

CERTIFICATION EXAMINATION FOR IRB PROFESSIONALS

HANDBOOK FOR CANDIDATES

SPRING 2012 TESTING PERIOD

Application Deadline: January 15, 2012

First Day of Testing: Saturday, March 3, 2012

Last Day of Testing: Saturday, March 17, 2012

FALL 2012 TESTING PERIOD

Application Deadline: August 1, 2012

First Day of Testing: Saturday, September 8, 2012

Last Day of Testing: Saturday, September 22, 2012



PROFESSIONAL TESTING CORPORATION®

1350 BROADWAY · 17th FLOOR
NEW YORK, NY 10018
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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; and
- Protect the integrity and content of the Certification Examination for IRB Professionals.

Effective Date: March 23, 2002

Revised: October 13, 2007

Reviewed: October 10, 2011

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

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This handbook contains necessary information about the IRB Professionals (CCIP) Examination. Please retain it for future reference. Candidates are responsible for reading these instructions carefully. This handbook is subject to change.

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 appropriately qualified 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.

ADMINISTRATION

The Certification Program is overseen by the Council for Certification of IRB Professionals (CCIP), a credentialing program 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. Questions concerning the examination should be referred to PTC.

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 continuing personal and professional growth in the practice of human research protection programs.
3. Increasing knowledge and understanding of human research review laws, regulations, guidance, and established best practices through preparation for initial examination and re-certification.
4. Establishing and measuring the level of knowledge required for certification in IRB administration.
5. Demonstrating a standard level of knowledge about human subject research review under United States rules and regulations, thereby assisting employers, the public, and members of the research professions in the assessment of IRB professionals.

ELIGIBILITY REQUIREMENTS

This certification program is for individuals whose primary job responsibilities include substantial participation in overseeing, administering, or performing the daily activities of an IRB.

Individuals involved in IRB activities who meet the following eligibility requirements are eligible to take the examination:

1. A Bachelor's degree plus two (2) years of relevant IRB experience*, completed on or before the first day of your chosen testing period (see front cover), within the past seven years;
OR
Three (3) years of relevant IRB experience*, completed on or before the first day of your chosen testing period (see front cover), within the past seven 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" requires substantial and ongoing performance of IRB Office or IRB administrative functions, represented by a commitment to the area of human subjects protection, such as:

- Serving as a resource during IRB meetings;
- Supporting IRB meetings;
- Preparing IRB correspondence;
- Maintaining IRB documentation;
- Managing and/or supervising the office that provides support of the IRB;
- Training of, and serving as a resource to, investigators, staff, and IRB members on issues pertinent to the protection of human subjects;
- Developing and implementing IRB policies and procedures;
- Reviewing research protocols and consent forms and applying required ethical principles and regulations to the reviews; and
- Performing monitoring activities for/directed by the IRB.

IRB chairs, members, and organizational officials who perform these functions may meet the definition of relevant IRB experience and may be appropriate candidates to sit for the certification exam. Service as an IRB member is not, in and of itself, sufficient to fulfill the requirements for relevant IRB experience. Likewise, merely interacting with an IRB office does not meet the requirements for relevant IRB experience (as is common with sponsor personnel as well as study site personnel working in study coordinator, study administrator, or investigator positions). Individuals who have questions about their eligibility should contact the CCIP prior to applying to sit for the exam.

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 as long as they remain certified and will receive certificates from the CCIP. A registry of Certified IRB Professionals will be maintained by the CCIP and may be reported in CCIP and PRIM&R publications.

To maintain certification, a CIP must recertify every three (3) years from the time of most recent recertification. Recertification may always be achieved by re-taking and passing the CIP examination. However, CIPs also have the option to recertify by completing a continuing education (CE) requirement twice before being required to recertify by examination. CE may only be used as a basis for recertification twice in a nine-year period.

For example: If the CIP's initial certification was in 2006, the CIP may complete the CE requirement or take, and pass, the certification examination prior to the expiration date in 2009. A second recertification by continuing education would also be permitted prior to the expiration date in 2012. After two recertifications by continuing education, the CIP must retake and pass the certification examination prior to the expiration date in 2015.

Recertification must be accomplished prior to the certification expiration to avoid a lapse in certification. If there is a lapse in certification of greater than six (6) months, the individual must retake the examination to renew certification.

A person who holds certification and takes the examination but does not pass will lose his or her 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 choose 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.

A person denied recertification due to improper or incomplete documentation may appeal that decision by writing a letter to CCIP (in care of PTC). This appeal must be postmarked no later than thirty (30) days from the postmark date on the original notification letter sent from CCIP or PTC. The letter must clearly describe the reasons why the candidate believes that recertification was improperly denied and include any documentation available to support such claim. The appeal will be considered by CCIP and written notice of the final decision will be provided to the candidate.

CCIP strives to ensure the reliability, validity, and fairness of exams. Candidates who have a question or comment about a test item or the exam itself may complete the Candidate Comment form at the end of the examination or send a letter to CCIP (in care of PTC) postmarked no later than 14 days after taking the examination. Submissions after this time cannot be used to modify test results but will be considered when future exams are prepared. Letters should provide sufficient information to allow CCIP to identify the test item or exam process you are commenting on or questioning and to understand your concern. Candidates commenting within the 14-day window will be notified in writing of CCIP's decision and any actions to be taken by CCIP as a result of the review.

Examination material is not available for review by candidates.

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.

CCIP provides an appeal mechanism for challenging revocation of certification. It is the responsibility of the individual to initiate this process by sending CCIP (in care of PTC) a written request that describes the basis of the appeal and provides supporting documentation as appropriate. The candidate will be notified in writing of the final decision of CCIP.

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.

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.

NOTE: The name you enter on your Application must match exactly the name shown on your current government-issued photo ID such as driver's license or passport. Do not use nicknames or abbreviations.

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 the first day of your chosen testing period. Do not submit an application if you have not met the eligibility requirements.

OPTIONAL INFORMATION: Answering these questions is 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: Your signature on the Application is your certification that the information provided is accurate, that you are eligible to take the exam, and that you agree to abide by the CIP Code of Ethics.

Fold the completed Application. Mail the Application with the appropriate fee (see FEES on page 7) in time to be received by the deadline shown on the cover of this Handbook to:

CCIP EXAMINATION
PROFESSIONAL TESTING CORPORATION
1350 Broadway – 17th Floor
New York, New York 10018

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

FEES

Application fees 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

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

In order to obtain the special members only registration rate, PRIM&R members must provide proof of their membership. To do so, please follow the instructions listed on the following link:
<http://www.primr.org/Certification.aspx?id=9211>.

Receipts are available upon request. Candidates can request a receipt by phone (212-356-0660), fax (212-356-0678) or e-mail (ptcny@ptcny.com). Receipts can be faxed, emailed, or mailed to the candidate.

RESCHEDULING AND REFUNDS

Candidates who are unable to take the examination as scheduled may request a transfer to the next testing period. The transfer request must be made in writing and be submitted to PTC within 30 days of the originally scheduled test date with a rescheduling fee of \$200. Candidates are responsible for contacting PSI and canceling their original appointment, if they have made one (see Changing Your Examination Appointment on page 9).

Please note that the rescheduling fee is based on cost recovery only and is not punitive in nature.

If a candidate is unable to attend the examination on the date for which he or she registered and a timely request to transfer is not made, the application will be closed and all fees will be forfeited. There will be no refund of fees.

Dates may be changed within the two-week testing period for which you are registered at no additional charge.

SCHEDULING YOUR EXAMINATION APPOINTMENT

Once your application has been received and processed and your eligibility verified, you will be mailed an Eligibility Notice within five weeks prior to the first day of the testing period. The Eligibility Notice plus current government-issued photo identification **MUST** be presented in order to gain admission to the testing center. If you do not receive an Eligibility Notice at least two weeks before the beginning of the testing period, immediately 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 during 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.

It is your responsibility as the candidate to call PSI to schedule the examination appointment.

It is highly recommended that you become familiar with the testing site.

Arrival at the testing site at the appointed time is the responsibility of the candidate. Please plan for weather, traffic, parking, and any security requirements that are specific to the testing location. Late arrival may prevent you from testing.

TESTING SOFTWARE DEMONSTRATION

A Testing Software Demonstration can be viewed online.

- Go to <http://www.ptcny.com/cbt/demo.htm>

This online Testing Software Demonstration can give you an idea about the features of the testing software.

EXAMINATION PROCESS

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 PSI. PSI 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 <http://www.ptcny.com/cbt/sites.htm> or call PSI 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.

SPECIAL TEST CENTERS, EXCLUDING THE UNITED STATES AND PARTS OF CANADA

It may be possible to establish a special testing center to take a paper-and-pencil examination in your own country for an additional fee of \$100. A letter must be sent with your application and fees, specifying your preferred city and country, and must be received eight weeks before the testing period begins. If there are no computer test centers in your province in Canada, you can follow this same procedure or travel to the closest computerized testing center in the United States to take the exam.

SPECIAL NEEDS

Special testing arrangements will be made for individuals with special needs. Submit the Application, Examination Fee, and a completed and signed Request for Special Accommodations Form, available from www.ptcny.com or by calling PTC at (212) 356-0660. Requests for special testing for individuals with special needs must be received at least EIGHT weeks before the testing period begins.

Please notify PTC at least two weeks prior to your examination appointment if you need to bring a service dog, medicine, food, or beverages necessary for a medical condition with you to the test center.

CHANGING YOUR EXAMINATION APPOINTMENT

If you need to cancel your examination appointment or reschedule you must contact PSI at (800) 211-2754 no later than noon, Eastern Standard Time, two business days PRIOR to your scheduled appointment. Examination appointments can only be rescheduled to a different date within the two-week testing period.

RULES FOR THE EXAMINATION

1. Electronic devices, including but not limited to cell phones, pagers, Bluetooth type devices, MP3 players (IPOD, I-Touch, etc.), cameras, and voice recorders cannot be operative during the examination.
2. No papers, books, or reference materials may be taken into nor removed from the examination room.
3. Because these are generic testing centers, no questions concerning content of the examination may be asked during the examination. The candidate should read carefully the directions provided on screen at the beginning of the examination session.

Violation of any of the rules listed above may lead to forfeiture of fees, dismissal from testing room, and cancellation of your test scores.

REPORT OF RESULTS

Candidates will be mailed their results in writing by PTC within four weeks of the close of the testing period. 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 11.
3. The questions for the examination are based on existing regulations and widely accepted guidance and best practices. They are obtained from individuals with expertise in human research protection programs and are reviewed for construction, accuracy, and appropriateness by CCIP. NOTE: The CIP examination does not test on additional institutional policies and procedures developed by individual IRBs.
4. The CCIP, with the advice and assistance of the Professional Testing Corporation, prepares the examination.
5. The questions for 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..... 12%
 - III. IRB Functions and Operations..... 45%
 - IV. Records and Reports 18%

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
 - a. IRB Members and Staff
 - b. Investigators and Key Personnel
 - c. Institutional
 - 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
 - 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 and Resources)

C. Institutional Considerations

1. Scientific Review
2. Grants and Contracts Review
3. Other Committee Review (RDRC, Biosafety)
4. Institutional Review
5. Institutional Responsibilities
6. Research Misconduct

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
 - 4. FERPA
 - 5. GINA/GWAS
- 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
 - e. School Research (PPRA)
- 8. Human Subject Private Information
 - a. Data bases
 - b. Document Repositories/Archives
 - c. Record Repositories/Collections
 - d. Specimen/Tissue Banks
 - e. Mixed Use Sources
- 9. International Research
- B. IRB Staff Review
 - 1. Staff Pre-screening
 - 2. Post-meeting Communications/Review
 - 3. Auditing
 - a. IRB Office
 - b. Investigators/Research Sites
 - c. Program Assessment
- 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. IRB 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 usually demands that subjects
 - a. gain direct benefit from the research.
 - b. receive payment for their participation.
 - c. be provided with an advocate.
 - d. enter into research voluntarily and with adequate information.
2. A poorly designed protocol is considered unethical because
 - a. the data would never be published in scientific journals.
 - b. data produced would not benefit all segments of the population.
 - c. research subjects may be put at risk or inconvenienced for insufficient reason.
 - d. conflict of interest is inherent.
3. When should an IRB suspend or terminate approval of research?
 - a. Only when the institutional attorney has recommended suspending the research
 - b. Only if the Institutional Official has given the IRB permission
 - c. Only when volunteer subjects withdraw consent to participation
 - d. When it is not being conducted in accordance with the IRB's requirements
4. A quorum for a convened IRB meeting requires the presence of
 - a. a scientific member.
 - b. an unaffiliated member.
 - c. a nonscientific member.
 - d. members of more than one profession.
5. Which of the following is required in research involving no more than minimal risk with children?
 - a. Consent is provided by a parent or guardian only
 - b. Consent is provided by the child and parent or guardian
 - c. Adequate provisions are made for assent of the child and permission of parent or guardian
 - d. Adequate provisions are made to inform the child and obtain consent of parent or guardian

6. Federal regulations require each IRB to have written procedures for
 - a. determining which studies should continue to receive internal grant funding.
 - b. monitoring studies and publicizing results.
 - c. IRB administrative office operation, including hiring practices and performance evaluation of employees.
 - d. initial and continuing review of research and for reporting its findings and actions to the investigator and the institution.

CORRECT ANSWERS TO SAMPLE QUESTIONS

1. d; 2. c; 3. d; 4. c; 5. c; 6. d

EXAM PREPARATION TIPS

- This is a closed-book, time-limited exam.
- No electronic or paper reference materials are allowed during the exam.
- This exam tests regulatory knowledge, concepts of IRB practice, IRB functions and operations, and the application of such knowledge.
- The answers called for may be the “best” of several acceptable responses.
- It is recommended that applicants start their review preparation for the exam a few months before the actual exam dates.
- It is recommended that applicants evaluate their areas of weakness (e.g., biomedical, international, history, social/behavioral) and emphasize those areas in their study.
- The exam does not test on your specific institutional requirements. Therefore, questions about administration and inter-institutional relations are generally from a generic point-of-view. It is important that you understand how your local (institutional and state) policies and procedures differ from federal requirements.

REFERENCES

The Council for Certification of IRB Professionals (CCIP) has prepared the reference list below as an example to assist candidates in preparing for the Certification Examination for IRB Professionals. These references, which are listed alphabetically, 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 or educational materials.

Note: The CIP examination does not test on additional institutional policies and procedures developed by individual IRBs.

BOOKS

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

Citro, C., Ilgen, R. & Marrett, C. Protecting Participants and Facilitating Social and Behavioral Sciences Research. National Academies Press, 2003

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

PERIODICALS

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

GUIDANCE

FDA Information Sheets for Institutional Review Boards and Clinical Investigators. Food and Drug Administration
(<http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/GuidancesInformationSheetsandNotices/ucm113709.htm>)

OHRP Policy Guidance
(<http://www.hhs.gov/ohrp/policy/index.html>)

REGULATIONS

(www.gpoaccess.gov/cfr/index.html)

21 CFR 50/56 (informed consent/protection of human subjects, IRB)

21 CFR 312 (investigational drugs)

21 CFR 361 (radioactive drugs for research purposes)

21 CFR 600 (biologics)

21 CFR 812.2 (investigational devices)

45 CFR 46 (Subparts A, B, C, D) (IRB, human subjects, special protections)

45 CFR 160/164 (HIPAA)

OTHER

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

(www.hhs.gov/ohrp/humansubjects/guidance/belmont.htm)

Council for International Organizations of Medical Sciences (CIOMS) International Ethical Guidelines for Biomedical Research (http://www.cioms.ch/publications/layout_guide202.pdf)

International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH): Good Clinical Practice (E6)

(www.ich.org/lob/media/media482.pdf)

Declaration of Helsinki

(www.wma.net/e/policy/pdf/17c.pdf)

Nuremberg Code

(www.hhs.gov/ohrp/references/nurcode.htm)

OHRP Assurance Training Online (HHS)

(<http://ohrp-ed.od.nih.gov/CBTs/Assurance/login.asp>)

The Privacy Rule and Research (NIH)

(<http://privacyruleandresearch.nih.gov/>)

PTC11140

ANNOUNCING THE ONLINE PRACTICE TEST FOR IRB PROFESSIONALS

| | |
|------------------|--|
| WHAT IS IT | A practice test consisting of 75 questions with a testing time of 2 hours taken over the Internet |
| WHEN | Available now |
| WHY TAKE IT | To experience taking a computerized exam, to review an example of the type of content included in the Certification Examination for IRB Professionals, and to learn more about question format, style, and level of difficulty |
| SCORE REPORT | <p>After completing the online practice test, you will receive an instant score report showing test performance in each of the content areas. The score report does not provide correct answers or indicate which questions were answered correctly and incorrectly</p> <p>NOTE: Performance on the online practice test may differ from actual performance on the Certification Examination. Thus, there is no guarantee that taking this practice test will help you pass the Certification Examination. Participants may find it helpful to review content in any areas of weakness indicated on the score report prior to taking the Certification Examination</p> |
| CONTENT INCLUDED | <ol style="list-style-type: none">I. Foundations and Concepts of IRB PracticeII. Organizational and Personnel KnowledgeIII. IRB Functions and OperationsIV. Records and Reports |
| FEE | \$50 by credit card |
| HOW TO APPLY | Go to www.ptcny.com and click on the Online Practice Test for IRB Professionals |
| FURTHER INFO | Visit www.ptcny.com or call Professional Testing Corporation at (212) 356-0668 |



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

Please enter your Name exactly as it appears on a Government-Issued Photo I.D.

Mr. First Name _____ Middle Initial _____
 Mrs. _____
 Ms. _____
 Dr. _____

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

Home Address - Number and Street _____ Apartment Number _____

City _____ State/Province _____ Zip/Postal Code _____

Daytime Phone _____ - _____ - _____ Evening Phone _____ - _____ - _____

Email Address (Please enter only ONE email address. Use two lines if your email address does not fit on one line.)

Eligibility and Background Information

Examination Date

Spring Fall

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)

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