

CERTIFICATION EXAMINATION FOR IRB PROFESSIONALS

Handbook for Candidates

SPRING 2010 TESTING PERIOD

Application Deadline: January 15, 2010

First Day of Testing: Saturday, March 6, 2010

Last Day of Testing: Saturday, March 20, 2010

FALL 2010 TESTING PERIOD

Application Deadline: August 1, 2010

First Day of Testing: Saturday, September 11, 2010

Last Day of Testing: Saturday, September 25, 2010



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(212) 356-0660
WWW.PTCNY.COM

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 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.

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

The certification program is for individuals participating in and overseeing the daily activities associated with 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 within the past seven years*;
OR
Three (3) years of relevant IRB experience 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 must have been substantial and ongoing, represented by a commitment to the area of human subjects protection. Qualifying experience requires performance of a broad range 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 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.

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 provided that the expiring certification was by examination. CE may only be used as a basis for recertification once in a six-year period.

For example: If the CIP's initial certification was in 2004, the CIP may complete the CE requirement or take, and pass, the certification examination prior to the expiration date in 2007. If the CIP recertified through CE in 2007, the CIP must take, and pass, the certification examination prior to the expiration date in 2010

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 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 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.

A person denied recertification due to improper or incomplete documentation, may appeal that decision by writing a letter to CCIP (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 (care of PTC) postmarked no later than 14 days after taking the examination. Submissions after this time can not 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.

REVOCACTION 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.ptcnyc.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.

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: 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 below) 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 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

Visa, MasterCard, and American Express are also accepted. Please complete and sign 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. Fees are transferable within the two week block of dates for which you are registered (see Changing Your Examination Appointment below).

SCHEDULING YOUR EXAMINATION APPOINTMENT

Once your application has been received and processed, and your eligibility verified, you will be mailed an Eligibility Notice within 5 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. A candidate not receiving an Eligibility Notice or other correspondence at least two weeks before the beginning of the two-week testing period should 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 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.

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/LaserGrade Computer Testing, Inc. PSI/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 or call PSI/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.

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.

CHANGING YOUR EXAMINATION APPOINTMENT

If you need to cancel your examination appointment or reschedule you must contact PSI/LaserGrade 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. No signaling devices, including cellular phones, pagers, PDAs 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 notes of any kind are to be taken from the examination room.
4. Because these are generic testing centers, 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 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 9.
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 Practice25%
 - II .Organizational and Personnel Knowledge12%
 - III. IRB Functions and Operations45%
 - IV. Records and Reports18%

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. 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
 5. Institutional Responsibilities
 6. Scientific 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
- 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

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 Publishers, 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

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

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

Protecting Human Research Subjects Newsletter U.S. Department of Energy
(<http://humansubjects.energy.gov/doe-resources/newsletter/default.htm>)

GUIDANCE

FDA Information Sheets for Institutional Review Boards and Clinical Investigators. Food and Drug Administration
(www.fda.gov/oc/ohrt/irbs/default.htm)

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

Protecting Human Research Subjects: Institutional Review Board Guidebook. (1993). Bethesda, MD. Office for Protection from Research Risks
(www.hhs.gov/ohrp/irb/irb_guidebook.htm)

REGULATIONS

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

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

Council for International Organizations of Medical Sciences (CIOMS) International Ethical Guidelines for Biomedical Research (www.cioms.ch/frame_guidelines_nov_2002.htm)

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)

Ethical and Legal Aspects of Human Subjects Research on the Internet (<http://www.aaas.org/spp/sfrr/projects/intres/report.pdf>)

Ethical Principles and Guidelines for the Protection of Human Subjects of Research (Belmont Report) (www.hhs.gov/ohrp/humansubjects/guidance/belmont.htm)

IRB Review of Stand-Alone HIPAA Authorizations Under FDA Regulations (FDA) (<http://www.fda.gov/OHRMS/DOCKETS/98fr/03d-0204-gdl0001.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/>)

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