CERTIFIED PRINCIPAL INVESTIGATOR

Certification Handbook

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APPLYING FOR CERTIFICATION

Welcome and Congratulations

The Academy of Clinical Research Professionals (the Academy) would like to congratulate you on your decision to pursue certification in your chosen field of work. As a professional in clinical research, you deserve to be recognized and appreciated for what you do, and like most professionals, you want to become better at it. You look for opportunities for ongoing professional development and practical ways to evaluate your own work that will help you develop as a professional.

ACRP Certification Overview

In order to achieve certification, all applicants must meet the eligibility requirements and pass an exam**.** Exams are administered twice annually, Spring and Fall, at over 600 testing centers in more than 80 counties**.**

The applicant should determine his/her own eligibility before submitting an application to the program. Upon submission of a complete application, an eligibility review is conducted by the Academy. The candidate is then notified of the eligibility review outcome via e-mail. All eligible candidates must then schedule an appointment to take the exam.

Candidates who meet the eligibility requirements and pass the exam will be certified as having met the Academy standards for becoming a CPI. Maintenance of one's certification is required every two (2) years.

Application Deadline

All application materials, including application, CV or resume, job description(s) and payment must be received by August 14, 2017 for the September/October examination. Applications received by June 14, 2017 qualify for the early-bird rate.

Confidentiality

Application for, and achievement of, certification is between the Academy and an individual candidate. Therefore, ALL application, eligibility, and exam details are confidential to the individual and cannot be disclosed, regardless of payer. Only the candidate is permitted to withdraw an application or cancel an exam appointment, regardless of payer.

Application Process and Requirements

Professional Level Experience Requirements

To be eligible for the examination, an applicant must have the required minimum number of years in the professional practice of clinical research. Volunteer experiences will not count toward the hours requirement.

NOTE: The Academy reserves the right to request backup documentation to substantiate the reported information at any time during the application process and/or once the candidate has been certified.

CPI Eligibility Requirements

In order to be deemed eligible to take the PI Certification exam, applicants for the CPI credential must be able to provide *evidence* through a job description, detailed CV or other documentation that they:

- Have proof of employment as a PI during at least two (2) of the most recent five (5) years ***AND;***
- Perform all of the **Essential Duties** as detailed below. ***AND***;
- Hold a doctoral level degree (DDS, MD, or equivalent degree such as DO, MBBS, or MBChB, PhD, PharmD, DNP, or a licensed Physician's Assistant or Nurse Practitioner that has served in a PI role.)

Employment

Employment is broadly defined as paid services, fellowships and internships. Employment experience must include service as a primary, sub- or co-investigator or a medical monitor, supervisor or designer of one or more clinical trials during at least two (2) of the most recent five (5) years. Documentation that supports this role and employment must include the applicant's name and be signed and dated. A least one form of acceptable documentation will need to be provided for EACH of the two (2) years within the most recent five (5) years supporting employment as a PI during that time.

PI Essential Duties

As defined by the Academy, and determined through ACRP's 2015 Job Analysis Survey, **principal investigators (PIs)** who are eligible for PI certification must document performance of the essential PI duties using a job description for each relevant position held during the dates of employment listed on the application.

The ***Essential PI Duties*** are as follows:

- Responsible for the safe and ethical conduct of a clinical trial;
- Evaluates the study proposal and decides on participation;
- Facilitates or verifies formal approvals according to regulatory requirements and International Conference on Harmonisation (ICH) Good Clinical Practice (GCP);
- Ensures that all site initiation activities are performed to start and conduct the study;
- Participates in the selection of trial subjects according to the recruitment strategy;
- Performs or supervises the conduct of study-related procedures and monitors the safety of the trial subjects and investigational staff;

- Collects accurate and verifiable data and other essential study documents;
- Ensures compliance with regulatory requirements and ICH GCP, the protocol and the handling of the investigational product;
- Communicates with subjects, sponsor's personnel, and Institutional Review Board
- Ensures adequate close-out of the study

Requirements	Required Documentation to be Submitted
Education	▪ Doctorate level degree (DDS, MD, or equivalent degree such as DO, MBBS, or MBChB, PhD, PharmD, DNP,) or a licensed Physician's Assistant or Nurse Practitioner that has served in a PI role. ▪ CV must reflect name of educational institution, location (city, country), title of degree and date awarded.
Experience	For at least TWO (2) of the most recent five (5) years*: ▪ 1572 / PHS 398 / QIU (or equivalent) **OR** ▪ IRB/IEC approval letter to conduct the study **OR** ▪ Protocol approval letter for the study **OR** ▪ Signed copy of an investigator agreement/protocol signature page **OR** ▪ Other regulatory authority document verifying your role as a Principal Investigator on the clinical trial being submitted in support of eligibility *Any proprietary details may be blocked out.*

*see section for options of substitutions for work experience

Substitution for Work Experience Requirements

Applicants may only choose one option below as a valid substitute. Under no circumstance will an applicant be permitted to use more than one substitution for the same application.

Clinical Research Certifications (Option 1)

The Academy acknowledges that there is a shared knowledge base between CCRA and CCRC certificant holders and those who seek the CPI designation. Any candidate for the CPI designation who has a current CCRA or CCRC designation will have achieved a valid substitute for 1,500 hours of the required professional experience performing the essential duties of a PI.

Clinical Research Education Programs (Option 2)

The Academy considers applicants who have completed a clinical research education program that meets the following standards to have achieved a valid substitute for 1,500 hours of professional experience for the CPI program.

Acceptable programs must:

- Be at least 216 contact hours in length (at least 15 semester credits) ***and*;**
- Cover content that substantially maps to the topics found on the **Detailed Content Outline (DCO)** ***and*;**

- Be accredited by an accrediting agency recognized by the Council on Higher Education Accreditation (CHEA) or the appropriate authorizing authority in the country in which the institution operations. A list of recognized US accrediting agencies can be found from the CHEA website: **www.chea.org.**

If an applicant opts to use an educational program as a substitute, he or she may send an email to **certification@acrptnet.org** for additional requirement details.

Application and Exam Fees

The cost to apply includes an exam and application fee, paid together at the submission of the application. Credit card, check, or bank transfers are acceptable forms of payment. The fees are as follows:

	Member	Non-Member
EARLY BIRD DATES **May 1 – June 14, 2017**	$135 application fee	$135 application fee
	$300 exam fee	$350 exam fee
	Total - $435	Total - $485

	Member	Non-Member
REGULAR DATES **June 15 – August 14, 2017**	$135 application fee	$200 application fee
	$325 exam fee	$400 exam fee
	Total - $460	Total - $600

The application fee is non-refundable regardless of eligibility status or cancellation.
Submission of the application confirms your understanding and agreement.

Application for Certification

Once an applicant has carefully self-determined he/she meets the eligibility requirements, the application process can begin. Applications are submitted online or via a printable method.

The following must be uploaded or submitted together by the due date (***received, not postmarked***) to be considered for review of eligibility:

1. Application Form ***AND***
2. Supporting documents—proof of employment ***AND***
3. Detailed job description(s) for positions listed on the (CV)/ résumé ***AND***
4. Full payment

*If you cannot obtain a job description from your (former) employer, you may create and supply your own. If necessary, you may email **certification@acrpnet.org** for a sample CV or job description.

All documentation must be provided in English. If the original documentation was translated into English, it must also be submitted in the original language, with the certified translated document.

Services for People with Disabilities

The Academy is committed to ensuring that no individual with a disability is deprived of the opportunity to take an exam solely by reason of that disability. The Academy will provide reasonable accommodations for candidates with disabilities pursuant to the Americans with Disabilities Act (ADA). The following reasonable accommodations may be addressed:

- Wheelchair access is available at all established test centers.
- Candidates with visual, sensory, cognitive, or physical disabilities that would prevent them from taking an exam under standard conditions may request reasonable accommodations and arrangements.

To request a reasonable accommodation, one is required to check the designated box on the exam application and also submit:

- **Special Accommodations Form** signed by a licensed health professional approving the request as accurate and reasonable. **This MUST be submitted at the time of application.**

Completing the Application Form

There are two ways candidates can complete their applications: online (recommended) or a printable version*. Both versions are accessible on the **Certification Resources** web page**.** Copies are not available for print so it is recommended to take screen shots, if and as needed.

Note: The application will time out within five minutes of inactivity. Therefore, it is imperative to have all documentation and information ready so that data in the online application is captured and not lost.

*If paying by check or bank transfer, applicants must submit the printable version of the application. Be sure to include the check or receipt of bank transfer with the application.

Submitting the Application

Only applications received with required supporting documentation and full payment will be processed.

Note: Incomplete applications, or applications submitted without the correct fee, will not be considered. It is the candidate's responsibility to submit all relevant documents and payment at the time of application, by the due date.

Submission of the application constitutes agreement that the candidate has read, understood, and agrees to abide by the **ACRP Code of Ethics and Professional Conduct.** Applicants are required to sign a Candidate Statement of Authorization and Agreement attesting to the accuracy of the information provided as part of the application process. By submitting an application, the applicant consents to and authorizes the Academy to verify the candidate's academic and employment records.

Receipt of Application

An e-mail confirmation of payment is automatically sent once payment is processed. At that point, applications will enter the Eligibility Review process.

THE ELIGIBILITY REVIEW PROCESS

Eligibility Review
The eligibility review process includes determining completeness of the application and whether or not the applicant meets the eligibility criteria for the exam and performs all essential duties. Applicants should expect to receive an update on application status (via email) within seven to ten days after the application has been received.

Applicants will have seven (7) calendar days to respond to any request for additional information from an eligibility reviewer. These requests will only come via e-mail.

Incomplete Applications
Applicants who do not respond to the requests for additional or clarifying information will automatically have their applications determined incomplete and therefore will be found ineligible to take the exam.

Eligibility Reviewers

Our Eligibility Reviewers are clinical research professionals hired by the Academy for the purpose of reviewing applications and determining eligibility. An applicant may receive a request for additional and/or clarifying information from a reviewer in support of his or her application. This is not unusual or uncommon. Reviewers only communicate via email and are not available to speak with an applicant via phone concerning his or her application therefore it is imperative that an applicant contact ACRP in the event communication about the review outcome has not been received through email.

Confirmation of Eligibility

Upon conclusion of review, an applicant will be found to be: Eligible or Ineligible.

Eligible applicants will be e-mailed an Eligibility Notice, with instructions as to how to schedule an exam appointment. Exam appointments can only be scheduled *after* eligibility is determined.

Ineligible applicants *automatically* receive up to two levels of review. Applicants are notified via e-mail at each step of the review with an explanation of the deficiency identified. Each level of review can take up to seven days. If after two reviews and the applicant is found Ineligible, a review will be conducted by the Certification Manager and the applicant will be notified via email with the final result.

Ineligible applicants (who do not initiate the appeals process* within 15 days of notice) will be refunded the exam fee and will need to re-apply and pay all fees if they decide to pursue certification in the future.

*If the applicant is still determined to be ineligible after three levels of review, the applicant can choose to appeal to the Academy Board of Trustees. However, after the third review, applicants can no longer submit new documents to overturn an eligibility decision.

View the Academy's **Policy on Appeals.**

CPI EXAMINATION INFORMATION

Exam Structure

The CPI Exam is designed as a practice-based exam to assess proficiency of the six (6) core knowledge areas:

1. Scientific Concepts and Research Design
2. Ethical and Participant Safety Considerations
3. Product Development and Regulation
4. Clinical Trial Operations (GCPs)
5. Study and Site Management
6. Data Management and Informatics

Exam Delivery

The ACRP exam consists of 125 multiple-choice questions (25 of these questions are pre-test items, do not affect a candidate's score and are not identified to candidates). Each candidate is allowed a maximum of three (3) hours to complete the 125 questions. Candidates are presented with a question and are asked to choose the single **best** answer from the four options provided. Only one answer is correct. There are no "trick" questions on the exam and there is no penalty for guessing.

Language

The exam is provided in English.
Exam candidates may bring a hard-copy, **translation only** (word-to-word) dictionary to the exam. Electronic dictionaries are not permitted. Dictionaries containing any word definitions or other extraneous markings are strictly prohibited. The dictionary will be inspected by the proctor before and after the exam is completed. No additional time is given to those using a translation dictionary.

Exam Administration

The Academy partners with Prometric, a trusted provider of technology-enabled testing, to administer its exams. Once a candidate has been found eligible, coordination of scheduling (including confirming, rescheduling or canceling) his or her exam will occur directly through or with Prometric via online or phone.

Examination Window

The candidate must test during the window for which he or she is approved. The Academy offers its exams each year during two testing windows, March and September. The Fall 2017 testing window begins September 8, 2017 and concludes October 7, 2017.
Candidates will not be permitted to schedule an appointment outside of this testing window under any circumstances.

Exam Appointment Scheduling

The exams are administered via a secure network of computer-based testing sites. Over 600 locations in more than 80 countries are available at which to take the exam. All candidates who have been found eligible must schedule an appointment to take the exam.

Candidates who do not schedule an exam risk forfeiting all fees.

Appointments can be scheduled online (recommended) or by phone. To view testing locations, visit **www.prometric.com/acrp** at any time.

Confirmation Number

When a candidate schedules his or her appointment, a confirmation number will be provided. Make sure to keep a record of your confirmation number and appointment information. You will need your confirmation number if you want to confirm, reschedule, or cancel your appointment with Prometric.

Confirming Your Appointment

It is the responsibility of a candidate to verify that they have been scheduled for the date, time, and place he or she has requested. An appointment can be confirmed online even if scheduled via phone. One may confirm his or her appointment in two ways:

- Confirm an appointment online at www.prometric.com/ACRP
- Call (800) 967-1139 or the applicable international number and select the option for confirming your appointment

Rescheduling Your Appointment

Rescheduling an exam appointment is permitted by Prometric up to five (5) days *BEFORE* your scheduled appointment. There may be fees associated with appointment changes. Rescheduling availability may vary, depending on the test center location and number of days prior to the exam appointment date.

Candidates ***must*** contact Prometric directly to reschedule an exam appointment. ACRP cannot reschedule your appointment. You may reschedule by phone or online and the appointment confirmation number will be needed.

Cancellations, No Shows, Re-Examination, Refunds and Transfers

Cancellations

Candidates who wish to cancel their application may submit an **Application Cancellation Request Form** to obtain a refund of the exam fee **only**. The application fee covers costs associated with reviewing the application and is non-refundable**.**

Emergency Cancellations

Candidate unable to keep their exam appointment due to an emergency situation within five (5) days of the exam date, must submit an **Emergency Cancellation Form** and official documentation to **certification@acrpnet.org**. This information may be received up to seven (7) calendar days after the candidate's scheduled exam date.

The following situations will be considered with documentation: Emergency room visit or hospitalization, severe medical condition requiring hospitalization, death of an immediate family member (e.g., spouse, child/dependent, parent, grandparent, sibling), call to active military duty, or jury duty.

No Shows and Missed Exams
If a candidate schedules an exam appointment and fails to take the exam, he or she forfeits all fees. If a candidate arrives late for a scheduled exam appointment, he or she may not be allowed to test and, subsequently, will not be eligible for a refund. Missed exams due to lateness are not eligible for a refund.

Re-Examination
Candidates who do not pass the certification exam on first attempt will be allowed to re-take the exam ONLY in the next examination period. A "Re-Examination Form" will be included with the official exam results confirmation letter.

Refunds
Refundable fee: examination fee only.
The application fee covers the cost associated with reviewing the application and therefore is non-refundable.

No one other than the candidate may request a cancellation or refund.
Refunds are issued to candidates under two circumstances only: **ineligibility** or **cancellation**.

Ineligibility
Ineligible applicants will receive a refund of the exam fee, within three weeks of the final ineligibility notification.

Cancellation
To receive a refund, the cancellation request must be received at least five (5) calendar days ***BEFORE*** an exam appointment. Requests within five days of an exam appointment will not be honored.

Refunds are ***not*** available to candidates who do not schedule or attend the exam.
Refunds will be sent to the party who initially paid for the exam. If payment was made by credit card, that card will receive the credit. If that card is no longer valid, a check will be mailed. If the payment was made by check, ACRP will mail a refund check to the original payer.

Transfers
The Academy offers a **one-time** transfer from the current exam offering to the next. There are two situations in which candidates may take advantage of this:

1. If a candidate is determined **ineligible** for the current exam window, but will have met the eligibility requirements by the next exam window; or
2. If an **eligible** candidate withdraws from taking the original exam for any reason (up to five [5] days before a scheduled exam appointment)

Transfers are applied toward the next exam **only**. Transfer of eligibility and associated fees will be applied only to the original candidate and are not transferable to another person, even if paid for by a third party. Exam fees are transferred toward the next exam ***only*** and not toward other products or services.

If you choose to transfer to the next exam window for one of the two reasons above, you must submit a **Request to Transfer Exam Application Form** before the end of the exam window for which you had originally applied.

If you have an exam appointment scheduled, you must **first cancel** it directly with Prometric before submitting the **Request to Transfer Exam Application Form** to ACRP. *Fees, payable to Prometric directly, apply for appointment cancellations made within thirty (30) to five (5) days prior to an appointment date. Cancellations are not permitted less than five (5) days prior to an appointment.*

If a transfer candidate does not submit the request before the end of the current exam testing window, then all funds originally submitted will be forfeited. Transferring is not an option for re-examination candidates (from the previous exam cycle).

When a transfer request has been approved, all fees (application and exam fees) are applied automatically at the start of the next application period. All **eligible** transfer candidates will receive an email notice of Eligibility when the Eligibility ID has been reactivated and an exam appointment can be scheduled. Contact certification@acrpnet.org if you did not receive your new Eligibility notice. Candidates who are required to submit documentation for subsequent eligibility review must do so at the start of the next application period.

View full **Policy on Transfers, Cancellation, No Shows, Refunds and Re-Examination**

Preparing for the Exam

The CPI exam is specific to the role that you play in the conduct of a clinical trial. It requires a general working knowledge of the roles and responsibilities to perform in your role safely and effectively, with grounding in ICH GCP and the application of those guidelines.

The exam content expects that you will have a basic working knowledge of general laboratory terms, tests, and procedures, as well as how to perform basic math. It does not cover country-specific (FDA, EMA, etc.) regulations and does not test how your employer or you personally carry out those duties.

The best preparation is to understand the PI knowledge requirements and their application to clinical research. You might want to review the *Detailed Content Outline* for topics or subtopics with which you are less familiar. If you find a particular area with which you are not familiar or comfortable, that would be an area on which to focus your study or review. Or, you may want to do a surface review of all the content areas, even those you believe you know well.

Because of the nature of the exam, there is not one comprehensive source to go to in order to study. However, ACRP does recommend that you review the content areas covered on the exam by using the Detailed Content Outline.

What's Covered on the Exam?

To be certified, PIs are expected to have *general knowledge* of: laboratory terminology, tests, and procedures; and basic math, including adding, subtracting, multiplying, dividing, and calculating percentages.

Detailed Content Outline

The DCO is derived from the 2015 ACRP Job Analysis Survey, a careful description of the tasks performed by clinical research coordinators. Each question on the exam is based on this outline. Therefore, to

prepare to take the exam, one should study this outline and especially consider the underlying knowledge, skills, and abilities needed to perform in his/ her role as a principal, co-, or sub- investigator. The complete DCO is located at the end of this handbook.

Study Texts
ACRP Certification exams are based on five ICH Guidelines and the Declaration of Helsinki:

- Guideline for Good Clinical Practice E6(R2);
- Definitions and Standards for Expedited Reporting E2A;
- General Considerations for Clinical Trials E8;
- Statistical Principles for Clinical Trials E9;
- Clinical Investigation of Medicinal Products in the Pediatric Population E11

ICH Guidelines
Declaration of Helsinki

Preparation Support

Certification Abbreviation List
The Abbreviations List contains abbreviations that may be used throughout the exam and exam Detailed Content Outline. The abbreviations list is accessible on each screen during the exam and can be found on our **website**.

Exam Practice Exercise
The Exam Practice Exercise is not intended to be a pre-test to determine a candidate's future success on the actual exam. Candidates should understand that this not considered a "practice test/exam". It is considered a practice exercise.

It functions to assist candidates in becoming more comfortable with the type of items on the exam. The exercise includes 50 retired items and also provides the correct answer, the ICH Guideline reference that supports the correct answer, and a narrative explanation for the answer.

Additional Optional Support
ACRP provides optional exam preparation support which is available for purchase online, from the **Exam Preparation** webpage. There are options to purchase components separately or in a package. Visit the webpage for details and pricing for each option.

Further Study Tips

In addition to reviewing the DCO and ICH Guidelines, one way to review is to select texts and training materials you used when first taking on your role. You can select a publication that you may already have or borrow from a colleague. You should select books or publications that cover topics found on the Detailed Content Outline, the ICH Guidelines, or the tenets of GCP.

If you have time, take a workshop or attend a conference session on topics in which you need to become more familiar. ***Any*** professional development courses that cover clinical research topics will add to your knowledge base and therefore will help you prepare for the exam.

IMPORTANT: ACRP **DOES NOT** sponsor or endorse any specific educational courses; even if the course is advertised as a "prep" or "review" course for the exam. Those creating the course **do not have ANY** inside information about the exam. Participation in these courses may help you learn or review topics covered on the exam, **but you should not expect them to directly cover exam content**. The same information that is included in this handbook to help you prepare is publicly available to those creating educational content.

Taking the Exam

It is important for candidates to understand their rights and responsibilities in the secure testing environment of the Prometric test center. It is recommended that you review the full **Policy on Testing Experience Issues.**

Exam Appointment Arrival

It is the candidate's responsibility to arrive on time for the exam appointment. If the candidate is late by 15 minutes or more, the test center has the authority to turn the candidate away and not permit the candidate to take the test. Plan to arrive 30 minutes before your appointment. If you miss your scheduled exam appointment for any non-emergency reason (lack of child care, lateness due to work or traffic, etc.) your opportunity to test will be lost.

Required Identification

To access a secure testing center you must present proper identification (ID) containing your legal name. Examples of proper ID include a passport, driver's license, state or government-issued ID.

Your legal name MUST match the **first name** and **last name** listed on your Eligibility Notice (emailed from ACRP) and on the Appointment Confirmation (from Prometric). Middle names are excluded. Your ID must meet **each** of the following criteria:

- ☐ government-issued **AND**
- ☐ current (non-expired) **AND**
- ☐ photo-bearing **AND**
- ☐ signature-bearing identification (ID)

The photo must look like the examinee. Signature on ID must match the signature provided during the sign-in process. Major discrepancies will result in a candidate being denied from the testing center and result in forfeiture of all fees paid.
If the name listed with ACRP and Prometric is not your legal name, you must submit a **Name Change Request** to **certification@acrpnet.org** immediately.

Exam Security and Test Center Guidelines

Prometric is serious about test center security. You will be presented with **Prometric Test Center Regulations** upon arrival at the test site. Those who violate security will not have their exams scored or processed, and will be required to leave immediately. Attempting to remove exam material or content from the test center will result in severe consequences.

Once seated, you will follow a brief on-screen tutorial for navigating through the exam. Your exam will begin after the tutorial. Each exam will be delivered via individual video-monitored testing carrels. Immediately raise your hand at any time if your computer or any provided resources are not functioning properly!

What Not to Bring: Any and all personal items will be locked in a locker. Examples include a purse, keys, wallet, calculators, watch, cell phone, all electronic devices, tissues, outerwear (heavy coats), food, and all books and papers.

Attire: Prometric **will not** allow you to remove any article of clothing (headbands, jewelry, scarves, shoes, light sweaters, etc.) that you wear into the room. Whatever you choose to wear, please plan to wear the entire length of the exam.

Resources Available at the Test Center

The following resources will be available, issued only by the test center:

- An abbreviations list is also available on screen
- Hand-held calculator (an on-screen calculator is also available)
- Noise cancelling head set
- White board and dry-erase marker

Exam Scores

The passing *scaled* score for the exam is 600. A candidate scoring below 600 has not been successful on the exam and cannot be certified.

One point is granted for each correct answer. There is no penalty assessed for an incorrect answer. The number of questions answered correctly (or total points) is a candidate's "raw score." Prometric then converts a candidate's raw score to a scaled score. The "Total Scaled Score" will determine whether a candidate has passed the exam. The exam is not scored on a curve and there is no predetermined number of candidates permitted to pass. Your score does not depend on the other candidates testing with you that day.

Note: The passing point set for the exam cannot be appealed.

Specific questions on the exam and/or answers to exam questions will not be discussed or released. Due to the security of the item bank and because exam questions can be used on various exams, exam questions will not be discussed with candidates and candidates may not have access to the exam or their answers.

For more information on scaled scoring, please contact us at **certification@acrpnet.org**.

Exam Results and Notification

Computer-based testing immediately provides participants with preliminary results. You will receive a printed proficiency assessment before you leave the test center. You will receive official confirmation of your certification status via email and postal mail, approximately 30 days following the **close** of the testing window.

Candidates, are not yet considered certified until *official* notification of certification status is received from the Academy.

Candidates who pass the exam will be sent an official letter, a certificate, a certification pin, and Maintenance of Certification information. They will also be added to the Academy Certification registry unless this option was de-selected at the time of application. The registry will be updated within 30 days following the close of the testing window and can be accessed at **www.avectraacrp.com/Certlist**.

Candidates who do not pass the exam are advised to review the content area proficiency ratings and use this information to assist in preparing for future exams. Final exam results will **not** be given out over the telephone or by fax, nor will results be sent to employers, schools, other individuals, or organizations under any circumstances.

Appendix – 2017 CPI Detailed Content Outline (DCO)

ACADEMY
OF CLINICAL RESEARCH PROFESSIONALS

Certified Principal Investigator (CPI®) Examination
Detailed Content Outline

(Effective 1 January 2017)

This document contains the Detailed Content Outline (DCO) for the Principal Investigator Examination. Each question on the exam is based on this outline.

Introduction

The CPI program is accredited by the National Commission for Certifying Agencies (NCCA®). NCCA Accreditation is an impartial, third-party validation that the CPI program has met recognized national and international credentialing industry standards for development, implementation, and maintenance of certification programs. The Academy of Clinical Research Professionals (the Academy) develops the CPI exam using certification industry best practices, as aligned with the NCCA Standards for Accreditation of Certification Programs.

In following these best practices, the Academy conducts a Job Analysis Study every five (5) years to ensure content validity of the CPI Examination. Program content validity is demonstrated with a comprehensive job analysis conducted and analyzed by experts, with data gathered from practitioners within the profession. The process utilizes knowledge and task focused guidelines to assess clinical research professionals' competence, and determine the level of importance and frequency of specific knowledge and tasks required to perform in the role of a principal investigator. View Executive Summary for the most recent Job Analysis Study.

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Using the CPI Detailed Content Outline (DCO)

The CPI DCO was constructed from the results of the most recent (2015) Job Analysis Study. The results of the study provided the framework for the knowledge and tasks important to the role of a CPI and therefore the content of the CPI Exam. To be certified, a PI is expected to have proficiency in the six (6) main content areas of clinical research, displayed in the chart below. The percent of questions dedicated to each content area are provided.

	Content Areas	Percentage of Items on Exam
I.	Scientific Concepts and Research Design	17%
II.	Ethical and Participant Safety Considerations	25%
III.	Product Development and Regulation	10%
IV.	Clinical Trial Operations (GCPs)	15%
V.	Study and Site Management	23%
VI.	Data Management and Informatics	10%
	Total	**100%**

Certified Principal Investigators (CPIs) are expected to have general knowledge of:
- laboratory terminology, tests, and procedures
- basic math, including adding, subtracting, multiplying, dividing, and calculating percentages

The specific knowledge and tasks identified as important are provided in the CPI DCO, below. Therefore, to prepare to take the CPI Exam, one should study this outline and especially consider the underlying knowledge, skills, and abilities needed to perform as a CPI. It is recommended that an eligible CPI Exam candidate use this outline to identify knowledge gaps for constructing a relevant preparation plan.

ACADEMY
OF CLINICAL RESEARCH PROFESSIONALS

Certified Principal Investigator (CPI®) Examination
Detailed Content Outline

(Effective 1 January 2017)

As defined by the most recent ACRP Job Analysis Survey, a CPI® shall have proficient **knowledge** (middle column) in the following six (6) content areas of clinical research. A CPI typically uses this knowledge to perform the **tasks** listed (last column).

Content Area	CPIs must demonstrate proficient knowledge within the following areas:	CPIs typically perform the following tasks:
1. Scientific Concepts and Research Design (17%)	**1.1 elements of an Investigational Brochure (IB) and/or investigational device use (instructions for use)**	Review/Analyze background information (e.g., product development plan, IB)
		Identify the expected or unexpected results associated with investigational products
		Develop research question and/or hypothesis
		Identify the safety and expected therapeutic effects of the investigational product by verifying the preclinical and clinical research done so far (using the IB)
		Develop, update, and/or review the Investigators' Brochure
	1.2 elements of a protocol	Develop the protocol (e.g., inclusion/exclusion criteria, procedures, schedule of events, safety and efficacy parameters)
		Implement plan of action for management of adverse event(s) [e.g., stop investigational product, retest, treat subject]
		Identify and/or explain study objective(s) and endpoints
		Identify and/or explain study design
	1.3 rationale for complying with a protocol	Evaluate protocol for scientific soundness (e.g., risks, benefits, validity of study procedures, endpoints)
		Evaluate protocol for feasibility (in terms of practicality of execution, not evaluation by site)
		Ensure compliance with study requirements and regulations

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Content Area	CPIs must demonstrate proficient knowledge within the following areas:	CPIs typically perform the following tasks:
		Ensure consistency between the sites' standard operating procedures (SOPs) and the study requirements
	1.4 study objective(s) and end points/outcomes	Identify and/or explain study objective(s) and endpoints
		Critically analyze study results
		Prepare clinical trial/study report
	1.5 elements of and rationale for subject eligibility requirements	Develop and/or follow a recruitment strategy
		Conduct prescreening activities with potential study subjects
		Screen trial subjects
	1.6 statistical principles	Critically analyze study results
		Identify and/or explain study design
		Prepare clinical trial/study report
		Develop and/or maintain randomization procedures of investigational product
	1.7 study design characteristics (e.g., double-blind, crossover, randomized)	Identify and/or explain study design
		Conduct unblinding procedures as applicable
		Evaluate study for feasibility (site determining ability to successfully conduct the study)
		Develop and/or maintain randomization procedures of investigational product
		Develop and/or Maintain unblinding procedures of investigational product
	1.8 treatment assignments (e.g., randomization, open label, registries)	Develop and/or maintain randomization procedures of investigational product
		Ensure clinical trial registry requirements are met
		Minimize potential risks to subject safety

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Content Area	CPIs must demonstrate proficient knowledge within the following areas:	CPIs typically perform the following tasks:
	1.9 supplemental/rescue/comparator product(s) in study design	Assess subject safety during study participation
		Ensure and document follow-up medical care for study subjects, as applicable
		Assess, manage, and/or review subject laboratory values, test results, and alerts
2. Ethical and Participant Safety Considerations (25%)	**2.1 protection of human subjects**	Develop and/or review informed consent form
		Comply with subject privacy regulations
		Ensure adequate consent and documentation
		Verify adequate implementation and documentation of the informed consent process
		Implement plan of action for management of adverse event(s) [e.g., stop investigational product, retest, treat subject]
	2.2 vulnerable subject populations	Identify and/or address potential ethical issues involved with study conduct
		Minimize potential risks to subject safety
		Develop and/or implement study education plan and/or tools for subjects
		Participate in and document the informed consent process(es)
	2.3 subject safety issues	Assess, manage, and/or review subject laboratory values, test results, and alerts
		Differentiate the types of adverse events that occur
		Assess AE causality
		Maintain follow-up to determine resolution of adverse event(s)
		Ensure timely review of safety data
	2.4 confidentiality and privacy requirements	Comply with subject privacy regulations
		Ensure compliance with study requirements and regulations
		Prepare the study site for audits and inspections

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Content Area	CPIs must demonstrate proficient knowledge within the following areas:	CPIs typically perform the following tasks:
	2.5 conflicts of interest in clinical research	Comply with IRB/IEC requirements
		Identify the role and proper composition of IRB/IECs
		Ensure IRB/IEC review/written approval of study and study documents
		Ensure compliance with study requirements and regulations
	2.6 elements of the IB	Review/Analyze background information (e.g., product development plan, IB)
		Identify the expected or unexpected results associated with investigational products
		Develop research question and/or hypothesis
		Identify the safety and expected therapeutic effects of the investigational product by verifying the preclinical and clinical research done so far (using the IB)
		Develop, update, and/or review the Investigators' Brochure
	2.7 recruitment plan/strategies	Develop and/or follow a recruitment strategy
		Prepare and/or submit documents for IRB/IEC and/or sponsor review/approval
		Ensure IRB/IEC review/written approval of study and study documents
		Re-evaluate the recruitment strategy as needed
	2.8 elements of the informed consent form	Develop and/or review informed consent form
		Ensure adequate consent and documentation
		Instruct subjects on proper use of investigational product
		Implement protocol amendments
	2.9 informed consent process requirements	Verify adequate implementation and documentation of the informed consent process
		Delegate study-related roles and responsibilities

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Content Area	CPIs must demonstrate proficient knowledge within the following areas:	CPIs typically perform the following tasks:
		Escalate significant findings as appropriate
		Comply with IRB/IEC requirements
	2.10 components of subject eligibility requirements	Screen trial subjects
		Document reasons for subject discontinuation (i.e., causes, contact efforts)
		Ensure investigator/site protocol compliance
		Assess subject compliance
	2.11 blinding/unblinding procedures	Develop and/or Maintain unblinding procedures of investigational product
		Manage investigational product recall at the site and from study subjects
		Conduct unblinding procedures as applicable
	2.12 safety monitoring	Verify appropriate reporting and documentation of adverse event(s)
		Ensure timely review of safety data
		Assess subject safety during study participation
		Oversee the management of safety risks (e.g., clinical holds, product recalls)
	2.13 adverse events classification, documentation and reporting	Assess AE causality
		Maintain follow-up to determine resolution of adverse event(s)
		Verify appropriate reporting and documentation of adverse event(s)
	2.14 subject discontinuation criteria/procedures	Document reasons for subject discontinuation (i.e., causes, contact efforts)
		Ensure timely review of safety data
		Assess subject safety during study participation
	2.15 subject retention strategies	Develop and/or implement study education plan and/or tools for subjects
		Schedule subjects
		Conduct subject visits
		Develop trial management tools
	2.16 protocol deviation/violation identification, documentation, and	Identify and report potential fraud and misconduct

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Content Area	CPIs must demonstrate proficient knowledge within the following areas:	CPIs typically perform the following tasks:
	reporting processes	Investigate potential fraud and misconduct
		Develop or participate in protocol training
3. Product Development and Regulation (10%)	**3.1 clinical development process (e.g., preclinical, clinical trial phases, device class)**	Develop and/or review the product development plan
		Develop research question and/or hypothesis
		Review/Analyze background information (e.g., product development plan, IB)
		Identify the safety and expected therapeutic effects of the investigational product by verifying the preclinical and clinical research done so far (using the IB)
	3.2 IRB/IEC role, composition and purpose	Comply with IRB/IEC requirements
		Identify the role and proper composition of IRB/IECs
		Coordinate protocol and/or protocol amendments through appropriate approval processes (e.g., IRB/IEC, sponsor, regulatory authority)
	3.3 IRB/IEC reporting requirements	Ensure IRB/IEC review/written approval of study and study documents
		Inform the sponsor and IRB/IEC of any deviations from the protocol and document as appropriate
		Prepare study summary and/or close-out letter for IRB/IEC
	3.4 regulatory reporting requirements	Inform study subjects of trial results, in accordance with regulatory requirements
		Inform the sponsor and IRB/IEC of any deviations from the protocol and document as appropriate
		Ensure compliance with study requirements and regulations
		Submit documents to regulatory authorities
		Prepare for and/or participate in audits and inspections
		Respond to or facilitate response to

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Content Area	CPIs must demonstrate proficient knowledge within the following areas:	CPIs typically perform the following tasks:
		audit/inspection findings
	3.5 protocol and protocol amendment submission and approval processes	Prepare and/or submit documents for IRB/IEC and/or sponsor review/approval
		Ensure IRB/IEC review/written approval of study and study documents
		Submit documents to regulatory authorities
		Identify issues requiring protocol amendments
		Implement protocol amendments
	3.6 safety reporting requirements	Develop, update, and/or review the Investigators' Brochure
		Submit documents to regulatory authorities
		Verify appropriate reporting and documentation of adverse event(s)
	3.7 elements of fraud and misconduct	Identify and report potential fraud and misconduct
		Investigate potential fraud and misconduct
		Select qualified investigational staff
		Verify that investigational staff is qualified
	3.8 audit and inspection processes (preparation, participation, documentation, and follow-up)	Prepare the study site for audits and inspections
		Prepare for and/or participate in audits and inspections
		Respond to or facilitate response to audit/inspection findings
		Ensure appropriate staff, facility, and equipment availability throughout the study
	3.9 significant milestones in the evaluation of efficacy and safety (e.g., interim analysis result, DSMB review)	Ensure timely review of safety data
		Assess subject safety during study participation
		Ensure timely review of study data
4. Clinical Trial Operations	**4.1 roles of various clinical trial entities (e.g., CROs, sponsors, regulatory authority, vendors, etc.)**	Delegate study-related roles and responsibilities
		Develop project management tools

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Content Area	CPIs must demonstrate proficient knowledge within the following areas:	CPIs typically perform the following tasks:
(GCPs) (15%)		Obtain/verify vendor credentials (e.g., lab certification/licensure)
		Select qualified investigational staff
	4.2 project feasibility considerations	Schedule, coordinate, and/or participate in pre-study site visit
		Evaluate protocol for feasibility (in terms of practicality of execution, not evaluation by site)
		Evaluate study for feasibility (site determining ability to successfully conduct the study)
		Identify issues requiring protocol amendments
		Facilitate site budget/contract approval process
	4.3 principal investigator responsibilities	Verify that investigational staff is qualified
		Develop or participate in protocol training
		Prepare, conduct and/or participate in study initiation activities
		Plan, conduct and/or participate in training of the investigational staff
	4.4 indemnification/insurance requirements	Obtain/verify vendor credentials (e.g., lab certification/licensure)
		Facilitate site budget/contract approval process
		Evaluate and/or verify investigator indemnification/ insurance
	4.5 delegation of duties	Verify that investigational staff is qualified
		Delegate study-related roles and responsibilities
		Plan, conduct and/or participate in training of the investigational staff
		Ensure investigator/site protocol compliance
		Maintain study related logs (e.g., site signature

Content Area	CPIs must demonstrate proficient knowledge within the following areas:	CPIs typically perform the following tasks:
		log, screening log)
		Identify and/or maintain Essential Documents required for study conduct
	4.6 staff training requirements	Ensure appropriate staff, facility, and equipment availability throughout the study
		Select qualified investigational staff
		Delegate study-related roles and responsibilities
	4.7 site initiation activities	Verify Essential Documents required for study conduct
		Develop source document templates
		Develop and implement monitoring guidelines/plans
		Prepare, conduct and/or participate in study initiation activities
		Schedule, coordinate, and/or participate in pre-study site visit
	4.8 staff oversight	Prepare, conduct, and/or participate in interim monitoring visit(s)
		Perform onsite monitoring activities
		Create, document, and/or implement corrective and preventive action (CAPA) plans
	4.9 principles of study monitoring (e.g., risk-based, full SDV, remote, etc.)	Develop and implement monitoring guidelines/plans
		Prepare, conduct, and/or participate in interim monitoring visit(s)
		Perform onsite monitoring activities
		Document, communicate, and follow up on site visit findings
	4.10 elements of an effective corrective and preventive action (CAPA) plan	Document, communicate, and follow up on site visit findings
		Create, document, and/or implement

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Content Area	CPIs must demonstrate proficient knowledge within the following areas:	CPIs typically perform the following tasks:
		corrective and preventive action (CAPA) plans
		Escalate significant findings as appropriate
		Identify issues and recommend investigator/site corrective actions
	4.11 site close-out activities	Prepare for and participate in close-out monitoring visit(s)
		Reconcile investigational product and related supplies
		Ensure proper storage, dispensing, handling, and disposition of investigational product and related supplies
		Ensure proper collection, processing, and shipment of specimens (e.g., centrifuge, preparation of slides, freezing, refrigeration)
		Manage study records retention and availability
5. Study and Site Management (23%)	**5.1 roles of various clinical trial entities (e.g., CROs, sponsors, regulatory authority, vendors, etc.)**	Delegate study-related roles and responsibilities
		Develop project management tools
		Obtain/verify vendor credentials (e.g., lab certification/licensure)
		Select qualified investigational staff
	5.2 elements of a study budget	Facilitate site budget/contract approval process
		Develop trial management tools
		Evaluate study for feasibility (site determining ability to successfully conduct the study)
	5.3 contract budget negotiations and approval process	Facilitate site budget/contract approval process
		Evaluate and/or verify investigator indemnification/ insurance
		Coordinate protocol and/or protocol amendments through appropriate approval processes (e.g., IRB/IEC, sponsor, regulatory

Content Area	CPIs must demonstrate proficient knowledge within the following areas:	CPIs typically perform the following tasks:
		authority)
	5.4 project and/or study timelines	Manage study supplies (e.g., lab kits, case report forms)
		Ensure adequacy of investigational product and other supplies at site
		Monitor investigational product expiration and/or manage resupply
		Develop project management tools
		Develop trial management tools
		Schedule subjects
	5.5 investigational product characteristics (e.g., mechanism of action, stability, etc.)	Prepare investigational product for administration
		Dispense investigational product
		Reconcile investigational product and related supplies
		Maintain accountability of investigational product
		Monitor investigational product expiration and/or manage resupply
	5.6 investigational product reference materials (e.g., Investigational Brochure, instructions for use, user manual)	Ensure proper storage, dispensing, handling, and disposition of investigational product and related supplies
		Prepare investigational product for administration
		Dispense investigational product
	5.7 investigational product storage	Ensure proper storage, dispensing, handling, and disposition of investigational product and related supplies
		Ensure adequacy of investigational product and other supplies at site
		Monitor investigational product expiration and/or manage resupply
		Maintain accountability of investigational product
	5.8 investigational product	Reconcile investigational product and related

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Content Area	CPIs must demonstrate proficient knowledge within the following areas:	CPIs typically perform the following tasks:
	accountability and documentation requirements	supplies
		Maintain accountability of investigational product
		Ensure proper storage, dispensing, handling, and disposition of investigational product and related supplies
	5.9 equipment and supplies use and maintenance	Obtain/verify vendor credentials (e.g., lab certification/licensure)
		Manage study supplies (e.g., lab kits, case report forms)
		Perform and/or verify equipment calibration and maintenance
	5.10 sample collection, shipment, and storage requirements	Ensure proper collection, processing, and shipment of specimens (e.g., centrifuge, preparation of slides, freezing, refrigeration)
		Follow standards for handling hazardous goods (e.g., International Air Transport Association (IATA)
		Manage study supplies (e.g., lab kits, case report forms)
	5.11 subject responsibilities for study participation	Instruct subjects on proper use of investigational product
		Assess subject compliance
		Ensure adequate consent and documentation
	5.12 subject visit activities	Conduct prescreening activities with potential study subjects
		Assess subject compliance
		Conduct subject visits
	5.13 subject compliance assessment	Assess subject compliance
		Reconcile investigational product and related supplies
		Ensure investigator/site protocol compliance
	5.14 communication documentation requirements (e.g., telephone, email, etc.)	Develop source document templates
		Document, communicate, and follow up on site visit findings

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Content Area	CPIs must demonstrate proficient knowledge within the following areas:	CPIs typically perform the following tasks:
		Develop trial management tools
	5.15 purpose of and process(es) for protocol compliance	Ensure investigator/site protocol compliance
		Plan, conduct and/or participate in training of the investigational staff
		Develop trial management tools
	5.16 corrective and preventive action (CAPA) process(es) and plan	Create, document, and/or implement corrective and preventive action (CAPA) plans
		Escalate significant findings as appropriate
		Identify issues and recommend investigator/site corrective actions
	5.17 investigational product shipment	Maintain accountability of investigational product
		Manage investigational product recall at the site and from study subjects
		Monitor investigational product expiration and/or manage resupply
		Verify Essential Documents required for study conduct
6. Data Management and Informatics (10%)	**6.1 essential documents for the conduct of a clinical trial (e.g., trial master file)**	Identify and/or maintain Essential Documents required for study conduct
		Verify Essential Documents required for study conduct
		Manage study records retention and availability
	6.2 elements and purposes of data collection tools (e.g., eCRF, EDC)	Review and approve completed eCRF/CRF
		Collect, record, and report accurate and verifiable data
		Transmit data to Data Management
	6.3 source documentation requirements	Develop source document templates
		Collect, record, and report accurate and verifiable data
		Perform query resolution
	6.4 data privacy principles	Ensure compliance with electronic data requirements (e.g., passwords and access)
		Ensure access to source data by authorized parties, and protect confidentiality by limiting unauthorized access

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Content Area	CPIs must demonstrate proficient knowledge within the following areas:	CPIs typically perform the following tasks:
		Ensure consistency between the sites' standard operating procedures (SOPs) and the study requirements
		Comply with subject privacy regulations
	6.5 study documentation practices (accurate, complete, timely, legible, dated, and identify the trial)	Collect, record, and report accurate and verifiable data
		Perform query resolution
		Manage study records retention and availability
	6.6 source data review (SDR) and source data verification (SDV) purpose and process	Perform query resolution
		Ensure access to source data by authorized parties, and protect confidentiality by limiting unauthorized access
		Perform onsite monitoring activities
		Document, communicate, and follow up on site visit findings
	6.7 data management principles	Develop trial management tools
		Collect, record, and report accurate and verifiable data
		Transmit data to Data Management
		Ensure timely review of study data
		Ensure compliance with electronic data requirements (e.g., passwords and access)
	6.8 record retention and destruction practices and requirements	Ensure access to source data by authorized parties, and protect confidentiality by limiting unauthorized access
		Manage study records retention and availability
		Ensure timely review of study data
		Maintain study related logs (e.g., site signature log, screening log)