answer (1 point)

Which of the following practices can be effective in minimizing group harms?

- Ongoing consultation
- Planning disclosure of research results
- Collaborative IRB review
- Community consultation
- All of the above

Question 2 Multiple Choice/Single Answer - select only one answer (1 point)

Which of the following studies has the LEAST potential to create group harm?

- Phase 3 clinical trial of a new anticancer agent in middle-aged women diagnosed with breast cancer.
- 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.
- A genetic study to identify ancestral relationships between DNA obtained from a Cherokee Indian burial site and members of a Central Asian community.
- A study that surveys the perceptions of nurses and other health care workers about illegal drug use among cardiovascular surgeons in New York City.

Question 3 Multiple Choice/Single Answer - select only one answer (1 point)

The results from research have been known to produce harms to members of the sampled population who do not actually participate in the research study. An example of the type of research that could result in group harms is:

- A study designed to investigate genetic links between DNA samples found at a prehistoric central Asian archeological site and west coast American Indian tribes.
- A hair restoration study in middle aged men.
- A study to establish national reading standards in ten year old children.
- A study on the efficacy of a new birth control device in middle aged women.

#### FDA REGULATED RESEARCH

Question 1 Multiple Choice/Single Answer - select only one answer (1 point)

An academic medical center is selecting a new database system for clinical research. The system needs to be "Part 11 compliant" in order to allow:

- The investigator to email subjects about the research.
- The database system to assign passwords.
- The medical center to replace the use of paper records with electronic records for its research.
- The use of paper records meeting FDA requirements.

Question 2 Multiple Choice/Single Answer - select only one answer (1 point)

21 CFR Part 11 is intended to:

- Allow the use of electronic documents and signatures in the regulatory process for drugs and devices.
- Provide specific standards for accuracy, reliability and consistent performance for hospital computer systems.
- Prohibit the use of paper printouts of electronic records.
- Require use of electronic records for all drug research.

Question 3 Multiple Choice/Single Answer - select only one answer (1 point)

An investigator proposes to study a marketed product sold to treat high blood pressure in individuals over age 12 using a liquid formulation for children under age 12. The drug sponsor hopes that the information from the research can be used to change the labeling for use of the drug in children. Which of the following is the investigator's most appropriate course of action?

- Submit the research protocol to the Office for Human Research Protections (OHRP) for their review

- Submit the research protocol to the IRB for review, but do not submit an IND application to the FDA since the drug is already approved and marketed for this indication
- Submit the research protocol to the IRB for review and submit an IND application to the FDA before conducting the research
- Submit an Investigational Device Exemption (IDE) application to the FDA

Question 4 Multiple Choice/Single Answer - select only one answer (1 point)

An adult presents to a physician with attention deficit hyperactivity disorder (ADHD). To date, no behavioral or drug interventions have proven useful. The physician has just read several reports about a drug that is approved and marketed for another indication, but has shown some benefit for ADHD. The physician wants to prescribe this drug, in the labeled marketed dose, for the individual patient. Which of the following would be the most appropriate course of action?

- Submit an Investigational New Drug (IND) application before treating the subject
- Submit a research protocol for IRB review and approval before treating the patient
- Inform the patient that the drug cannot be prescribed
- Treat the patient with the drug based on physician's best medical judgment

Question 5 Multiple Choice/Single Answer - select only one answer (1 point)

A sponsor proposes research to evaluate reengineering a commercially available pacemaker. It is hoped that the new pacemaker will pose fewer risks to individuals when compared to the current commercially available product. How should this device be classified?

- Significant risk device
- Non-significant risk device

## WORKERS AS RESEARCH SUBJECTS

Question 1 Multiple Choice/Single Answer - select only one answer (1 point)

Researcher access to confidential records adds to the vulnerability of workers who participate in workplace studies. Inappropriate release of identifiable private information could adversely affect a worker's retention of a job, insurance or other employment related benefits. To avoid or minimize these risks, the study design must include adequate safeguards to protect the confidentiality of the information collected. A plan for the proper management of study data and records should clearly define:

- Who will have access to the data.

- If the study results, if any, will be included in the employee's personnel records.
- If personal identifiers will be retained and used in the data analysis.
- How the data will be collected and secured.
- All of the above

Question 2 True/False (1 point)

When a research project includes the collection of biological samples, all planned future uses of the samples, identifiers, and the data obtained from the samples, must be fully explained to the research subject.

- True
- False

Question 3 Multiple Choice/Single Answer - select only one answer (1 point)

Vulnerable persons are those who are less able to defend themselves than other persons in a given situation. The Common Rule (45 CFR 46) has specific requirements for the following vulnerable populations, except:

- Pregnant Women
- Workers
- Children
- Prisoners

Question 4 Multiple Choice/Single Answer - select only one answer (1 point)

When workers are asked to participate in a research study, vulnerabilities related to the subjects employment may include:

- Unions may encourage employees to participate with the expectation that "entitlements" may follow from study results.
- The employer may encourage or deny participation of workers.
- Employees may experience pressure from management to participate in the study because the employer perceives the study to be advantageous to the organization.
- The research study's finding could affect an employee's pay, benefits or promotion potential.
- All of the above

IRB MEMBER MODULE – “WHAT EVERY IRB MEMBER NEEDS TO KNOW”

Question 1 Multiple Choice/Single Answer - select only one answer (1 point)

**The Case:** A Full IRB Committee meeting is convened on October 18, 2006. The IRB

Committee roster consists of 15 members. However, only 8 members are in attendance for today's meeting. One agenda item is a new research proposal to evaluate how mothers interact with their learning disabled child. The inclusion criteria require the children to be a minimum of five years of age. The protocol requires the mother of the child to look at the child without any expression and not to talk to the child for three minutes. One of the IRB members, Susan, is Principal Investigator for the study and receives a portion of her salary from the supporting grant.

**The Question:** The proposal does not include adequate information regarding the potential risks to the minor subjects in the research study, but is otherwise approvable. The committee considers these risks to be more than minimal risk to the minor child. Which of the following best describes how the IRB should proceed?

- Approve the proposal if the IRB can deduce what the risks would be.
- Approve the proposal, but ask the investigator to write a letter to the IRB describing risks to the minor subjects and that might be appended to the IRB records.
- Conditionally approve the research, pending receipt of additional information from the investigator, and review by the IRB staff.
- Table the protocol and ask the investigator to provide the needed information for review by the full board at the next convened meeting.

Question 2 Multiple Choice/Single Answer - select only one answer (1 point)

**The Case:** A Full IRB Committee meeting is convened on October 18, 2006. The IRB Committee roster consists of 15 members. However, only 8 members are in attendance for today's meeting. One agenda item is a new research proposal to evaluate how mothers interact with their learning disabled child.

**The Question:** Which of the following IRB members must be present during the IRB's discussion and vote on a proposal?

- A social worker.
- A member who is unaffiliated with the institution.
- The non-scientist member.
- The Principal Investigator for the research proposal under deliberation.

Question 3 Multiple Choice/Single Answer - select only one answer (1 point)

**The Case:** A Full IRB Committee meeting is convened on October 18, 2006. The IRB Committee roster consists of 15 members. However, only 8 members are in attendance for today's meeting. One agenda item is a new research proposal to evaluate how mothers interact with their learning disabled child. The inclusion criteria require the children to be a minimum of five years of age. The protocol requires the mother of the child to look at the child without any expression and not to talk to the child for three minutes.

**The Question:** The Committee determined that the mother's required task may upset the

child. Which of the following actions best describes the most appropriate steps for the committee to take?

- Evaluate the study risks and study benefits and to determine if appropriate procedures are in place to minimize study risk to participants.
- Recommend an alternate age range of disabled children between ages 7-11.
- Check to make sure that there is an assent form for the child.
- Reject the study as too risky.

Question 4 Multiple Choice/Single Answer - select only one answer (1 point)

**The Case:** A Full IRB Committee meeting is convened on October 18, 2006. The IRB Committee roster consists of 15 members. However, only 8 members are in attendance for today's meeting. One agenda item is a new research proposal to evaluate how mothers interact with their learning disabled child. The inclusion criteria require the children to be a minimum of five years of age. The protocol requires the mother of the child to look at the child without any expression and not to talk to the child for three minutes. One of the IRB members, Susan, is Principal Investigator for the study and receives a portion of her salary from the supporting grant.

**The Question:** What is the minimum number of people required to conduct business at this Full IRB Committee meeting?

- 7
- 9
- 10
- 8

Question 5 Multiple Choice/Single Answer - select only one answer (1 point)

**The Case:** A Full IRB Committee meeting is convened on October 18, 2006. The IRB Committee roster consists of 15 members. However, only 8 members are in attendance for today's meeting. One agenda item is a new research proposal to evaluate how mothers interact with their learning disabled child. The inclusion criteria require the children to be a minimum of five years of age. The protocol requires the mother of the child to look at the child without any expression and not to talk to the child for three minutes. One of the IRB members, Susan, is Principal Investigator for the study and receives a portion of her salary from the supporting grant.

**The Question:** Susan, the principal investigator, must recuse herself from the room during both the final deliberations and the vote on the study. Which of the following best describes the committee's action after Susan leaves the IRB meeting?

- Defer the proposal to the next meeting because of a loss of quorum.
- Trust that the study is ethical because Susan is a member of the Committee and continue with the final deliberations and vote.

- Use an expert in child development as a consulting reviewer could help answer questions in Susan's absence.
- Continue with review, discussion and vote because the minutes will note that Susan abstained from the vote.

Question 6 Multiple Choice/Single Answer - select only one answer (1 point)

**The Case:** A Full IRB Committee meeting is convened on October 18, 2006. The IRB Committee roster consists of 15 members. However, only 8 members are in attendance for today's meeting. One agenda item is a new research proposal to evaluate how mothers interact with their learning disabled child. The inclusion criteria require the children to be a minimum of five years of age. The protocol requires the mother of the child to look at the child without any expression and not to talk to the child for three minutes. One of the IRB members, Susan, is Principal Investigator for the study and receives a portion of her salary from the supporting grant.

**The Question:** There were a number of problems with the protocol, but the IRB eventually approved the protocol at a duly constituted Full IRB Committee Review on February 15, 2007. Accrual and treatment are planned to continue through 2008. Which of the following best describes IRB continuation review requirements for this study?

- The research must be re-reviewed by the Full IRB Committee on or before February 14, 2008.
- The IRB may extend the deadline for continuing review by 30 days. After that, the research must cease.
- The continuation review may be conducted by a voting member of the IRB, delegated by the Chair.
- The continuation review can be conducted by the IRB Chair only.

## Tips for Taking the CIP Exam:

### **Many Months Before the Test**

Dedicate at least 4 hours per week to study / go over materials.

Use your best studying technique. Consider writing notes on index / flash cards and then testing yourself with these. Also note which days/time works best for studying. Are you a morning person, night person, etc?

If you are a late night studier, when you wake up the next morning, briefly read through the items you studied within the first 30 minutes of waking up.

When you register, choose a testing center that is close to home. Also take the exam on a Saturday if possible to avoid traffic.

Map out the directions to the testing center. Visit the testing center before the exam if you are unfamiliar with the area. Then you won't have to stress out trying to find the place the day of the exam.

### **Night Before the Test**

Don't stay up all night cramming the night before the exam. Get lots of sleep, you'll need the energy.

Set a back-up alarm (e.g. cell phone alarm, additional clock) in case your regular alarm clock fails.

Pack a snack in your pants pocket. When you take a water/bathroom break, eat the snack for extra energy & brain power.

### **Test Day**

Relax and do not stress. There is no pressure to pass. If you don't pass, you can always take it again.

Arrive at least 15 minutes early.

Go to the bathroom before walking into the exam room. You don't want to waste anytime worrying about your bodily needs during the test.

Eat a good breakfast.

Drink a large coffee right before taking the test, caffeine helps your memory.

Do not bring any valuables or cell phones as they will not let you take them in the exam room.

## **During the Exam**

Get up and take a 5 minute bathroom / water break at least once.

When choosing an answer, think about what we do in practice. This may help you choose the correct answer.

One strategy is to skip all questions that are a paragraph long and go back to these at the end of the test.

When you are stuck and don't know an answer, skip the question and move on. If you battle it out, you may lose your confidence and "psych" yourself out. You can go back to these questions at the end and make a best guess.

About 30 minutes before the test is over, go over each skipped question. If you don't know the answer, eliminate as many choices as possible and then make a best guess.

About 5 minutes before the test is over, look at the answer sheet and make sure you don't leave anything unanswered. Never leave anything unanswered!

Pray, chant, etc... call on your higher power for help, you'll need it!

# CERTIFICATION EXAMINATION FOR IRB PROFESSIONALS

Handbook for Candidates

## SPRING 2008 TESTING PERIOD

Application Deadline: January 15, 2008  
First Day of Testing: Saturday, March 1, 2008  
Last Day of Testing: Saturday, March 15, 2008

## FALL 2008 TESTING PERIOD

Application Deadline: August 1, 2008  
First Day of Testing: Saturday, September 13, 2008  
Last Day of Testing: Saturday, September 27, 2008



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Code of Ethics  
for  
Certified IRB Professionals

The following code of ethics was developed in recognition of the vital role that Certified IRB Professionals play in the ethical conduct of human subject research. It is the responsibility of each Certified IRB Professional to aspire to the highest possible standards of conduct in order to enhance the protection of persons who participate in research.

As a Certified IRB Professional committed to the protection of human research subjects, I will:

- Conduct myself personally and professionally with honesty and integrity at all times to inspire trust and confidence in my actions;
- Give prime consideration to protection of the rights and welfare of human research subjects;
- Apply the principles of the Belmont Report and other ethical standards pertaining to the conduct of research involving human subjects;
- Adhere to federal, state and local laws and regulations;
- Respect the rights, dignity and worth of all people and be sensitive to cultural and individual differences;
- Fully disclose or avoid all potential conflicts of interest when rendering professional services, judgements and assessments;
- Avoid using proprietary knowledge or private information for personal gain;
- Ensure that all confidential and private information that comes into my possession is protected;
- Pursue education, network with colleagues and consult with others to develop and maintain the highest possible level of knowledge and understanding;
- Facilitate and encourage open communication among all parties, recognizing the shared responsibility for the ethical conduct of human subject research.
- Protect the integrity and content of the Certification Examination for IRB Professionals

Effective Date: March 23, 2002

Revised: October 13, 2007

All questions about this code of ethics should be addressed to the Council for Certification of IRB Professionals.

## CERTIFICATION

The Council for Certification of IRB Professionals (CCIP), an initiative of Public Responsibility in Medicine and Research (PRIM&R), endorses the concept of voluntary, periodic certification by examination for all IRB (Institutional Review Board) professionals. Certification is one part of a process called credentialing. Certification focuses specifically on the individual and is an indication of current knowledge in a specialized area of practice. Certification for IRB professionals is highly valued and provides formal recognition of knowledge of IRB functions and human research protection programs.

## PURPOSES OF CERTIFICATION

TO PROMOTE IRB ADMINISTRATION PRACTICE AND TO ADVANCE THE QUALITY OF HUMAN RESEARCH PROTECTION PROGRAMS THROUGH THE CERTIFICATION OF QUALIFIED IRB PROFESSIONALS BY:

1. Recognizing formally those individuals who meet the eligibility requirements of the Council for Certification of IRB Professionals (CCIP) and pass the Certification Examination for IRB Professionals.
2. Encouraging continued personal and professional growth in the practice of human research protection programs.
3. Establishing and measuring the level of knowledge required for certification in IRB administration.
4. Demonstrating a standard level of knowledge about human subject research review under United States rules and regulations; thereby assisting the employer, public, and members of the research professions in the assessment of IRB professionals.

## ELIGIBILITY REQUIREMENTS

The certification program is for individuals participating in and overseeing the daily activities associated with an IRB, although other individuals involved in IRB activities who meet the following eligibility requirements are also eligible to take the examination.

1. A Bachelor's degree plus two (2) years of relevant IRB experience within the past seven years\*;  
OR  
Four (4) years of relevant IRB experience within the past ten years\*;  
OR  
Currently certified as a CIP.
2. Completion and filing of an Application for the Certification Examination for IRB Professionals.
3. Payment of required fee.

\*Relevant IRB experience must have been substantial and ongoing, represented by a commitment to the area of human subjects protection. Qualifying experience requires performance of IRB functions such as: applying ethical principles and regulations to the review of research protocols and informed consent documents; supporting and/or serving as a resource during IRB meetings; preparation of IRB correspondence and/or documentation; managing the office that provides support of the IRB; training investigators, staff, and IRB members; serving as a human subject protection resource or advisor to investigators, staff, and IRB members; developing IRB policies and procedures; and/or overseeing others in the performance of these activities. IRB chairs and organizational officials who perform these functions may be appropriate candidates for certification. Service as an IRB member is not, in and of itself, sufficient to fulfill the requirements for experience. Likewise, interacting with an IRB as sponsor personnel or study site personnel such as coordinator, administrator or investigator does not fulfill the experience requirements.

## ADMINISTRATION

The Certification Program is sponsored by the Council for Certification of IRB Professionals (CCIP), an initiative of PRIM&R. The Certification Examination for IRB Professionals is administered for the CCIP by the Professional Testing Corporation (PTC), 1350 Broadway - 17th Floor, New York, New York 10018, (212) 356-0660, [www.ptcny.com](http://www.ptcny.com). Questions concerning the examination should be referred to PTC.

## ATTAINMENT OF CERTIFICATION AND RECERTIFICATION

Eligible candidates who pass the Certification Examination for IRB Professionals are eligible to use the registered designation CIP after their names and will receive certificates from the CCIP. A registry of Certified IRB Professionals will be maintained by the CCIP and may be reported in its publications.

Certification is recognized for a period of three years at which time the candidate must retake and pass the current Certification Examination for IRB Professionals or meet such alternative requirements as are in effect at that time in order to retain certification.

Recertification must be accomplished prior to the certification expiration to avoid a lapse in certification. Applications to recertify by continuing education must be date stamped by the post office or other documented mode of transmission no later than 30 days after the date of certification lapse or recertification by examination will be required.

A person who holds certification and takes the examination but does not pass, will lose their certification. This is effective on the date that the notification of the results from the examination is received. Also, certification holders should be aware that those who are eligible to recertify by continuing education, but chose to take the examination instead and do not pass may not subsequently use continuing education to recertify. i.e., the examination must be passed before the credential can be reissued.

### REVOCATION OF CERTIFICATION

Certification may be revoked by CCIP for any of the following reasons:

1. Falsification of an Application.
2. Misrepresentation of certification status.
3. Violation of the CCIP Code of Ethics.

The Appeals Committee of the CCIP provides an appeal mechanism for challenging revocation of certification. It is the responsibility of the individual to initiate this process by sending a written request to CCIP care of PTC.

### APPLICATION PROCEDURE

Obtain a Handbook for Candidates and an Application for the Certification Examination for IRB Professionals from the Professional Testing Corporation, 1350 Broadway - 17th Floor, New York, New York 10018, (212) 356-0660, [www.ptcny.com](http://www.ptcny.com).

Read and follow the directions on the Application and in this Handbook for Candidates.

### COMPLETION OF APPLICATION

Complete or fill in as appropriate ALL information requested on the Application. Mark only one response unless otherwise indicated.

**CANDIDATE INFORMATION:** Starting at the top of the Application, print your name, address, daytime phone number, evening phone number, e-mail address, and examination date which you are applying for in the appropriate row of empty boxes.

**ELIGIBILITY AND BACKGROUND INFORMATION:** All questions must be answered. Mark only one response unless otherwise indicated. Note that training and experience requirements must be completed before submitting your application. Do not submit an application if you have not met the eligibility requirements.

**OPTIONAL INFORMATION:** These questions are optional. The information requested is to assist in complying with equal opportunity guidelines and will be used only in statistical summaries. Such information will in no way affect your test results.

**CANDIDATE SIGNATURE:** When you have completed all required information, sign and date the Application in the space provided.

Fold the completed Application. Mail the Application with the appropriate fee (see FEES below) in time to be received by the deadline shown on the cover of this Handbook to:

CCIP EXAMINATION  
PROFESSIONAL TESTING CORPORATION  
1350 Broadway – 17<sup>th</sup> Floor  
New York, New York 10018

**NOTE: ALL APPLICATIONS ARE SUBJECT TO AUDIT AND REQUEST FOR SUPPORTING DOCUMENTATION.**

**FEES**

1. Application fee for the Certification Examination for IRB Professionals:

PRIM&R Members .....	\$335.00
Non-PRIM&R Members .....	\$435.00

**MAKE CHECK OR MONEY ORDER PAYABLE TO:**

CCIP EXAMINATION

DO NOT SEND CASH.

Visa, MasterCard, and American Express are also accepted. Please complete the credit card payment form on the application.

**REFUNDS**

There will be no refund of fees. Fees will not be transferred from one testing period to another.

## EXAMINATION ADMINISTRATION

The Certification Examination for IRB Professionals is administered during an established two-week testing period on a daily basis, Monday through Saturday, excluding holidays, at computer-based testing facilities managed by LaserGrade Computer Testing, Inc. LaserGrade has several hundred testing sites in the United States as well as Canada. Scheduling is done on a first-come, first-serve basis. To find a testing center near you visit: [www.lasergrade.com](http://www.lasergrade.com) or call LaserGrade at (800) 211-2754. Please note: Hours and days of availability vary at different centers. You will not be able to schedule your examination appointment until you have received an Eligibility Notice from PTC.

## SCHEDULING YOUR EXAMINATION APPOINTMENT

Once your application has been received and processed, and your eligibility verified, you will be mailed an Eligibility Notice. The Eligibility Notice plus photo identification **MUST** be presented in order to gain admission to the testing center. A candidate not receiving an Eligibility Notice or other correspondence at least two weeks before the beginning of the two-week testing period should contact the Professional Testing Corporation by telephone at (212) 356-0660.

The Eligibility Notice will indicate where to call to schedule your examination appointment as well as the dates in which testing is available. Appointment times are first-come, first-serve, so schedule your appointment as soon as you receive your Eligibility Notice in order to maximize your chance of testing at your preferred location and on your preferred date.

## SPECIAL NEEDS

Special testing arrangements may be made for special needs individuals submitting the Application, examination fee, and a letter describing the nature of the disability and the special accommodations needed for testing. Requests for special testing needs individuals must be received at least EIGHT weeks before the testing period begins.

## CHANGING YOUR EXAMINATION APPOINTMENT

If you need to cancel your examination appointment or reschedule to a different date within the two-week testing period you must contact LaserGrade at (800) 211-2754 no later than noon, Eastern Standard Time, of the second business day **PRIOR** to your scheduled appointment.

If you fail to arrive for your appointment or cancel without giving the required notice, you will forfeit your testing fee.

## RULES FOR THE EXAMINATION

1. No signaling devices, including cellular phones, pagers, and alarms, may be operative during the examination.
2. No books or other reference materials may be taken into the examination room.

3. No test materials, documents, or memoranda of any sort are to be taken from the examination room.
4. No questions concerning content of the examination may be asked during the testing period. The candidate should read carefully the directions provided on screen at the beginning of the examination session.

### REPORT OF RESULTS

Candidates will be notified in writing by PTC within four weeks of the close of the testing period whether they have passed or failed the examination. Scores on the major areas of the examination and on the total examination will be reported. Successful candidates will also receive certificates from the CCIP.

### REEXAMINATION

The Certification Examination for IRB Professionals may be taken as often as desired upon filing of a new Application and fee. There is no limit to the number of times the examination may be repeated.

### CONFIDENTIALITY

1. The CCIP will release the individual test scores ONLY to the individual candidate.
2. Any questions concerning test results should be referred to Professional Testing Corporation.
3. Names of successful candidates may be published in PRIM&R publications and CCIP documents.
4. Confirmation of CIP status, i.e. certified or not certified, certificate number and dates of certification, may be provided to persons other than the individual candidate.

### CONTENT OF EXAMINATION

1. The Certification Examination for IRB Professionals is a written examination composed of a maximum of 250 multiple-choice, objective questions with a total testing time of four (4) hours.
2. The content for the examination is described in the Content Outline starting on page 7.
3. The questions for the examination are based on existing regulations and widely accepted guidance. They are obtained from individuals with expertise in human research protection programs and are reviewed for construction, accuracy, and appropriateness by CCIP.
4. The CCIP, with the advice and assistance of the Professional Testing Corporation, prepares the examination.
5. The Certification Examination for IRB Professionals will be weighted in approximately the following manner:
  - I. Foundations and Concepts of IRB Practice..... 25%
  - II. Organizational and Personnel Knowledge ..... 15%
  - III. IRB Functions and Operations ..... 45%
  - IV. Records and Reports ..... 15%

## CONTENT OUTLINE

- I. Foundations and Concepts of IRB Practice
  - A. Historical Background
  - B. Research Ethics
    1. Belmont Principles
      - a. Respect for Persons
      - b. Beneficence
      - c. Justice
    2. International Codes/Standards
      - a. Nuremberg Code
      - b. Declaration of Helsinki
      - c. Council for International Organizations of Medical Sciences
      - d. International Conference on Harmonisation
    3. Professional Codes
      - a. CIP Code of Ethics
      - b. Professional Association Codes
    4. Conflict of Interest
  - C. Research Design Issues
    1. Types of Study Designs
    2. Minimizing Risks
    3. Study Monitoring (DMC, Plans, etc.)
    4. Sample Size/Statistics
    5. Privacy, Confidentiality, and Data Security
    6. Deception
  - D. Regulatory Application
    1. HHS Regulations
      - a. Applicability
      - b. Exemptions
    2. Common Rule
      - a. Applicability
      - b. Agency Differences (e.g. DOD, DOEd, DOJ)
      - c. Exemptions
    3. FDA Regulations (Human Subjects)
      - a. Applicability
      - b. Exemptions
    4. FDA Regulations (Drugs/Biologics/Devices)
      - a. Applicability
      - b. Exemptions
    5. State/Local Regulation
    6. Regulatory Audits
      - a. FDA Bioresearch Monitoring Program
      - b. OHRP Monitoring and Site Visits
      - c. Sponsor/Cooperative Group Monitoring
      - d. Joint Commission on Accreditation of Healthcare Organizations
    7. Health Insurance Portability and Accountability Act (HIPAA)
  - E. Definitions
    1. Research
    2. Human Subjects
    3. Minimal Risk
    4. Vulnerable Populations
    5. Engaged in Research
- II. Organizational and Personnel Knowledge
  - A. IRB Committee Organization
    1. Authority
      - a. Approve/Disapprove/Modify
      - b. Suspend/Terminate
    2. Membership Requirements
    3. Quorum Requirements

4. Reporting Lines
  5. Leadership Issues
  - B. IRB Office Organization
    1. Staff Responsibilities and Authorities
    2. Reporting Lines
    3. Management (Personnel, Budget, and Billing)
  - C. Institutional Considerations
    1. Scientific Review
    2. Grants and Contracts Review
    3. Other Committee Review (RDRC, Biosafety)
    4. Institutional Review
  - D. Educational Program Design/Implementation
    1. Education Programs for IRB Staff
    2. Education Programs for IRB Members
    3. Education Programs for Investigators/Research Sites
    4. Education Programs for Institutional Officials
- III. IRB Functions and Operations
- A. IRB Review
    1. Levels of Review
      - a. Exempt Procedures
      - b. Expedited Review
      - c. Convened Meeting Review
    2. Types of Review
      - a. Initial Review
      - b. Continuing Review
      - c. Amendment Review
      - d. Adverse Event/ Unanticipated Problems Review
      - e. Final Reports/Study Closure
    3. Criteria for Approval of Research
      - a. Risk Determination and Minimization of Risks
        1. Minimal/Minor Increase/Greater than Minimal
        2. Significant/Non-significant Risk Devices
        3. Procedure Review
      - b. Risk-Benefit Analysis
      - c. Equitable Subject Selection
        1. Inclusion/Exclusion of Children, Minorities and Women
        2. Inclusion/Exclusion of Other Vulnerable Populations
      - d. Informed Consent
        1. General Conditions
        2. Elements
        3. Waiver of Consent
        4. Documentation
        5. Waiver of Documentation
        6. HIPAA
      - e. Monitoring Plans
      - f. Protection of Privacy and Maintenance of Confidentiality
        1. Common Rule
        2. HIPAA
        3. Certificates of Confidentiality
      - g. Additional Safeguards for Vulnerable Subjects
    4. Emergency Uses
    5. Treatment Uses
    6. Subject Recruitment
      - a. Advertisements
      - b. Inclusion/Exclusion Criteria
      - c. Incentives
    7. Special Regulatory Requirements
      - a. Fetuses, Pregnant Women, IVF

- b. Prisoners
      - c. Children
      - d. Emergency-setting Research
    - 8. Data, Documents, Records, Specimens, Repositories
    - 9. International Research
  - B. IRB Staff Review
    - 1. Staff Pre-screening
    - 2. Post-meeting Communications/Review
    - 3. Auditing
      - a. IRB office (Internal)
      - b. Investigators/Research Sites
      - c. Program Assessment (TQM/CQI)
  - C. Post Approval Monitoring
    - 1. Consent Process
    - 2. Research
    - 3. Protocol Deviations
- IV. Records and Reports
- A. Policies, Procedures and Membership
    - 1. IRB Membership Records
    - 2. IRB Policies
    - 3. IRB Procedures and Forms
  - B. Assurances and Registration
    - 1. Federalwide Assurance of Protection for Human Subjects (FWA)
    - 2. IRB Registration
  - C. Regulatory Reports (Internal/External)
    - 1. Noncompliance
    - 2. Terminations/Suspensions
    - 3. Subjects' Rights and Welfare (Injury, Adverse Events, and Unanticipated Problems)
  - D. Audit Reports, Monitoring and Other Communications
    - 1. Internal Procedure Audits
    - 2. Study Monitoring Reports
    - 3. External Audits (OHRP, FDA)
    - 4. Accreditation
    - 5. Clinical Trial Registries
  - E. Meeting Minutes
    - 1. Attendance, Quorum, Voting
    - 2. Discussion and Findings
    - 3. Reports to the IRB
  - F. Document and File Maintenance
    - 1. Study Files
    - 2. IRB Management Files
    - 3. Regulatory Documents
  - G. Archiving Requirements
    - 1. IRB Records
    - 2. Investigator Records
    - 3. HIPAA Records
  - H. Information Management
    - 1. File Tracking
    - 2. Data Collection
  - I. Training Documentation
    - 1. IRB Members and Staff
    - 2. Investigators and Other Key Personnel
    - 3. Institutional Officials

## SAMPLE EXAMINATION QUESTIONS

In the following questions, choose the one best answer.

1. According to the Belmont Report, respect for persons typically demands that subjects
  1. share in the benefits of the research.
  2. gain maximum benefit from research.
  3. waive any rights or benefits from research.
  4. enter into research voluntarily with adequate information.
2. Which of the following is used to avoid bias in assigning subjects to experimental groups?
  1. Double blind
  2. Placebo control
  3. Clinical equipoise
  4. Paying subjects to participate
3. In most research, which of the following best assures confidentiality?
  1. Obtaining releases of information
  2. Storing research records in a locked cabinet for at least three years
  3. Following acceptable practices for coding and storing data
  4. Removing identifiers after the research ends
4. When reviewing research, the IRB should ensure that the consent process
  1. includes a consent monitor.
  2. is conducted by a third party.
  3. is the same for all populations.
  4. provides the subject sufficient opportunity to consider whether or not to participate.

## CORRECT ANSWERS TO SAMPLE QUESTIONS

1. 4; 2. 1; 3. 3; 4. 4

## REFERENCES

The Council for Certification of IRB Professionals (CCIP) has prepared a suggested reference list to assist in preparing for the Certification Examination for IRB Professionals. These references contain journals and textbooks which include information of significance to human research protection programs practice. Inclusion of references on this list does not constitute an endorsement by the CCIP or PRIM&R of specific professional literature which, if used, would guarantee candidates successful passing of the certification examination. Note: The examination does not test on additional policies and procedures developed by individual IRBs.

### BOOKS

Bankert, E. & Amdur, R. Institutional Review Board: Management and Function, Second Edition. Sudbury, MA: Jones and Barlett Publishers, 2006.

Davis, A., et al. Study Guide for Institutional Review Board: Management and Function, Second Edition. Sudbury, MA: Jones and Barlett Publishers, 2006.

Dunn, C. & Chadwick, G. Protecting Study Volunteers in Research: A Manual for Investigative Sites. (3<sup>rd</sup> ed.). Boston: Center Watch, 2004.

### PERIODICALS

Human Research Report. Omaha, NE. The Deem Corp.

IRB: A Review of Human Subjects Research. Briarcliff Manor, NY. The Hastings Center

### GUIDANCES

FDA Information Sheets for Institutional Review Boards and Clinical Investigators. Food and Drug Administration

Protecting Human Research Subjects: Institutional Review Board Guidebook. (1993). Bethesda, MD. Office for Protection from Research Risks

### REGULATIONS

21 CFR 11

21 CFR 50/56

21 CFR 54

21 CFR 312

21 CFR 361

21 CFR 600

21 CFR 812

45 CFR 46 (Subparts A, B, C, D)

45 CFR 160/164

## OTHER

Ethical Principles and Guidelines for the Protection of Human Subjects of Research (Belmont Report)

Declaration of Helsinki

Nuremberg Code

Cooper, J. & Selwitz, A. Investigator 101(CD-ROM), PRIM&R, Boston, MA 2001.

Council for International Organizations of Medical Sciences (CIOMS) International Ethical Guidelines for Biomedical Research

International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH): Good Clinical Practice

## ONLINE RESOURCES

[www.primr.org/membership/about.html](http://www.primr.org/membership/about.html)

[www.bioethics.gov](http://www.bioethics.gov)

[www.fda.gov](http://www.fda.gov)

[www.fda.gov/oc/gcp/](http://www.fda.gov/oc/gcp/)

[www.hhs.gov/ocr/hipaa/](http://www.hhs.gov/ocr/hipaa/)

[www.ich.org](http://www.ich.org)

[www.nih.gov](http://www.nih.gov)

[www.hhs.gov/ohrp](http://www.hhs.gov/ohrp)

[www.thehastingscenter.org](http://www.thehastingscenter.org)

PTC06144-R



# Application for Certification Examination for IRB Professionals

Please read the directions in the Handbook for Candidates carefully before completing this Application.

**MARKING INSTRUCTIONS:** This form will be scanned by computer, so please make your marks heavy and dark, filling the circles completely. Please print uppercase letters and avoid contact with the edge of the box. See example provided. →

A	B	C	D	E	F	1	2	3	4	5	6
---	---	---	---	---	---	---	---	---	---	---	---

## Candidate Information

Last Name and Suffix (Jr., Sr., etc.)

First Name  Middle Initial

Number and Street  Apartment Number

City  State/Province  Zip/Postal Code

Daytime Phone  -  -  Evening Phone  -  -

E-mail Address

**Examination Date**     Spring     Fall

## Eligibility and Background Information

Darken only one choice for each question unless otherwise directed.

- A. PERCENT OF WORKING TIME CURRENTLY SPENT IN IRB ACTIVITIES:**  
 Less than half-time     Full-time  
 More than half-time
- B. PRIMARY ROLE IN IRB ACTIVITIES:** (*Darken only one response.*)  
 IRB Staff/Administrator/Manager  
 IRB Chair with IRB administrative responsibility  
 Organizational Official with direct IRB admin. responsibility  
 Other (explain) \_\_\_\_\_
- C. EXPERIENCE IN IRB ACTIVITIES:**  
 2 years     5 years     More than 10 years  
 3 to 4 years     6 to 10 years
- D. PRIMARY EMPLOYER:** (*Darken only one response.*)  
 Academic Nonmedical     Clinic  
 Academic Medical     Independent IRB  
 Industrial/Corporate     VA or Military Medical  
 Government     Health Maint./Managed Care  
 Medical Center     Research Institute/Foundation  
 Community Hospital     Other

- E. HIGHEST ACADEMIC LEVEL:**  
 High School Graduate     Master's Degree  
 Some College     Doctoral Degree  
 Associate Degree     Other (specify below) \_\_\_\_\_  
 Bachelor's Degree
- F. NUMBER OF FULL-TIME OR EQUIVALENT PEOPLE IN YOUR OFFICE SUPPORTING IRB ACTIVITIES:**  
 Less than 1.0     5.0 to 9.9  
 1.0 to 2.9     More than 10  
 3.0 to 4.9
- G. SCOPE OF IRB REVIEW:** (*Darken only one response.*)  
 Biomedical only  
 Behavioral/Social only  
 Both Biomedical and Behavioral/Social
- H. HAVE YOU TAKEN THIS EXAMINATION BEFORE?**  
 No     Yes  
*If yes, indicate month, year and name under which the examination was taken.*  
 Date (month/year): \_\_\_\_\_  
 Name: \_\_\_\_\_

(Complete Page 2)



