

Certification Examination for IRB Professionals

Candidate Handbook

The CIP Examination is available
for continuous testing.

Note: The CIP exam is regularly reviewed and updated to ensure it reflects current regulations and guidance. The CIP exam does not include questions about pending draft guidance, including the FDA NPRM on the Protection of Human Subjects and Institutional Review Boards.

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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 (CIP Council).

Administration

The Certification Program is overseen by the CIP Council. The Certification Examination for IRB Professionals is administered by PSI Services.

Certification

The Council for Certification of IRB Professionals (CIP Council), 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.

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

PRIM&R
CIP Program
20 Park Plaza, Suite 1421
Boston, MA 02116
Phone: 617-423-4112
Fax: 617-423-1185
Email: certification@primr.org
Website: <http://primr.org/cip>

Questions concerning examination scheduling should be referred to:

PSI Candidate Services
18000 W. 105th St.
Olathe, KS 66061-7543
Phone: 833-518-7455
Fax: 913-895-4650
Email: examschedule@psionline.com
Website: <https://test-takers.psiexams.com/primr>

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 (CIP Council) 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 recertification.
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. Two years of full-time, relevant HRPP experience, completed within two weeks of the conclusion of the chosen testing period
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 and supplemental work verification form. Applicants who are seeking initial certification 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:

- Managing Human Research Protection Program (HRPP) policies and procedures
- Managing pre-review of IRB materials
- Managing review of IRB materials
- Managing exempt study review determinations
- Managing research protocol approval or reliance process
- Managing regulatory documentation
- Managing IRB records and databases
- Facilitating IRB meeting (e.g., ensure quorum, distribute meeting materials)
- Developing and provide education on IRB regulations and processes
- Providing consultation on IRB submission
- Monitoring for changes in federal regulations and guidance
- Managing review of noncompliance and unanticipated problems
- Managing IRB meeting minutes

Please note that ‘managing’ encompasses administering, coordinating, executing, and overseeing these tasks. 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 CIP Council prior to submitting their applications. 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 CIP Council. A registry of Certified IRB Professionals will be maintained by the CIP Council 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 a CIP has maintained certification for ten (10) consecutive years, with no lapses, they may exclusively recertify by continuing education.

For example: Those who passed the CIP® exam in 2016 were able to recertify by either examination or CE in 2019 and 2022. If they recertified by CE both times, they must take the examination in 2025 in order to maintain their certification. Those who have been continuously certified since 2013 may recertify by CE in 2025, regardless of their method of certification in 2016, 2019 and 2022 .

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, multiple email reminders regarding expiring certifications are sent to current CIPs. These reminders are sent 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 currently holds certification and takes the examination but does not pass will be able to reapply for the examination again after 90 days. Candidates will remain certified through the end of their six month grace period. If a candidate is unable to pass the exam before the end of the grace period they will lose their certification and will have to pass the exam before the credential can be reissued. Credential holders should be aware that those who are eligible to recertify by continuing education but choose to take the examination instead must pass the exam before recertification is achieved.

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 the CIP Council 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 their name exactly as it appears on their current government issued photo ID such as a driver's license or passport. We recommend that candidates apply for the exam only.

1. Apply online. Go to test-takers.psiexams.com/primr, Sign in or create an account, Click on View Available Tests, Select the test that you would like to take, Click the Apply Now button, Complete the fields in the application. If you need to save your progress to return later, there is an option to Save Application at the bottom of the page. When finished, click the Submit Application button. You do not have to pay at the time of application. All candidates applying for initial certification must upload a copy of their current CV/résumé that includes their relevant HRPP/IRB experience, as well as their work verification form, as part of 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 <https://test-takers.psiexams.com/primr>. 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.

Once your application is received, PSI will email you a receipt confirmation recording payment and will coordinate the eligibility review process. Remember to save the login ID and password that you created and add the domains @psionline.com to your safe senders list. This receipt confirmation includes your unique candidate ID number, and you should retain this for your records.

Fees

Exam fees for the Certification Examination for IRB Professionals Testing within the United States: \$425

Testing in U.S.-territory or international
Test Centers*: \$535

*The \$110 international Test Center fee will be waived for candidates who test by Live Remote Online Proctoring.

Application Review and Communication with Candidates

The CIP Council aims to view complete applications within two weeks of receipt. Incomplete applications will result in a slower review time; if a component of your application is missing or incomplete, someone from PRIM&R will reach out to you for that additional information.

Eligible candidates will receive confirmation emails from both PSI and PRIM&R. Please retain these emails, as they contain the candidate's unique Candidate ID/Assigned ID number, as well as important information about the 90-day window in which the candidate is authorized to test and instructions on how to schedule an exam appointment.

Ineligible candidates will receive emails from PRIM&R informing them of the decision and the reason for the determination.

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.

Authorization Window

Eligible candidates have a 90-day window in which they are authorized to take their exam. This 90 day eligibility period begins instantly upon approval.

Candidates will have one opportunity, for a fee, to transfer their exam window to a new 90-day period.

Candidates who fail to take the exam during their authorization window, fail to transfer their exam window, or are ineligible to transfer their exam window will forfeit their exam fee and have to resubmit their application.

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. Sign in using the same email and password that you created when applying to access your account. You will be able to view available tests, select the test for which you are eligible, and schedule.
2. Telephone Scheduling. Call PSI at 833-518-7455 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.

Test Center Administration

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 Friday. Saturday appointments may be scheduled based on availability. 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 <https://test-takers.psiexams.com/primr>. Candidates are monitored throughout the duration of the examination in real-time by human test center administrators.

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 <https://test-takers.psiexams.com/primr>. 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 US mail within 3-5 business days after completion of the examination to the applicant's address of record.

Live Remote Online Proctoring

Examinations are delivered by Live Remote Online Proctoring to a candidate using their own computer from their home. The candidate must have a computer with a web camera that can be moved to display the entire room, a microphone, and stable internet connection to download the PSI secure browser. It is recommended that candidates use hard-wired internet connections (ethernet cord) when taking their exams. The secure browser does not give PSI remote access to candidates' computers; instead, candidates download a secure, lock-down browser that, when taking their exam, blocks their access to all other programs and features such as hyperlinks, chat screens, copy/paste/screenshot functions, right mouse click menus, and peripheral monitors. Candidates are monitored throughout the duration of the examination in real-time by human exam administrators.

It is mandatory for candidates to run a Tutorial Test before exam day. The Tutorial Test ensures that a candidate's

system is fully compatible with the exam software and will alert to anything that is incompatible. Candidates will find their unique link to the Tutorial Test in the exam appointment scheduling confirmation email from PSI. Candidates only have three total attempts at running the tutorial so if the computer is found to be incompatible, save an attempt to try on another computer. The Tutorial Test expires 2.5 hours before the scheduled exam so this must be done in advance of exam day.

Additionally, candidates may perform an online proctoring compatibility check at any time to see whether their computer's webcam, microphone, and internet bandwidth are compatible with the online exam at <https://syscheck.bridge.psiexams.com/>. Candidates must use the Google Chrome Browser to access the compatibility check. Please note an additional compatibility check would need to be made after any type of systems update (i.e. software, server, firewall, webcam, etc.) as that may impact compatibility. Please note that this online proctoring compatibility check does not take the place of the required Tutorial Test.

Virtual Private Networks (VPNs) must be disconnected. We recommend candidates use a computer that does not have a VPN installed; even when disabled, the VPN might prevent the exam package from downloading or interrupt the connection to the testing platform when taking the exam. Candidates must use a personal computer. Employer-issued computers often have incompatible programs and require administrator privileges. If a candidate attempts to launch the exam using a work computer, it is possible that their network's VPN, security, or firewall settings will prevent them from downloading the exam package or interrupt the connection to the exam platform while taking the test. Please review PSI's [online proctoring guide](#) and [system requirements](#) to get familiarized with the technical requirements.

If a candidate's computer is unable to meet all of these requirements, they will need to take the exam at a test center. Please note that if a candidate attempts to launch the exam with an incompatible system, the candidate will be unable to begin the exam and will have to pay another exam fee to schedule a new appointment. In some cases, candidates may have to go through the application process again if the candidate has reached the end of your eligibility window.

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.

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 included in this handbook or online at https://psi-cdexp.zendesk.com/hc/en-us/requests/new?ticket_form_id=360000150872. The information you provide and any documentation regarding your disability and your need for accommodations will be treated with strict confidentiality. Candidates who have questions about special accommodations may call PSI at 800-367-1565 ext. 6750.

Examination Appointment Changes

You may reschedule an examination appointment to another date within the testing window once at no charge by calling PSI at 833-518-7455 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

Eligibility Extension Request

Candidates who cannot take the examination as scheduled and are unable to reschedule to another date within their eligibility window may request a 90-day extension. Candidates can submit the 90-day extension request in their PSI profile. This request must be made at least 2 business days in advance of the scheduled examination

date. The candidate's originally scheduled date will automatically cancel once the extension request is complete. Candidates will pay an extension fee of \$150 at the time of making the request. Please note that the extension fee is based on cost and is not punitive.

The eligibility extension can only be requested one time. 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 extend 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.psionline.com/openings 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 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.

Testing at a PSI Test Center

On the day of your examination appointment, report to the Test Center 30 minutes before 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.

Test Center Experience Video

A video overview of the testing process and what to expect on your test day can be viewed at <https://psi.wistia.com/medias/3321yp1ic8>.

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.

Test Center Exam 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. You are prohibited from reproducing, communicating or transmitting any test content in any form for any purpose.
- 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 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

- The use of any writing device or scratch paper is prohibited. 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.
- No calculators are allowed, nor is one required for the examination.
- Eating, drinking or smoking is not permitted in the Test Center.
- You may take a break, but you will not be allowed additional time to make up for time lost during breaks.

Testing by Live Remote Online Proctoring

Candidates may log in to their account up to 30 minutes prior to the scheduled start time, but will not be connected with a proctor until their exam time. By not starting your exam within 15 minutes after your scheduled appointment time, you forfeit your examination scheduling fee or exam eligibility. Fees and exam eligibilities are non-refundable.

If you have any questions regarding your compatibility check, or if you experience issues launching your exam, you may contact our remote proctoring technical support team at (844) 267-1017. You may also initiate a chat after you close the Secure Browser Software by [clicking here](#).

Remote Online Proctoring Experience Video

A video overview of the live remote online proctoring testing process and what to expect on your test day can be viewed at <https://psi.wistia.com/medias/5kidxdd0ry>.

Identification

Candidates must provide proper identification to the remote online proctor. 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.

Examples of valid primary forms of identification are: driver's license with photograph; state identification card with photograph; or passport. **NOTE: A military identification card is not acceptable for remote online proctored exams.**

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).

Failure to provide appropriate identification at the time of the examination is considered a missed appointment. There will be no refund of examination fees.

Online Exam Security

PSI administration and security standards are designed to ensure all candidates are provided the same opportunity to demonstrate their abilities. The following security procedures apply during the examination:

- You are prohibited from reproducing, communicating or transmitting any test content in any form for any purpose. This behavior will result in the disqualification of examination results, will be reported to your Licensing Authority/Sponsor and may lead to legal action.
- With the exception of your testing machine, electronic devices and recording devices of any kind (including but not limited to cell phones, pagers, and cameras) are NOT permitted during the remote online proctored exam.
- You will be asked to scan the room where you are testing prior to launching your exam. If there are notes, drinks, a box of tissues or any such items on your desk, you will be asked to remove them prior to releasing the exam. Walls should be clear of any materials though art and decor are permitted.
- Other people are not allowed in the room while you are testing. Someone else entering the room and/or talking to you is considered an exam violation and may result in termination of your exam.

Restrictions

- The use of any writing device or scratch paper is prohibited during the remote online exam duration. There is a comment space available on each question screen which can be used to make notes to determine an answer to the question or to make comments about the question.
- No calculators are allowed, nor is one required for the examination.
- No questions concerning the content of the examination may be asked during the examination.
- Breaks are allowed; however, you must return within 15 minutes. You will not be allowed additional time to make up for time lost during breaks.
- No food or drink is allowed.

Misconduct

For all examination delivery modes, 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 or exit the camera view 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.

Copyrighted Examination Questions

All examination questions are the copyrighted property of PRIM&R. It is forbidden to copy, reproduce, record, distribute or display these examination questions by any means, in whole or in part. Doing so may subject the candidate to disciplinary action as well as legal sanctions.

Practice Examination

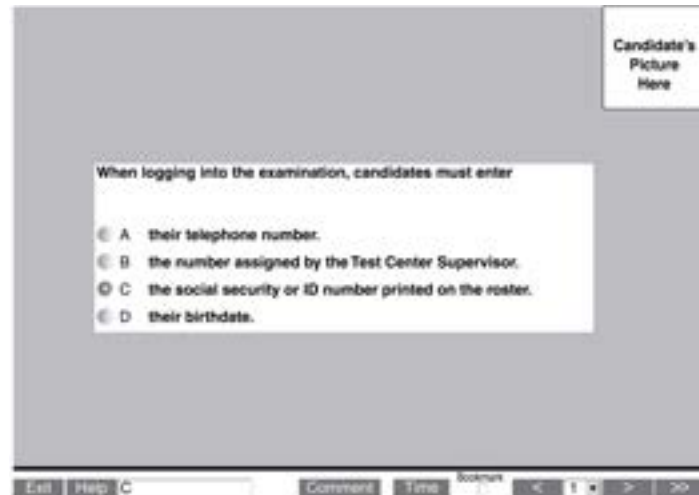
Prior to attempting the timed examination, you will be given the opportunity to practice taking an examination on computer. The time you use for this practice examination is not counted as part of your examination time. When you are comfortable with the computer testing process, you may quit the practice 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 130 questions – 115 of these questions will be scored, and 15 questions are pre-test items that will not be scored. The pre-test items are randomly disbursed, and candidates will not know which questions are scored and which are unscored. Three (3) hours are allotted to complete the examination.

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 exam.



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. During the examination, you may make comments for any question by clicking on the Comment button to the left of the Time button. This opens a dialogue box where comments may be entered. Comments will be reviewed, but individual responses will not be provided.

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.

Note: The passing score for the exam cannot be appealed.

Report of Results

Candidates will receive secured score reports from PSI within an hour of completing their exams. Scores on the major areas of the examination and on the total examination will be reported.

Certificates

PRIM&R staff will be in touch with successful candidates about their certificate within two weeks of the day on which they passed their exam. All certificates are distributed by PRIM&R.

Reexamination

Candidates who are unsuccessful in passing the exam will be eligible to re-take their test 90 days after their first exam attempt. 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 CIP Council 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 CIP Council 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 130 objective, multiple-choice questions with a total testing time of three (3) hours. Of the 130 total questions, 115 of these questions are scored; 15 questions are pre-test items that will not be scored. Candidates will not know which questions are scored and which are unscored.
2. The content for the examination is described in the Body of Knowledge/Content Outline on page 11.
3. The questions for the examination are based on existing regulations and guidance. They are developed by individuals with expertise in human research protection programs and are reviewed for construction, accuracy, and appropriateness by the CIP Council. NOTE: The CIP examination does not test on additional institutional policies and procedures developed by individual IRBs.
4. The CIP Council, 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:

1. Human Subjects Protection	29%
2. IRB Responsibilities	54%
3. Institutional Responsibilities	17%

CIP Body of Knowledge/Content Outline

1. Human Subjects Protection 29%
 - A. Historical Background
 - B. Research Ethics
 1. Belmont Principles
 2. International Codes and Standards (e.g., Nuremburg, Helsinki, ICH GCP-E6)
 - C. Regulatory Applicability
 1. Common Rule
 2. FDA (e.g., human subjects, drugs/biologics, devices)
 3. Other FDA (e.g., HUD, expanded access, emergency use)
 4. Agency Differences (e.g., DOD, DOJ, NIH)
2. IRB Responsibilities 54%
 - A. IRB Membership and Authority
 - B. Levels of Review
 - C. Types of Review
 - D. Regulatory Criteria for Approval
 - E. Informed Consent
 - F. Privacy and Confidentiality Considerations (e.g., HIPAA, CoC)
 - G. Vulnerable Populations
 - H. Monitoring and Review of Reportable Events (e.g., unanticipated problems, noncompliance, research misconduct)
 - I. Meeting Minutes
3. Institutional Responsibilities 17%
 - A. Cooperative Research (e.g., reliance, local context, sIRB)
 - B. Policies, Procedures and IRB Records
 - C. Conflict of Interest (e.g., IRB, researchers, institutional)
 - D. Regulatory Reporting Obligations
 - E. Document Management and Retention
 - F. Educational Programs

Note: The CIP exam is regularly reviewed and updated to ensure it reflects current regulations and guidance. The CIP exam does not include questions about pending draft guidance, including the FDA NPRM on the Protection of Human Subjects and Institutional Review Boards.

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 References and Resources

Regulations	
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	Investigational Devices
34 CFR 98	PPRA – Protection of Pupil Rights Amendment
34 CFR 99	FERPA – Family Educational Rights and Privacy
45 CFR 46 (Subparts A, B, C, D)	IRB, Human Subjects, Special Protections
45 CFR 160/164	HIPAA
21 CFR 814 (Subpart H)	Humanitarian Use Devices
Ethical Codes	
Belmont Report	Ethical Principles and Guidelines for the Protection of Human Subjects of Research
CIOMS	International Ethical Guidelines for Biomedical Research
ICH	International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH): Good Clinical Practice (E6)
Declaration of Helsinki	
Nuremberg Code	
Training Modules	
OHRP Protection Foundational Training	
Guidance	
FDA Information Sheets for Institutional	
Review Boards and Clinical Investigators	
OHRP Policy Guidance	

Note: Some of the files are webpages, others are documents that will appear in your downloads folder.

The CIP® Council has prepared the 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 CIP® Council 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. & Gordon, B. Institutional Review Board: Management and Function, Third Edition. Sudbury, MA: Jones and Bartlett Learning, 2021.
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
IRB: A Review of Human Subjects Research . Briarcliff Manor, NY. The Hastings Center

Common Research Oversight-Related 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
AAHRPP	Association for the Accreditation of Human Research Protection Programs, Inc.
AALAS	American Association for Laboratory Animal Science
AE	Adverse Event
APHIS, AC	Animal and Plant Health Inspection Service, Animal Care (USDA)
AV	Attending Veterinarian
AVMA	American Veterinary Medical Association
AWA	Animal Welfare Act
AWAR/AWR	Animal Welfare Act Regulations
AWIC	Animal Welfare Information Center (USDA)
CDC	Centers for Disease Control and Prevention
CEO	Chief Executive Officer
CER	Comparative Effectiveness Research
CFR	Code of Federal Regulations
CIOMS	Council for International Organizations of Medical Sciences
COC	Certificate of Confidentiality
COI	Conflict of Interest
DEA	Drug Enforcement Agency
DHHS	Department of Health and Human Services
DMC	Data Monitoring Committee
DMR	Designated Member Review
DOD	Department of Defense
DOEd	Department of Education
DOJ	Department of Justice
DSMB	Data Safety Monitoring Board
DSMP	Data Safety Monitoring Plan
EPA	Environmental Protection Agency
ESCRO	Embryonic Stem Cell Research Oversight Committee
FBR	Full Board Review
FCR	Full Committee Review
FDA	Food and Drug Administration
FDP	Federal Demonstration Partnership
FERPA	Family Educational Rights and Privacy Act
FFP	Fabrication, Falsification, and Plagiarism
FOIA	Freedom of Information Act
FWA	Federalwide Assurance
GCP	Good Clinical Practice
GDPR	General Data Protection Regulation
GINA	Genetic Information Nondiscrimination Act
GLP	Good Laboratory Practice
GWAS	Genome-Wide Association Studies
HDE	Humanitarian Device Exemption
HHS	Department of Health and Human Services
HIPAA	Health Insurance Portability and Accountability Act
HPA	Horse Protection Act
HRPP	Human Research Protections Program

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HUD	Humanitarian Use Device
IACUC	Institutional Animal Care and Use Committee
IBC	Institutional Biosafety Committee
ICF	Individual Consent Form/Informed Consent Form
ICH	International Conference on Harmonisation
IDE	Investigational Device Exemption
ILAR	Institute for Laboratory Animal Research
IND	Investigational New Drug
IO	Institutional Official
IRB	Institutional Review Board
IVD	In Vitro Diagnostics
LAR	Legally Authorized Representative
MOU	Memorandum of Understanding
NCI	National Cancer Institute
NDA	New Drug Application
NHP	Nonhuman Primate
NIH	National Institutes of Health
NSF	National Science Foundation
NSR	Non-Significant Risk
OCR	Office for Civil Rights
OEHS	Occupational and Environmental Health and Safety
OHRP	Office of Human Research Protections (HHS)
OIG	Office of Inspector General
OLAW	Office of Laboratory Animal Welfare (NIH)
ORI	Office of Research Integrity
OSHA	Occupational Safety and Health Administration
PAM	Post-Approval Monitoring
PCOR	Patient-Centered Outcomes Research
PHI	Protected Health Information
PHS	Public Health Service
PI	Principal Investigator
PPRA	Protection of Pupil Rights Amendment
QA	Quality Assurance
QI	Quality Improvement
QRP	Questionable Research Practices
RCR	Responsible Conduct of Research
RIO	Research Integrity Officer
RM	Research Misconduct
SACHRP	Secretary's Advisory Committee on Human Research Protections
SAE	Serious Adverse Event
SBER	Social, Behavioral, and Educational Research
SOP	Standard Operating Procedure
SR	Significant Risk
USDA	United States Department of Agriculture
VA	Department of Veterans Affairs
VMO	Veterinary Medical Officer
VVC	Veterinary Verification and Consultation
WHO	World Health Organization

Last Updated: May 20, 2025

CIP® Examination Work Experience Verification Supplemental Form

The Certified IRB Professional (CIP®) 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 an HRPP. Eligible individuals typically work within an IRB/HRPP office, reviewing IRB submissions, managing the review of IRB materials at IRB meetings, writing IRB minutes, and providing consultation to study teams on IRB submissions. This includes managing the review of protocol materials submitted to the IRB by research teams, for new approval, modification, continuing review, exemptions, reliance activities, and non-compliance/unanticipated problems. Eligible individuals may also be involved in updating the policies and procedures within the IRB/HRPP, providing education to IRB staff and the research community on updates to the federal regulations and guidance documents on human subject protection.

This form is to be completed by the applicant,
and must be included with their CIP Certification Exam Application and CV/resume.

Candidate Name _____
Job Title _____
Organization _____
Start Date _____ End Date _____
Percentage of work time dedicated to HRPP/IRB administration duties _____ %

Please check the HRPP/IRB administration-related duties for which you are responsible:
(not all need to be checked)

<input type="checkbox"/>	Conducting review of materials submitted to the IRB— inclusive of completeness, accuracy of materials
<input type="checkbox"/>	Conducting expedited and exempt determinations
<input type="checkbox"/>	Developing and providing education to IRB staff and the research community regarding the laws, regulations and guidance documents on human subject protection
<input type="checkbox"/>	Managing HRPP policies and procedures
<input type="checkbox"/>	Managing research protocol approval or reliance process
<input type="checkbox"/>	Managing review of noncompliance and unanticipated problems on behalf of the HRPP/IRB
<input type="checkbox"/>	Monitoring and providing regulatory support and expertise during IRB meetings (e.g., monitoring quorum, documenting regulatory determinations, drafting IRB meeting minutes, providing guidance on required determinations)

CIP® Examination Work Experience Verification Supplemental Form

Please describe the HRPP/IRB administration-related duties for which you are responsible:
(Not all duties need to be described)
(Provide description for duties indicated in checklist)

Describe how you conduct review of materials submitted to the IRB

Describe how you conduct expedited and exempt determinations

Describe how you develop and provide education to IRB staff and the research community regarding human subject protection

Describe how you Manage HRPP policies and procedures

Describe how you manage research protocol approval or reliance process

Describe how you manage review of noncompliance and unanticipated problems on behalf of the HRPP/IRB

CIP® Examination Work Experience Verification Supplemental Form

Describe how you monitor and provide regulatory support and expertise during IRB meetings

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

If your eligible experience is from more than one position, please fill out separate forms for each job.

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 information and provide the Documentation of Disability-Related Needs on the next page 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

or submit your accommodations request online at

https://psi-cdexp.zendesk.com/hc/en-us/requests/new?ticket_form_id=360000150872.

If you have questions, call Candidate Services at 800-367-1565 ext. 6750.



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

or attach this form to your online request at

https://psi-cdexp.zendesk.com/hc/en-us/requests/new?ticket_form_id=360000150872.

If you have questions, call Candidate Services at 800-367-1565 ext. 6750.