

# **Certification Examination for IRB Professionals**

## **Candidate Handbook**

### **2019 CIP Examination Dates**

<b>Spring 2019</b>		
<b>Application Begin Date</b> September 24, 2018	<b>Application Deadline</b> February 8	<b>Testing Window</b> March 4-16
<b>Fall 2019</b>		
<b>Application Begin Date</b> March 18	<b>Application Deadline</b> August 16	<b>Testing Window</b> September 9-21

*The 2019 CIP Exam will be consistent with the pre-2018 Common Rule and any final guidance that has been released at the time of exam review. Due to continued lack of official guidance as of July 9, 2018, the 2019 CIP exam will not include questions resulting from new provisions of, or new concepts introduced in, the revised Common Rule.*



## Table of Contents

Code of Ethics for Certified IRB Professionals . . . . .	1
Certification . . . . .	1
Administration . . . . .	1
Purposes of Certification . . . . .	2
Eligibility Requirements . . . . .	2
Attainment of Certification and Recertification . . . . .	3
Revocation of Certification . . . . .	3
<b>APPLICATION PROCEDURE</b>	
Completion of Application . . . . .	4
Appeal of Eligibility Determination . . . . .	4
Fees . . . . .	4
Scheduling your Examination Appointment . . . . .	4
Requests for International Test Centers (Outside United States) . . . . .	5
Special Arrangements for Candidates with Disabilities . . . . .	5
Examination Appointment Changes . . . . .	5
Transferring to Another Examination Window . . . . .	5
Inclement Weather/Power Failure/Other Emergency . . . . .	6
<b>ON THE DAY OF YOUR EXAMINATION</b>	
Testing Overview Video . . . . .	6
Identification . . . . .	6
Security . . . . .	6
Personal Belongings . . . . .	6
Restrictions . . . . .	7
Misconduct . . . . .	7
Practice Examination . . . . .	7
Timed Examination . . . . .	7
Challenges to Examination . . . . .	8
Report of Results . . . . .	8
Reexamination . . . . .	8
Confidentiality . . . . .	8
<b>CONTENT OF EXAMINATION</b>	
Content Outline . . . . .	9
Sample Examination Questions . . . . .	11
Exam Preparation Tips . . . . .	11
CIP Exam Resources and References . . . . .	12
<b>EXAMINATION APPLICATION</b> . . . . .	15
<b>WORK EXPERIENCE VERIFICATION SUPPLEMENTAL FORM</b> . . . . .	17
<b>REQUEST FOR SPECIAL EXAMINATION ACCOMMODATIONS FORM</b> . . . . .	19
<b>DOCUMENTATION OF DISABILITY-RELATED NEEDS FORM</b> . . . . .	20
<b>PRIM&amp;R TRANSFER REQUEST FORM</b> . . . . .	21

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



## **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, judgments, 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 21, 2014

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 and credentialing program of Public Responsibility in Medicine and Research (PRIM&R), endorses the concept of voluntary, periodic certification by examination and continuing education 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 an individual's knowledge of IRB functions and human research protection programs.

## **Administration**

The Certification Program is overseen by the Council for Certification of IRB Professionals (CCIP). The Certification Examination for IRB Professionals is administered for the CCIP by PSI Services.

### ***Questions and requests for information about certification should be directed to:***

PRIM&R  
CIP Program  
20 Park Plaza, Suite 720  
Boston, MA 02116  
Phone: 617-423-4112  
Fax: 617-423-1185  
Email: [certification@primr.org](mailto:certification@primr.org)  
Website: [www.primr.org/certification](http://www.primr.org/certification)

### ***Questions concerning examination scheduling should be referred to:***

PSI Candidate Services  
18000 W. 105th St.  
Olathe, KS 66061-7543  
Phone: 888-519-9901  
Fax: 913-895-4650  
Email: [info@goAMP.com](mailto:info@goAMP.com)  
Website: [www.goAMP.com](http://www.goAMP.com)

## Purposes of Certification

To promote IRB administration practice and to advance the quality of human research protection programs (HRPPs) 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 administration of IRBs and HRPPs.
5. Demonstrating a standard level of knowledge about human subject research 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 as part of a human research protection program (HRPP). 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 HRPP experience\*, completed on or before the first day of your chosen testing period (see front cover);

**or**

Three (3) years of relevant HRPP experience\*, completed on or before the first day of your chosen testing period (see front cover);

**or**

Currently certified as a CIP.

2. Agreement to abide by the Code of Ethics for Certified IRB Professionals.
3. Completion and filing of an Application for the Certification Examination for IRB Professionals. Applicants who have never taken the exam must include a CV/résumé showing relevant HRPP experience.
4. Payment of required fee.

\* Relevant HRPP Experience requires **substantial** and **ongoing** performance **within the last seven years** of IRB administrative functions or duties relevant to an IRB office within a HRPP, which demonstrates a commitment to human subject protection, such as:

- Serving as a regulatory/technical resource during IRB meetings
- Supporting IRB meetings
- Preparing, reviewing and maintaining IRB correspondence and documentation
- Providing required ancillary services to the IRB such as conditions of approval, reconciliations, and tracking consent form changes
- Managing and/or supervising the office that provides support for the operation of the IRB
- Developing and implementing IRB policies and procedures
- Performing IRB directed reviews such as exemption determinations and expedited reviews
- Performing monitoring activities (audits) for/directed by the IRB
- Ongoing training of, and serving as a resource to staff, investigators, and IRB members on issues pertinent to the protection of human subjects
- Performing oversight activities of IRBs for or on behalf of a Common Rule agency.

IRB chairs, members and organizational officials who perform these functions may have experience that meets the definition of relevant IRB experience and may be appropriate candidates to sit for the certification examination. Service as an IRB member is not, in and of itself, sufficient to fulfill the requirements for relevant IRB experience.

Merely interacting with an IRB office on an occasional, or even routine basis (as is common with sponsor personnel and study-site personnel working in study coordinator, study administrator, or investigator positions) **does not meet** the requirements for relevant HRPP experience for the CIP certification program.

Candidates must ensure their CV/résumé provides sufficient detail in demonstrating their relevant experience.

Individuals who have questions about their eligibility should contact the CCIP prior to applying to sit for the exam. The CIP designation is not intended to be used as a means of qualification for HRPP related employment for applicants who do not have sufficient HRPP related work experience.

## **Attainment of Certification and Recertification**

Eligible candidates who pass the Certification Examination for IRB Professionals are authorized 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 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 the nine-year period following initial certification. Once CIPs have maintained their certification for more than ten consecutive years, with no lapses, they may recertify solely through CE credit and need not sit for the examination.

*For example: Those who pass the CIP® exam in 2012 are able to recertify by either examination or CE in 2015 and 2018. If they recertified by CE both times, they must take the examination in 2021 in order to maintain their certification.*

*Those who have been continuously certified since 2007 may recertify by CE in 2017, regardless of their method of certification in 2012 and 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.

As a courtesy, two reminders regarding expiring certifications are sent to current CIPs. These reminders are mailed and emailed to the last known contact information. It is the credential holder’s responsibility to update PRIM&R on any changes to their contact information.

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, credential 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 in writing to PRIM&R staff, who will facilitate Council review. This appeal must be dated no later than 30 days from the date on the original notification from the Council, and the candidate must provide a rationale for his/her claim that the original disposition of the decision was arbitrary or capricious.

## **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 CIP Code of Ethics

An individual may appeal their revocation in writing to PRIM&R staff, who will facilitate Council review. This appeal must be dated no later than 30 days from the date on the original notification from the Council, and the candidate must provide a rationale for his/her claim that the decision to revoke was arbitrary or capricious.

## Application Procedure

### Completion of Application

The examination application can be submitted online or completed using the application form in this handbook. Candidates must complete the examination application in full, using your name exactly as it appears on your current government issued photo ID such as a driver's license or passport.

1. **Apply online.** The completed application, with all documentation (if required), can be submitted and paid for online at: [www.goAMP.com](http://www.goAMP.com). Click on "Candidates" and follow the simple, step-by-step instructions to choose your examination program and register for the examination. Please have your credit card available for online payment of examination fees.

All candidates applying for initial certification must upload a copy of their current résumé or CV with their online application. All applications are subject to audit and request for supporting documentation.

or

2. **Apply by mail.** Complete and sign the examination application found in this handbook. An electronic form is available on [www.goAMP.com](http://www.goAMP.com). Read and follow the directions on the application and in this handbook.

Mail the application, required documentation, and fee(s) to: **PSI, CIP Examination Application, 18000 W. 105th St., Olathe, KS 66061-7543.**

### Appeal of Eligibility Determination

Candidates' eligibility determination may be appealed within 30 days of the date on the original notification. Appeals must be directed to PRIM&R staff in writing, and must provide a rationale for the candidate's claim that the original determination was arbitrary or capricious. PRIM&R staff will facilitate the appeals process on behalf of the Council.

### Fees

Exam fees for the Certification Examination for IRB Professionals Testing within the United States:

PRIM&R Members	\$350
Nonmembers	\$475

Testing in U.S. territories or internationally:

PRIM&R Members	\$460
Nonmembers	\$585

Transfer fee to next testing window \$100

Make cashier's check, money order or company check payable to PSI Services Inc. VISA, MasterCard, American Express and Discover also are accepted. Please complete the credit card payment form on the application. Personal checks and cash are not accepted. Fees may not be transferred from one individual to another.

For candidates found ineligible and unable to schedule a testing appointment, PSI will refund the examination fee to the candidate, less a \$6 processing fee.

In order to obtain the special member registration rate, PRIM&R members must provide proof of their membership. To do so, please follow these instructions: <http://www.primr.org/Subpage.aspx?id=1571>

The application and appropriate fees for the examination must be received by PSI within the application dates for the corresponding 2019 Testing Window.	
For the March 4-16, 2019 Testing Window	
Apply beginning September 24, 2018	<b>Application Deadline February 8, 2019</b>
For the September 9-21, 2019 Testing Window	
Apply beginning March 18, 2019	<b>Application Deadline August 16, 2019</b>

### Scheduling Your Examination Appointment

Once your application has been received, processed, and your eligibility verified, PSI will notify you of your eligibility through email. You may schedule your examination appointment with PSI by one of the following methods:

1. **Online Scheduling.** Visit [www.goAMP.com](http://www.goAMP.com) and select "Candidates" to schedule an examination appointment.
2. **Telephone Scheduling.** Call PSI at 888-519-9901 to schedule an examination appointment. This toll-free number is answered from 7:00 a.m. to 9:00 p.m. (Central Time) Monday through Thursday, 7:00 a.m. to 7:00 p.m. on Friday and 8:30 a.m. to 5:00 p.m. on Saturday.

Examinations are delivered by computer at PSI Test Centers located throughout the United States and internationally. Computer examinations are administered by appointment only Monday through Saturday. Appointment times are first-come, first-served, so schedule your appointment as soon as you receive notice of your eligibility. Appointment starting times may vary by location.

It is your responsibility as the candidate to schedule your examination appointment. It is highly recommended that



you become familiar with the testing site prior to the exam. Specific address information will be provided when you schedule your examination appointment. Please plan for weather, traffic, parking, and any security requirements that are specific to the testing location. **A candidate who arrives more than 15 minutes after the scheduled examination time will not be admitted.**

PSI Test Centers have been selected to provide accessibility to the most candidates in all states and major metropolitan areas. A current listing of PSI Test Centers, including addresses and driving directions, may be viewed at [www.goAMP.com](http://www.goAMP.com).

### Requests for International Test Centers (Outside United States)

PRIM&R and PSI are making computerized examinations available outside of the United States. For information regarding the availability of international computerized Test Centers, please visit the website [www.goAMP.com](http://www.goAMP.com). PSI is continuing to expand its international locations, and more locations are being added throughout the year.

Individuals who reside in one of the U.S. territories or applicants who reside outside of the United States who are interested in testing at an international Test Center will need to submit a completed application form, the application fee, and an international Test Center fee of \$110. Candidate identification numbers will be assigned when the applications are processed. All other rules and regulations regarding the computerized examination apply to international examination applicants. All examinations will be given in computerized format only. International applicants will not receive instant score reports. Results will be sent via U.S. mail within 3-5 business days after completion of the examination to the applicant's address of record.

### Special Arrangements for Candidates with Disabilities

PSI complies with the Americans with Disabilities Act and ensures that no individual with a disability is deprived of the opportunity to take an examination solely by reason of that disability. PSI will provide reasonable accommodations for candidates with disabilities. Candidates requesting special accommodations must call PSI at 888-519-9901 to schedule their examination.

1. Wheelchair access is available at all established Test Centers. Candidates must advise PSI at the time of scheduling that wheelchair access is necessary.

2. Candidates with visual, sensory, physical or learning disabilities that would prevent them from taking the examination under standard conditions may request special accommodations and arrangements.

Verification of the disability and a statement of the specific type of assistance needed must be made in writing to PSI at least 45 calendar days prior to the desired examination date by completing the Request for Special Examination Accommodations and Documentation of Disability-Related Needs forms. The information you provide and any documentation regarding your disability and your need for accommodations will be treated with strict confidentiality.

### Examination Appointment Changes

You may reschedule an examination appointment to another date within the two-week testing window once at no charge by calling PSI at 888-519-9901 at least two business days prior to the scheduled testing appointment. (See table below.)

If your Examination is scheduled on...	You must contact PSI by 3:00 p.m. Central Time to reschedule the Examination by the previous...
Monday	Wednesday
Tuesday	Thursday
Wednesday	Friday/Saturday
Thursday	Monday
Friday/Saturday	Tuesday

### Transferring to Another Examination Window

Candidates who are unable to take the examination as scheduled may request a transfer to the next testing period. The transfer must be made in writing, submitted to PSI within 30 days of the originally scheduled testing date and must be submitted with a rescheduling fee of \$100.

Candidates are responsible for contacting PSI and canceling their original appointment prior to the scheduled exam date, if they have made one (see Examination Appointment Changes above for more details). Please note that the transfer fee is based on cost and is not punitive in nature. The Council reserves the right to review and adjudicate any additional requests to reschedule an exam beyond an initial request that has been approved. If a candidate is unable to attend the examination on the date for which they 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.

## **Inclement Weather/Power Failure/ Other Emergency**

In the event of inclement weather or unforeseen emergencies on the day of an examination, PSI will determine whether circumstances warrant the cancellation, and subsequent rescheduling, of an examination. The examination will usually not be rescheduled if the Test Center personnel are able to open the Test Center.

You may visit [www.goAMP.com](http://www.goAMP.com) prior to the examination to determine if PSI has been advised that any Test Centers are closed. Every attempt is made to administer the examination as scheduled; however, should an examination be canceled at a Test Center, all scheduled candidates will receive notification following the examination regarding rescheduling or reapplication procedures.

For computer based examinations, if power to a Test Center is temporarily interrupted during an administration, your examination will be restarted. The responses provided up to the point of interruption will be intact, but for security reasons the questions will be scrambled.

## **On the Day of Your Examination**

On the day of your examination appointment, report to the Test Center no later than your scheduled time. Once you enter the building, look for the signs indicating PSI Test Center Check-In. A candidate who arrives more than 15 minutes after the scheduled examination time will not be admitted.

## **Testing Overview Video**

A video overview of the testing process and what to expect on your test day can be viewed at <http://online.goamp.com/CandidateHome/CandidateInformation.aspx>.

## **Identification**

To gain admission to the Test Center, you must present two forms of identification. The primary form must be government issued, current and include your name, signature and photograph. No form of temporary identification will be accepted. You will also be required to sign a roster for verification of identity.

Examples of valid primary forms of identification are: driver's license with photograph; state identification card with photograph; passport; military identification card with photograph.

The secondary form of identification must display your name and signature for signature verification (e.g., credit

card with signature, social security card with signature, employment/student ID card with signature).

If your name on your registration is different than it appears on your identification, you must bring proof of your name change (e.g., marriage license, divorce decree or court order).

Candidates must have proper identification to gain admission to the Test Center. Failure to provide appropriate identification at the time of the examination is considered a missed appointment. There will be no refund of examination fees.

After your identification has been confirmed, you will be directed to a testing carrel. You will be prompted on-screen to enter your candidate identification number. Your photograph, taken before beginning the examination, will remain on-screen throughout your examination session. This photograph will also print on your score report.

## **Security**

PSI administration and security standards are designed to ensure all candidates are provided the same opportunity to demonstrate their abilities. The Test Center is continuously monitored by audio and video surveillance equipment for security purposes. The following security procedures apply during the examination:

- Examinations are proprietary. No cameras, notes, tape recorders, pagers or cellular/ smart phones are allowed in the testing room. Possession of a cellular/smart phone or other electronic devices is strictly prohibited and will result in dismissal from the examination.
- No calculators are allowed, nor is one required for the examination.
- No guests, visitors or family members are allowed in the testing room or reception areas.

## **Personal Belongings**

No personal items, valuables or weapons should be brought to the Test Center. Only wallets and keys are permitted. Large coats and jackets must be left outside the testing room. You will be provided a soft locker to store your wallet and/or keys with you in the testing room. The proctor will lock the soft locker prior to you entering the testing room. You will not have access to these items until after the examination is completed. Please note the following items will not be allowed in the testing room except securely locked in the soft locker.

- Watches
- Hats
- Wallets
- Keys

Once you have placed your personal belongings into the soft locker, you will be asked to pull out your pockets to ensure they are empty. If you bring personal items that will not fit in the soft locker, you will not be able to test. The site will not store or be responsible for your personal belongings. If any personal items are observed or heard (such as cellular/smart phones, alarms) in the testing room after the examination is started, you will be dismissed and the administration will be forfeited.

## Restrictions

- Pencils will be provided during check-in.
- You will be provided with one piece of scratch paper at a time to use during the examination, unless noted on the sign-in roster for a particular candidate. You must return the scratch paper to the proctor at the completion of testing or you will not receive your score report.
- No documents or notes of any kind may be removed from the Test Center.
- No questions concerning the content of the examination may be asked during the examination.
- Eating, drinking or smoking is not permitted in the Test Center.
- You may take a break whenever you wish, but you will not be allowed additional time to make up for time lost during breaks.

## Misconduct

If you engage in any of the following conduct during the examination you may be dismissed, your scores will not be reported and examination fees will not be refunded. Examples of misconduct are when you:

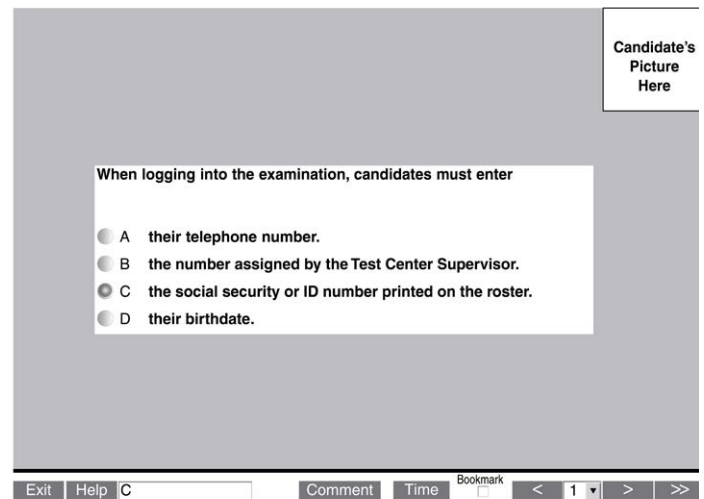
- Create a disturbance, are abusive or otherwise uncooperative;
- Display and/or use electronic communication devices such as pagers, cellular /smart phones;
- Talk or participate in conversation with other examination candidates;
- Give or receive help or are suspected of doing so;
- Leave the Test Center during the administration;
- Attempt to record examination questions or make notes;
- Attempt to take the examination for someone else;
- Are observed with personal belongings, or
- Are observed with unauthorized notes, books or other aids.

## Practice Examination

Prior to attempting the timed examination, you will be given the opportunity to practice taking an examination on computer. The time you use for this practice examination is not counted as part of your examination time. When you are comfortable with the computer testing process, you may quit the practice session and begin the timed examination.

## Timed Examination

Following the practice examination, you will begin the timed examination. Before beginning, instructions for taking the examination are provided on-screen. The examination contains 250 questions. Four hours are allotted to complete the examination. The following is a sample of what the computer screen will look like when candidates are attempting the examination:



The computer monitors the time you spend on the examination. The examination will terminate if you exceed the time limit. You may click on the Time button in the lower right portion of the screen to monitor your time. A digital clock indicates the time remaining for you to complete the examination. The time feature may also be turned off during the examination.

Only one examination question is presented at a time. The question number appears in the lower right portion of the screen. The entire examination question appears on-screen (i.e., stem and four options labeled: A, B, C, and D). Indicate your choice by either entering the letter of the option you think is correct (A, B, C, or D) or clicking on the option using the mouse. To change your answer, enter a different option by typing A, B, C, or D or clicking on the option using the mouse. You may change your answer as many times as you wish during the examination time limit. To move to the next question, click on the

forward arrow (>) in the lower right portion of the screen. This action will move you forward through the examination question by question. If you wish to review any questions, click the backward arrow (<) or use the left arrow key to move backward through the examination.

A question may be left unanswered for return later in the examination session. Questions may also be bookmarked for later review by clicking in the blank square to the right of the Time button. Click on the double arrows (>>) to advance to the next unanswered or bookmarked question on the examination. To identify all unanswered and bookmarked questions, repeatedly click on the double arrows (>>).

When the examination is completed, the number of questions answered is reported. If not all questions have been answered and there is time remaining, return to the examination and answer those questions. Be sure to answer each question before ending the examination.

**There is no penalty for guessing.**

## Challenges to Examination

Candidates may question the reliability, validity, and/or fairness of examination questions by completing the Candidate Comment Form at the time of examination. Additionally, candidates can formally challenge exam content by submitting their concern in writing to PRIM&R staff, who will facilitate the Council's review. The letter of challenge or complaint must be dated no later than 14 days from the date on which the complainant took the exam. The Council will not consider challenges or complaints sent after this deadline.

If the Council determines that changes are merited by an appeal and/or by its review of the relevant regulatory requirements and established regulatory guidance, then an amendment will be made to the answer key. The impact on passing scores will be assessed; if it is determined that a change would alter the outcome for an unsuccessful candidate, the Council shall either issue the certification or (if the candidate has already retaken and passed the exam) issue a refund of the examination fee. Examination material is not available for review by candidates.

## Report of Results

Candidates will be mailed their results by PSI within four to six 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 receive certificates from PRIM&R.

## 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 examination results should be referred to PSI.
3. Names and contact information of all successful candidates will be provided to PRIM&R. Names of successful candidates may also 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 250 multiple-choice, objective questions with a total testing time of four (4) hours.
2. The content for the examination is described in the Body of Knowledge/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 PSI, 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%

**CIP Body of Knowledge/Content Outline**

- I. Foundations and Concepts of IRB Practice 25%**
  - A. Historical Background
  - B. Research Ethics
    - 1. Belmont Report
      - 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 12%**
  - 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
    - 7. Reliance Agreements and Central 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 45%**
  - 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
- h. Investigator and Site Qualifications
- 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. Databases
  - b. Document Repositories/Archives
  - c. Record Repositories/Collections
  - d. Specimen/Tissue Banks
  - e. Data Security
- 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 18%**

- 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

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## 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.
  - D. 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

**The exam does not test on your specific institutional requirements.** Therefore, questions about administration and inter-institutional relations are 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.

- 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 possible 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.
- Candidates are strongly advised to thoroughly read and review the applicable federal regulations, guidance, and FAQ documents as part of their examination preparation.

## **CIP Exam Resources and References**

### **REGULATIONS**

<u>21 CFR 50/56</u>	Informed Consent/Protection of Human subjects, IRB
<u>21 CFR 312</u>	Investigational Drugs
<u>21 CFR 361</u>	Radioactive Drugs for Research Purposes
<u>21 CFR 600</u>	Biologics
<u>21 CFR 812</u>	Investigational Devices
<u>34 CFR 98</u>	PPRA—Protection of Pupil Rights Amendment
<u>34 CFR 99</u>	FERPA—Family Educational Rights and Privacy
<u>45 CFR 46</u> (Subparts A, B, C, D)	IRB, Human Subjects, Special Protections
<u>45 CFR 160/164</u>	HIPAA
<u>21 CFR 814 (Subpart H)</u>	Humanitarian Use Devices

### **Ethical Codes**

<u>Belmont Report</u>	Ethical Principles and Guidelines for the Protection of Human Subjects of Research
<u>CIOMS</u>	International Ethical Guidelines for Biomedical Research
<u>ICH</u>	International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH): Good Clinical Practice (E6)
<u>Declaration of Helsinki</u>	
<u>Nuremberg Code</u>	

### **Training Modules**

OHRP Assurance Training Online (HHS)

### **GUIDANCE**

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

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

### **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. (4th ed.). Boston: Center Watch, 2012.

### **PERIODICALS**

Human Research Report. Omaha, NE. The Deem Corp. [deemcorp.com/human\\_research.html](http://deemcorp.com/human_research.html).

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

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**RESEARCH OVERSIGHT ACRONYMS**

*Below is a list of common research oversight-related acronyms that you may encounter in your day-to-day work, or when preparing for the CIP examination.*

3Rs	Replacement, Reduction, and Refinement	HUD	Humanitarian Use Device
AAHRPP	Association for the Accreditation of Human Research Protection Programs, Inc.	IACUC	Institutional Animal Care and Use Committee
AE	Adverse Event	IBC	Institutional Biosafety Committee
APHIS, AC	Animal and Plant Health Inspection Service, Animal Care (USDA)	ICF	Individual Consent Form/Informed Consent Form
AV	Attending Veterinarian	ICH	International Conference on Harmonisation
AVMA	American Veterinary Medical Association	IDE	Investigational Device Exemption
AWA	Animal Welfare Act	ILAR	Institute for Laboratory Animal Research
AWAR/AWR	Animal Welfare Act Regulations	IND	Investigational New Drug
AWIC	Animal Welfare Information Center (USDA)	IO	Institutional Official
CDC	Centers for Disease Control and Prevention	IRB	Institutional Review Board
CEO	Chief Executive Officer	IVD	In Vitro Diagnostics
CER	Comparative Effectiveness Research	LAR	Legally Authorized Representative
CFR	Code of Federal Regulations	NCI	National Cancer Institute
CIOMS	Council for International Organizations of Medical Sciences	NDA	New Drug Application
COC	Certificate of Confidentiality	NHP	Nonhuman Primate
COI	Conflict of Interest	NIH	National Institutes of Health
DEA	Drug Enforcement Agency	NSF	National Science Foundation
DHHS	Department of Health and Human Services	NSR	Non-Significant Risk
DMC	Data Monitoring Committee	OEHS	Occupational and Environmental Health and Safety
DMR	Designated Member Review	OHRP	Office of Human Research Protections
DOD	Department of Defense	OIG	Office of Inspector General
DOEd	Department of Education	OLAW	Office of Laboratory Animal Welfare (NIH)
DOJ	Department of Justice	ORI	Office of Research Integrity
DSMB	Data Safety Monitoring Board	OSHA	Occupational Safety and Health Administration
DSMP	Data Safety Monitoring Plan	PAM	Post-Approval Monitoring
EPA	Environmental Protection Agency	PCOR	Patient-Centered Outcomes Research
ESCRO	Embryonic Stem Cell Research Oversight Committee	PHI	Protected Health Information
FCR	Full Committee Review	PHS	Public Health Service
FDA	Food and Drug Administration	PI	Principal Investigator
FERPA	Family Educational Rights and Privacy Act	PPRA	Protection of Pupil Rights Amendment
FFP	Fabrication, Falsification, and Plagiarism	QA	Quality Assurance
FOIA	Freedom of Information Act	QI	Quality Improvement
FWA	Federalwide Assurance	QRP	Questionable Research Practices
GCP	Good Clinical Practice	RCR	Responsible Conduct of Research
GINA	Genetic Information Nondiscrimination Act	RIO	Research Integrity Officer
GLP	Good Laboratory Practice	RM	Research Misconduct
GWAS	Genome-Wide Association Studies	SACHRP	Secretary's Advisory Committee on Human Research Protections
HDE	Humanitarian Device Exemption	SAE	Serious Adverse Event
HHS	Department of Health and Human Services	SBER	Social, Behavioral, and Educational Research
HIPAA	Health Insurance Portability and Accountability Act	SOP	Standard Operating Procedure
HPA	Horse Protection Act	SR	Significant Risk
HRPP	Human Research Protections Program	USDA	United States Department of Agriculture
		VA	Department of Veterans Affairs
		VMO	Veterinary Medical Officer
		VVC	Veterinary Verification and Consultation
		WHO	World Health Organization





**DEMOGRAPHIC QUESTIONS**

1. Which of the following best describes your certification status?
  - I have never been CIP certified.
  - I am currently CIP certified and am applying for recertification.
  - I was previously certified but my certification has lapsed and I am applying for reinstatement.
2. What percent of your working time is currently spent on IRB activities?
  - Less than half of my time
  - More than half of my time
  - All of my time is spent on IRB activities.
3. What is your primary role on IRB activities?
  - IRB Staff/Administrator/Manager
  - IRB Chair with IRB administrative responsibility
  - Organizational Official with direct IRB administrative responsibility
  - Other
4. How many years of experience do you have in IRB activities?
  - 2 years
  - 3 – 4 years
  - 5 years
  - 6 – 10 years
  - More than 10 years
5. Please select the status that best describes your organization:
  - Currently, my IRB serves as an IRB of record
  - Currently, my IRB serves as a relying IRB
  - Currently, my IRB serves as both an IRB of record and as a relying IRB
  - This question is not relevant to me at this time.
6. Which of the following is your primary employer?
  - Academic – Nonmedical
  - Academic – Medical
  - Industrial/Corporate
  - Government
  - Community Hospital
  - Independent IRB
  - Health Maintenance/Managed Care
  - Research Institute/Foundation
  - Other
7. What is the highest academic level you have achieved?
  - High school or equivalent
  - Some college
  - Associate’s degree
  - Bachelor’s degree
  - Master’s degree
  - Doctoral degree
8. What is the number of full-time or equivalent people in your office supporting IRB activities?
  - Less than 1.0
  - 1.0 – 2.9
  - 3 – 4.9
  - 5.0 – 9.9
  - More than 10
9. What is the scope of IRB review?
  - Biomedical only
  - Behavioral/social only
  - Both biomedical and behavioral/social
10. What other certifications do you hold? (Check all that apply)
  - None
  - CCRA
  - CCRC
  - CIM
  - Other
11. Where did you hear about the Certification Examination for IRB Professionals? (Check all that apply)
  - PRIM&R Conference
  - PRIM&R Newsletter
  - Job Requirement
  - Colleague
  - Other
12. What is the reason(s) you are taking the examination? (Check all that apply)
  - Job requirement
  - Job mobility
  - Personal satisfaction
  - Other
13. How did you prepare for the examination? (Check all that apply)
  - Self-study
  - Study group
  - Formal course
  - Practice exams
  - Social media group
14. Are you a member of PRIM&R? (Membership is not required for eligibility)
  - Yes
  - No
15. What is your ethnicity? (optional information that will be used only for statistical summaries)
  - American Indian or Alaska Native (including all Original Peoples of the Americas)
  - Asian (including Indian subcontinent and Philippines)
  - Black or African American (including Africa and Caribbean)
  - Native Hawaiian or Other Pacific Islander (Original Peoples)
  - White (including Middle East)
  - Hispanic/Latino (including Spain)
  - I prefer not to say.
  - Other
16. What is your age range? (optional information that will be used only for statistical summaries)
  - 19 – 24
  - 25 – 34
  - 35 – 44
  - 45 – 54
  - 55 – 65
  - 65 or older
  - I prefer not to say.
17. What is your gender? (optional information that will be used only for statistical summaries)
  - Female
  - Male
  - Transgender
  - Self-Identify \_\_\_\_\_
  - I prefer not to say.

**SIGNATURE**

I certify that I meet eligibility requirements for certification as a Certified IRB Professional, as outlined in the CIP Handbook. My HRPP experience has been substantial and ongoing, as described in the CIP Handbook. I have not had any disciplinary action taken against my professional license or certification which I currently hold or have held in the past. I have read and agree to abide by the Code of Ethics, as outlined in the CIP Handbook. All information provided in support of this application is current, accurate and complete.

I understand that any falsification of facts in the application, violation of testing procedures or violation of the CIP Code of Ethics may lead to revocation of CIP certification or may bar me from applying for such certification.

Names and contact information of all successful candidates will be provided to PRIM&R.

By signing and dating below, I certify to all of the above statements.

**Sign and date in ink.**

Name (Please Print): \_\_\_\_\_

Signature: \_\_\_\_\_ Date: \_\_\_\_\_



**CIP® Examination Work Experience Verification Supplemental Form**

This form is to be completely filled out by the applicant, and be included with their CIP Certification Exam Application and CV/resumé.

Candidate Name \_\_\_\_\_

Job Title \_\_\_\_\_

Organization \_\_\_\_\_

Start Date \_\_\_\_\_ End Date \_\_\_\_\_

Position Type       Full-Time       Part-Time *Percentage of effort dedicated to HRPP/IRB administration duties* \_\_\_\_\_

Please check the HRPP/IRB administration-related duties for which you are responsible:

- Serving as a regulatory/technical resource during IRB meetings
- Supporting IRB meetings
- Preparing, reviewing, and maintaining IRB correspondence and documentation
- Providing required ancillary services to the IRB such as conditions of approval, reconciliations, and tracking consent form changes
- Managing and/or supervising the office that provides support for the operation of the IRB
- Developing and implementing IRB policies and procedures
- Performing IRB directed reviews such as exemption determinations and expedited reviews
- Ongoing training of, and serving as a resource to staff, investigators, and IRB members on issues pertinent to the protection of human subjects
- Performing oversight activities of IRBs for or on behalf of a Common Rule agency
- Other HRPP/IRB administration-related duties (describe below)

Please briefly describe any other responsibilities relevant to your HRPP/IRB administration-related role that are not listed in the above checklist.

\_\_\_\_\_

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I certify that I meet eligibility requirements for certification as a Certified IRB Professional, as outlined in the CIP Handbook. My HRPP experience has been substantial and ongoing, as described in the CIP Handbook. I have not had any disciplinary action taken against my professional license or certification which I currently hold or have held in the past. I have read and agree to abide by the Code of Ethics, as outlined in the CIP Handbook. All information provided in support of this application is current, accurate and complete

Candidate Name (Print): \_\_\_\_\_

Candidate Signature: \_\_\_\_\_

Date: \_\_\_\_\_



# Request for Special Examination Accommodations

If you have a disability covered by the Americans with Disabilities Act, **please complete this form and provide the Documentation of Disability-Related Needs on the next page and submit it with your application at least 45 days prior to your requested examination date.** The information you provide and any documentation regarding your disability and your need for accommodation in testing will be treated with strict confidentiality.

## Candidate Information

Candidate ID # \_\_\_\_\_ Requested Test Center: \_\_\_\_\_

\_\_\_\_\_  
Name (Last, First, Middle Initial, Former Name)

\_\_\_\_\_  
Mailing Address

\_\_\_\_\_  
City State Zip Code

\_\_\_\_\_  
Daytime Telephone Number Email Address

## Special Accommodations

I request special accommodations for the \_\_\_\_\_ examination.

Please provide (check all that apply):

- Reader
- Extended testing time (time and a half)
- Reduced distraction environment
- Please specify below if other special accommodations are needed.

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Comments: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

### PLEASE READ AND SIGN:

I give my permission for my diagnosing professional to discuss with PSI staff my records and history as they relate to the requested accommodation.

Signature: \_\_\_\_\_ Date: \_\_\_\_\_

**Return this form with your examination application and fee to:  
PSI, 18000 W. 105th St., Olathe, KS 66061-7543  
If you have questions, call Candidate Services at 888-519-9901.**



## Documentation of Disability-Related Needs

Please have this section completed by an appropriate professional (education professional, physician, psychologist, psychiatrist) to ensure that PSI is able to provide the required accommodations.

**Professional Documentation**

I have known \_\_\_\_\_ since \_\_\_\_ / \_\_\_\_ / \_\_\_\_ in my capacity as a  
Candidate Name Date

\_\_\_\_\_  
My Professional Title

The candidate discussed with me the nature of the test to be administered. It is my opinion that, because of this candidate's disability described below, he/she should be accommodated by providing the special arrangements listed on the Request for Special Examination Accommodations form.

Description of Disability: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Signed: \_\_\_\_\_ Title: \_\_\_\_\_

Printed Name: \_\_\_\_\_

Address: \_\_\_\_\_  
\_\_\_\_\_

Telephone Number: \_\_\_\_\_ Email Address: \_\_\_\_\_

Date: \_\_\_\_\_ License # (if applicable): \_\_\_\_\_

**Return this form with your examination application and fee to:  
PSI, 18000 W. 105th St., Olathe, KS 66061-7543  
If you have questions, call Candidate Services at 888-519-9901.**



