ACRP CERTIFICATION HANDBOOK

ACADEMY
OF CLINICAL RESEARCH PROFESSIONALS

ACRP

LETTER FROM OUR EXECUTIVE DIRECTOR

Welcome!

Congratulations on your exciting decision to advance your knowledge in clinical research by pursuing certification through the Association of Clinical Research Professionals (ACRP), the most reputable credentialing program in clinical research. More than 40,000 professionals trust ACRP Certification as a respected endorsement of clinical research competency—so you're in excellent company amongst the best and brightest in the industry.

ACRP Certification includes its flagship certifications: ACRP Certified Professional (ACRP-CP®), Certified Clinical Research Associate (CCRA®), Certified Clinical Research Coordinator (CCRC®), and Certified Principal Investigator (CPI®), and the following specialty credential programs: ACRP Medical Device Professional (ACRP-MDP®), and ACRP Project Manager (ACRP-PM®).

These credentials provide clinical research professionals the opportunity to demonstrate their mastery of the core competencies needed to ensure quality and integrity in the clinical research process, all while advancing their career goals.

In this Handbook, you will find an overview of ACRP's Certification programs, eligibility and testing requirements, resources to help prepare for your exam, and guidance on exam scoring, results, as well as information to help you maintain your ACRP Certification.

We look forward to supporting you on your journey of professional excellence through ACRP Certification.

SUSAN P. LANDIS
Executive Director
Association of Clinical Research Professionals (ACRP)

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PART I

OVERVIEW
This handbook is designed to guide individuals pursuing ACRP Certification. Prospective candidates for the CCRA®, CCRC®, ACRP-CP®, and CPI® programs should read this handbook before applying.

THE ACADEMY
Established in 2006, The Academy of Clinical Research Professionals (The Academy) is an independent affiliate of ACRP responsible for the development and administration of ACRP's Certification programs.

MISSION STATEMENT
Promote and maintain high standards and best practices of clinical research by recognizing those professionals who demonstrate a well-defined competency through valid and reliable credentialing programs.

LEADERSHIP
The Academy's leadership is provided by a volunteer-based, member-elected Board of Trustees. Trustees serve a minimum term of three years and can be re-elected for one additional three-year term. Board elections are held annually.

ACRP MEMBERSHIP
Membership in the Association of Clinical Research Professionals (ACRP) is not required for certification. While ACRP Members do not receive an exemption from paying their certification dues, they are eligible for discounted rates on certification registration and exam fees and participation in ACRP Contact Hour activities, such as virtual training courses and webinars, the ACRP Annual Conference, and ACRP Home Study tests.

CERTIFICATION
ACRP's four certification programs aim to acknowledge professionals with 3,000 hours of experience in clinical research involving human subjects. This certification affirms that individuals meet industry standards, reinforcing credibility and highlighting their competence in the field of clinical research.

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SECRETARY/TREASURER

NCCA ACCREDITATION

ACRP's ACRP-CP, CCRC, CCRA, and CPI programs are accredited by the National Commission for Certifying Agencies (NCCA), which sets internationally recognized standards for the development and operation of certification programs. The standards assure that a program is valid, reflects current practice, and treats candidates fairly and are based on the established processes for developing certification exams.

SPECIALTY

The intent of ACRP's specialty program is to evaluate ACRP certificants seeking further validation of their knowledge and skills within a specific area of expertise. Specialty designations do not replace any of the flagship certifications. The CCRA®, CCRC®, ACRP-CP®, and CPI® programs are based on the body of knowledge needed to demonstrate the competence of a clinical research professional. Those seeking a specialty must first pass one of these certification exams. Specialty designation is offered to actively certified CCRCs, CCRAs, ACRP-CPs, and CPIs, who have specialized knowledge in medical device trials and project management, as it relates to clinical studies.

EXAM DEVELOPMENT

The development of ACRP's Certification examinations begins with a Job Analysis, which conducts research into the actual work done by various individuals to create a definitive description of the tasks required to perform a job role and the knowledge needed to complete those tasks. A Job Analysis is conducted via a survey and is typically conducted every five to seven years to assure the exam is testing current practice in a job role.

The results of the survey identify what the Academy will include on the Detailed Content Outlines (DCOs) for each exam. Each exam has a different DCO that reflects those task and knowledge statements that the majority of clinical research professionals respectively said were essential to their job role. The results of the Job Analysis also dictate how much of each topic is covered; tasks performed more frequently or deemed most critical are tested more heavily on the exam. Each exam has an outline that reflects the particular emphasis of their job role and function.

Individuals who are already certified as a CCRA®, CCRC®, CPI®, or ACRP-CP® are then trained to write test questions based on current practice and conduct of clinical research. We call these volunteers "Subject Matter Experts," or "SMEs." All questions must test knowledge and skills as defined by the DCO. The correct answer for each item must be supported by at least one citation of a reference found on the resource list, currently comprised of specific areas of ICH Guidelines, as described in this Handbook. Once the SMEs have written draft questions, the questions go to the Exam Committees for review. This process is constantly in motion, with new questions being written, current questions being reviewed, and older or non-performing questions being "retired" from the item bank.

An Exam Committee exists for each flagship certification. The CCRA®, CCRC®, CPI®, and ACRP-CP® Global Exam Committees consists of a separate group of currently practicing, ACRP certified professionals who review, edit, discuss, and rewrite the draft test questions. Many draft test questions are discarded in the process. Others are completely rewritten or heavily edited. Each question must meet minimum standards for applicability to the job role. All Exam Committee members must agree that the answer selected is in fact, the only correct possible answer. The Exam Committees verify the content tested falls within the appropriate DCO and that the reference(s) cited support the correct answer.

Once a draft question is approved by an Exam Committee, it then becomes a "pre-test question." All questions are pre-tested before they are counted toward a candidate's score. This means the Academy is collecting statistical data on the pre-test items to see if they are well-constructed enough to appear on the exam as a scored item. Hundreds of candidates answer a pre-test question before it can be determined if it can be used toward a candidate's score.

Once enough data has been collected, analyses are performed on the item statistics in conjunction with the Academy's professional test development partner to see if items have performed well enough to be used. If they have not performed well (for example, if many candidates choose the wrong answer; or each answer is selected equally, which indicates test-takers are guessing; or candidates who score well on the exam overall select a wrong answer), then the questions are set aside for further review and rewriting, or they may be discarded. Only those questions that demonstrate they are fair to the test taker and identify candidate proficiency are used.

Candidates must achieve a minimum score of 600 to have demonstrated sufficient knowledge and skill to pass the exam and become certified.

EXAM STRUCTURE

ACRP's Certification exams consists of 125 multiple-choice questions (25 of these questions are pre-test items and do not affect a candidate's score nor are they identified to the candidate). Each candidate is allowed a maximum of three hours to complete the 125 questions. ACRP's specialty exams consist of 60 multiple choice questions (10 pre-test items) and candidates are allotted 90 minutes to complete their exam. 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 answering incorrectly.

The exam is designed to assess proficiency of the six core knowledge areas:

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

The exam is provided in English. Candidates may bring a hard-copy, translation only (word-to-word) dictionary to the exam. 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. Additional time may be requested through the submission of an accommodation request.

PART II

REGISTRATION

SPRING 2024 REGISTRATION DATES		TESTING PERIOD	MEMBER	NON-MEMBER
Early Bird	10.15.2023 – 12.31.2023	2.15.2024 – 5.15.2024	$435	$485
Regular	1.1.2024 – 4.30.2024		$460	$600
FALL 2024 REGISTRATION DATES		**TESTING PERIOD**	**MEMBER**	**NON-MEMBER**
Early Bird	5.15.2024 – 7.15.2024	7.15.2024 – 10.15.2024	$435	$485
Regular	7.16.2024 – 9.30.2024		$460	$600

PATHWAYS TO CERTIFICATION

To qualify for ACRP Certification, applicants must be able to provide verifiable proof of employment. Verifiable employment means that ACRP can contact an employer, past or present, to verify the information listed on an application. Professional experience older than ten years from the date of application submission will not qualify. All applicants must submit a resume that outlines their work experience and primary duties held with each relevant employer.

CCRC®

Pathway 1: 3,000-hours of CRC work experience
Pathway 2: 1,500 hours of CRC work experience and; hold an active ACRP certification, or has completed an accredited clinical research education program

CCRA®

Pathway 1: 3,000-hours of CRA work experience
Pathway 2: 1,500 hours of CRA work experience and; hold an active ACRP certification, or has completed an accredited clinical research education program

CPI®

Pathway 1: 3,000-hours of work experience as an Investigator. Proof of employment as a Principal Investigator within the last five years.
Pathway 2: 1,500 hours of work experience as an Investigator and; earned a doctorate degree, or hold an active ACRP certification, or has completed an accredited clinical research education program

ACRP-CP®

Pathway 1: 3,000-hours of experience working in clinical research (not role specific)
Pathway 2: 1,500 hours of experience working in clinical research and; hold an active ACRP certification or has completed an accredited clinical research education program

ACRP-PM®

Pathway: ACRP Certified—experience related to project management

ACRP-MDP®

Pathway: ACRP Certified—experience related to medical devices

QUALIFYING WORK EXPERIENCE

Applicants must have the minimum number of required hours of experience in the professional practice of clinical research to qualify. Internship (paid or unpaid), volunteer experiences, and hours earned through educational programs will not count toward the experience requirement. Any experience older than ten years will not qualify.

ELIGIBILITY REQUIREMENTS

Eligibility for the Certified Clinical Research Coordinator (CCRC®)

All applicants seeking certification as a Certified Clinical Research Coordinator (CCRC) must fulfill specific eligibility requirements outlined in the Policy on Eligibility for Certification. Fulfillment of these requirements is necessary for approval to take the CCRC examination.

What is a Clinical Research Coordinator (CRC)?

CRC refers to a Clinical Research Coordinator. CRCs play an important role in the execution and coordination of clinical trials, ensuring that studies are conducted ethically, safely, and in accordance with regulatory requirements. CRCs work closely with Principal Investigators, sponsors, and other research staff to ensure the smooth conduct of clinical studies while adhering to regulatory standards and protocols.

Essential Duties: These duties encompass various responsibilities such as reporting safety issues, involvement in IRB activities, protocol review, subject visits, data collection, participation in audits/inspections, and engagement in the informed consent process.

Work Experience Requirements: Applicants must document at least 3,000 hours of employment performing the Essential Duties. If the applicant's experience falls within 120 hours of the requirement by the first day of the exam window, full consideration will be given towards eligibility.

Documentation Requirements: Applicants must provide a detailed resume outlining their experience as a CRC and a job description demonstrating the fulfillment of the essential duties.

Equivalent Substitutions: Candidates holding a current CCRA, ACRP-CP, or CPI designation can substitute 1,500 hours of professional experience. Completion of an accredited clinical research education program can also substitute 1,500 hours of experience.

NOTE: ACRP 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.

Eligibility for the Certified Clinical Research Associate (CCRA®)

All applicants seeking certification as a Certified Clinical Research Associate (CCRA) must fulfill specific eligibility requirements outlined in the Policy on Eligibility for Certification. Fulfillment of these requirements is necessary for approval to take the CCRA examination.

What is a Clinical Research Associate (CRA)?

A Clinical Research Associate is a professional involved in clinical research. Their primary responsibility is to manage and monitor the clinical trials conducted by pharmaceutical, biotechnology, or medical device companies. CRAs ensure that trials are conducted in compliance with protocols, regulatory requirements, and Good Clinical Practice (GCP) guidelines. They monitor data, conduct site visits, verify documentation, and ensure the safety and well-being of trial participants while maintaining the integrity of the data collected during the trial.

Work Experience Requirements: Applicants must document a minimum of 3,000 hours of employment performing the essential duties of a CRA. If the applicant's experience falls within 120 hours of the requirement by the first day of the exam window, full consideration will be given towards eligibility.

Essential Duties: Essential duties of a CRA revolve around ensuring compliance with clinical protocols, Good Clinical Practice guidelines, and regulatory standards to safeguard the ethical treatment of human subjects by research site personnel. This involves verifying adherence to the clinical protocol, promptly reporting safety concerns to the sponsor and IRB/IEC as needed, executing detailed monitoring tasks, meticulously reviewing site records, managing Investigational Product and related supplies, documenting all monitoring activities thoroughly, conducting independent routine monitoring visits, and overseeing the implementation of corrective actions to maintain site inspection readiness.

Documentation Requirements: Applicants must provide a detailed resume outlining their experience as a CRA and a job description demonstrating fulfillment of the essential duties.

Equivalent Substitutions: Candidates holding a current CCRC, ACRP-CP, or CPI designation can substitute 1,500 hours of professional experience. Completion of an accredited clinical research education program can also substitute 1,500 hours of experience.

Eligibility for the Certified Principal Investigator (CPI®)
All applicants seeking certification as a Certified Principal Investigator (CPI) must fulfill specific eligibility requirements outlined in the Policy on Eligibility for Certification. Fulfillment of these requirements is necessary for approval to take the CPI examination.

What is an Investigator?
A clinical investigator is a qualified individual responsible for conducting and overseeing a clinical trial. They are typically medical doctors, scientists, or other healthcare professionals with expertise in the area being studied. Clinical investigators lead the research team and are accountable for the overall conduct of the clinical trial, ensuring that it is conducted according to strict protocols, ethical standards, and regulatory requirements.

Work Experience Requirement: Applicants must document at least 3,000 hours of employment performing an investigator's essential duties. If the applicant's experience falls within 120 hours of the requirement by the first day of the exam window, full consideration will be given towards eligibility.

Applicants must document their role as an investigator on two separate studies during two out of the most recent five years by submitting proof of employment for each of those two years.

- 1572/PHS 398/QIU forms, IRB/IEC approval letters, protocol approval letters, investigator agreements, or other regulatory authority documents for the required years.

Essential Duties: Essential duties encompass overseeing the safe and ethical execution of clinical trials, evaluating study proposals, securing necessary approvals, initiating site activities, selecting trial subjects, supervising procedures while ensuring safety, collecting precise data, ensuring compliance with regulations, fostering communication among subjects, sponsors, and review boards, and ensures adequate close-out of the study.

Documentation Requirements: Applicants must provide a detailed resume outlining their experience as an Investigator and a job description demonstrating their fulfillment of the essential duties.

Equivalent Substitutions: Candidates holding a current CCRA, CCRC, or ACRP-CP designation or a doctorate degree, or has completed an accredited clinical research education program can substitute 1,500-hours of employment.

Eligibility for the ACRP-Certified Professional (ACRP-CP®)
All applicants seeking certification as an ACRP-Certified Professional (ACRP-CP) must fulfill specific eligibility requirements outlined in the Policy on Eligibility for Certification. Fulfillment of these requirements is necessary for approval to take the ACRP-CP examination.

What is a Clinical Research Professional?
A clinical research professional is an individual involved in various aspects of clinical research, contributing to the planning, execution, monitoring, and management of clinical trials and studies. Their roles encompass a wide range of responsibilities crucial to the success of clinical research endeavors. These professionals include various job titles and responsibilities, such as CRCs, CRAs, PIs, Sub-Investigators, Data Managers, Regulatory Affairs Specialists, Clinical Trial Managers, Clinical Scientists, Site Directors, and more.

Essential Duties: The ACRP-CP Detailed Content Outline (DCO) delineates the necessary knowledge statements and tasks candidates need to fulfill for qualification. Essential duties of a clinical research professional encompass:

Planning: Involvement in various planning aspects of clinical research, such as protocol design, feasibility assessment, business operations (budgeting, contracting, billing compliance), site selection activities, regulatory document preparation, site management, and clinical operations within academic medical centers or Contract Research Organizations (CROs).

Conducting: Experience in directly conducting clinical trials involving participants.

Overseeing (Management, Administration):
Experience in overseeing study site management, monitoring activities (including in-house, central, and remote monitoring), project management, quality control, quality assurance, data management, medical and safety monitoring (including medical safety liaison, pharmacovigilance, and IRB professional roles).

Work Experience Requirements: Applicants must document a minimum of 3,000 hours of employment performing one or more of the essential duties and attest to having experience performing the tasks listed in the DCO. If the applicant's experience falls within 120 hours of the requirement by the first day of the exam window, full consideration will be given towards eligibility.

Documentation Requirements: Applicants must provide a detailed resume outlining their experience as a clinical research professional and a job description demonstrating the fulfillment of the essential duties.

Equivalent Substitutions: Candidates holding a current CCRA, CCRC, or CPI designation can substitute 1,500 hours of professional experience. Completion of an accredited clinical research education program can also substitute 1,500 hours of experience.

Eligibility for the ACRP-Project Manager (ACRP-PM®)
All applicants seeking certification as an ACRP-Project Manager (ACRP-PM) must be actively certified with one of ACRP's flagship certifications (CCRC, CCRA, ACRP-CP, or CPI) to qualify.

What is a Clinical Project Manager?
A clinical project manager is a professional responsible for overseeing the planning, implementation, and execution of clinical trials or research projects. Their role involves coordinating various aspects of the project to ensure its successful completion within specified timelines, budget constraints, and regulatory requirements.

Applicants must attest to having earned 3,000 hours of employment performing the tasks outlined in the ACRP-PM DCO. If the applicant's experience falls within 120 hours of the requirement by the first day of the exam window, full consideration will be given towards eligibility.

Eligibility for the ACRP-Medical Device Professional (ACRP-MDP®)
All applicants seeking certification as an ACRP-Medical Device Professional (ACRP-MDP) must be actively certified with one of ACRP's flagship certifications (CCRC, CCRA, ACRP-CP, or CPI) to qualify.

What is a Medical Device Professional?
A medical device professional is an individual involved in various aspects of the development, manufacturing, regulation, sales, marketing, or use of medical devices. These professionals play critical roles in ensuring the safety, efficacy, quality, and proper functioning of medical devices used in healthcare settings.

Applicants must attest to having earned 3,000 hours of employment performing the tasks outlined in the ACRP-MDP DCO. If the applicant's experience falls within 120 hours of the requirement by the first day of the exam window, full consideration will be given towards eligibility.

NOTE: ACRP 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.

SUBSTITUTES FOR WORK EXPERIENCE
Some applicants may qualify for a substitute for work experience. Under no circumstance will an applicant be permitted to use more than one substitution for the same application.

ACRP Certifications (Option 1)
ACRP acknowledges that there is a shared knowledge base between ACRP-CP, CCRC, CCRA, and CPI certificants. Any candidate who is actively certified with ACRP at the time of application will earn a 1,500-hour substitute towards the required 3,000 hours of professional experience.

Clinical Research Education Program (Option 2)
ACRP considers applicants who have completed a clinical research educational program from an accredited institution will earn a 1,500-hour substitute of the required 3,000 hours of professional experience.

Clinical research education programs must be aligned with the topics found in the corresponding DCO and must have a valid third-party accreditation. Qualifying programs will provide applicants with knowledge that is equivalent to 1,500 hours of knowledge earned through employment. Program approval is at the discretion of ACRP.

APPLICATION PROCESS
Once an applicant has self-determined they meet the eligibility requirements, the application process can begin. To apply, candidates must:

- Log in to their ACRP account or create one at **acrpnet.org**
- Go to their account and click on My Profile
- Select the link on the right-hand side that says Apply for Certification

Applicants must submit a detailed resume, list their 3,000-hours of employment, and attest to the knowledge statement. Once all requirements are met, a button that says SUBMIT APPLICATION will appear. You must complete your submission by clicking this button and submitting payment. Any application that is not paid in full will not be received or reviewed by ACRP.

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 translated document.

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 ACRP to verify the candidate's academic and employment records.

FEES
The cost to apply includes application and exam fees, paid when the application is submitted. Credit cards (VISA, MasterCard, American Express), checks (including electronic checks), or bank transfers are acceptable forms of payment. The application fee is non-refundable regardless of eligibility status or cancellation. Submission of the application confirms your understanding and agreement. The table on the following page provides a breakdown of the fees.

ELIGIBILITY REVIEW
The eligibility review process is a random audit which includes determining completeness of the application and whether the applicant meets the eligibility criteria for the exam. Applicants should expect to receive an update on application status via email within ten business days after the application has been received.

Application and Exam Fees

SPRING 2024 REGISTRATION DATES		TESTING PERIOD	MEMBER	NON-MEMBER
Early Bird	10.15.2023 – 12.31.2023	2.15.2024 – 5.15.2024	$135 application + $300 exam	$135 application + $350 exam
Regular	1.1.2024 – 4.30.2024		$135 application + $325 exam	$200 application + $400 exam
FALL 2024 REGISTRATION DATES		**TESTING PERIOD**	**MEMBER**	**NON-MEMBER**
Early Bird	5.15.2024 – 7.15.2024	7.15.2024 – 10.15.2024	$135 application + $300 exam	$135 application + $350 exam
Regular	7.16.2024 – 9.30.2024		$135 application + $325 exam	$200 application + $400 exam
Retest			$300-$325	$350-$400
Transfer			$50	$50
Missed Appointment			$100	$100

Applicants will have seven business days to respond to any request for additional information froman eligibility reviewer. These requests will only come via email.

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

Upon conclusion of review, an applicant will be found to be eligible or ineligible. Eligible applicants will be emailed an eligibility notice with instructions on scheduling an exam appointment. Exam appointments can only be scheduled after eligibility is determined. Ineligible applicants automatically receive a second level review. Applicants are notified via email at each step of the review with an explanation of the deficiency identified. Each level of review can take up to seven business days. If after two reviews and the applicant is found Ineligible, a review will be conducted by the Certification Director and the applicant will be notified via email with the 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 ACRP Policy on Appeals.

CONFIDENTIALITY

Application for—and achievement of—certification is between ACRP 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.

PART III

PREPARATION

The exam is specific to the knowledge and tasks identified in the Detailed Content Outline (DCO). It requires a general working knowledge of the roles and responsibilities to perform in your role safely and effectively, with grounding in ICH Good Clinical Practice (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.

Candidates should 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.

DETAILED CONTENT OUTLINE (DCO)

The DCO is derived from an ACRP Job Analysis Survey, a careful description of the tasks performed by clinical research professionals. 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 as a clinical research professional.

ICH GUIDELINES

All ACRP Certification and Specialty exams are based on the following 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

ACRP-MDP examination only:

- ISO 14155:2011

ACRP's next update to the exam will be conducted in 2024. The 2025 examinations will reflect any updated ICH Guidelines at that time.

EXAM ABBREVIATION LIST

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

ADDITIONAL OPTIONAL SUPPORT

Various organizations offer exam preparation support and it's essential for candidates to ensure that the support aligns with the exam content. ACRP provides exam preparation materials that are sold as separate components or packages. Visit the **Exam Preparation** and **Exam Prep Packages** pages on the ACRP website.

DISCLAIMER

The Academy 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.

FURTHER STUDY TIPS

In addition to reviewing the 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 own 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, but do not focus on specific (i.e., FDA) regulations.

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.

TEST TAKING STRATEGIES

Most adults haven't taken a standardized exam recently. It can be helpful to be reminded of some key strategies for how to approach a multiple-choice exam:

- Read the entire question before you look at the possible answers.
- Come up with the correct answer in your head before looking at the possible answers; this way, the choices given on the test won't distract you from focusing on the question.
- Read all the choices before choosing your answer so that you select the one you feel is best.
- Eliminate answers you know are not correct.
- There is no guessing penalty, so it's always best to take an educated guess and select an answer if you are uncertain of the answer.
- Don't repeatedly change your answer; usually your first choice is the right one, unless you misread the question.
- Go through the exam and answer the questions you know first. Mark the others for review and then go back to those you skipped over. This will ensure that you don't lose time by focusing on questions where you are uncertain.

PART IV

TESTING PARTNER

ACRP partners with PSI, a trusted provider of technology-enabled testing, to administer its exams in over 150 countries, both remotely and in-person. ACRP exams are delivered in a computer-based format at PSI's in-person testing centers or via a live remote proctoring service. Candidates will select their delivery option at the time of scheduling. For the best testing experience, ACRP recommends testing at a testing center.

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

SCHEDULING

The exams are administered via a secure network of computer-based testing sites. Over 1,500 locations in more than 150 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 the **PSI website** and click on the 'Check for Available Dates' button. Candidates will need their ACRP Account information in order to schedule online. To schedule by phone, call the PSI Candidate Service Center at 1.800.211.2754.

CONFIRMING YOUR APPOINTMENT

It is the responsibility of a candidate to verify that they have been scheduled for the date, time, and place requested. Candidates will receive a reminder email 72 hours prior to testing. Be sure to add PSI as a safe sender to receive all communications.

RESCHEDULING YOUR APPOINTMENT

Candidates can make changes to their appointment up to 48 hours in advance.

If candidates need to reschedule or cancel an upcoming test, they will need to login to their account on the PSI website and navigate to the Manage Appointments section. To reschedule or cancel by phone, call the PSI Candidate Service Center at 1.800.211.2754.

APPOINTMENT ARRIVAL

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

IDENTIFICATION

To access an exam, candidates must present proper identification (ID) containing their legal name. Examples of proper ID include a passport, driver's license, or a 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 PSI). 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

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 any fees paid.

Please contact **ACRP Customer Care** to submit any name change request prior to scheduling.

EXAM SECURITY AND IN-PERSON TESTING GUIDELINES

Security is of the utmost importance to ACRP and our test vendor. 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. Breaks, such as using the restroom, are not permitted without a pre-approved accommodation.

- Conversation or any other form of communication among candidates is not permitted once you enter the examination area.
- Candidates are prohibited from reproducing, communicating, or transmitting any test content in any form for any purpose. Copying or communicating content is a violation of PSI security policy. Either one may result in the disqualification of examination results, may lead to legal action and will be reported to the Licensing Authority/Sponsor.
- Electronic and recording devices of any kind (including but not limited to cell phones, pagers, and cameras) are NOT permitted in PSI testing centers.
- NO personal items should be brought to the testing centers. PSI will not be responsible for any personal items and suggests leaving such items in another safe place of your choosing. Only non-programmable calculators that are silent, battery operated, and do not have paper tape printing capabilities or an alphabet keyboard will be allowed in the examination site.
- Candidates must present valid, unexpired, and acceptable ID(s) in order to take the test. Check the Candidate Information Bulletin or Licensing Authority/Sponsor for the specific rules that apply to each test.
- PSI requires all employees and test takers to conduct themselves in a professional and courteous manner at all times. Exhibiting abusive behavior towards a proctor or other candidates will be reported to the Licensing Authority/Sponsor and may result in criminal prosecution.
- Candidates must arrive at the testing center at least 30 minutes prior to the scheduled exam time.
- Persons not scheduled to take a test are not permitted to wait in the testing center or surrounding common areas.
- Candidates may not exit the building or use their cell phone or other electronic devices during the examination.

Access Additional Information and FAQs for In-Person Testing on the PSI Website.

EXAM SECURITY AND REMOTE TESTING GUIDELINES

ACRP also offers remote testing. Remote examinations are offered 24/7 during ACRP's spring and fall testing windows. The following requirements must be met in order to test remotely via PSI Web Delivery.

Remotely Proctored Exam:

- You MUST use a personal computer. Company issued computers generally are NOT compatible, even if they pass the system requirements test.
- If the candidate's sponsor allows Web Delivery as a testing modality, exams can be scheduled and taken from a home computer. Requirements include a web camera, speakers, microphone, and stable broadband internet connection. Please go through the compatibility check on the PSI scheduling website.
- If candidates need assistance during the exam, they should initiate a chat with the online test administrator using the Chat tool.
- No conversing or any other form of communication is permitted once the exam has been released.
- Candidates are prohibited from reproducing, communicating, or transmitting any test content in any form for any purpose. Copying or communicating content is a violation of PSI security policy. This may result in the disqualification of examination results, may lead to legal action, and will be reported to the Licensing Authority/Sponsor.
- With the exception of the home computer for testing purposes, electronic devices and recording devices of any kind (including but not limited to cell phones, pagers, and cameras) are NOT permitted.
- Candidates will be asked to scan the room from which they are testing prior to launching the exam. If there are notes, drinks, a box of tissues, or any such items, the candidate will be asked to remove them prior to starting the exam.

- Candidates must present valid, unexpired, and acceptable ID(s) in order to take your test. Check with Sponsor's or Licensing Authority/Sponsor for the specific rules that apply to your test. Military IDs are not accepted.
- PSI requires all employees and exam takers to conduct themselves in a professional and courteous manner at all times. Exhibiting abusive behavior towards a proctor via chat or other candidates will be reported to the Licensing Authority/Sponsor and may result in criminal prosecution.
- Candidates may connect with our Remote Proctors for testing up to 15 minutes prior to the scheduled start time. The launch button will be enabled when the exam is fully prepared for delivery.
- Candidates may not exit the camera view or use their cell phone or other electronic devices during the examination.
- Hands must be visible to the camera at all times. Talking or mouthing words while testing is prohibited.

Note: Individual Licensing Authority or Sponsor policies may supersede any of these regulations.

Access Additional Information and FAQs for Remote Testing on the **PSI Website**.

SPECIAL ACCOMODATIONS

ACRP 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. ACRP 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 PSI testing 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, candidates are required to check the designated box on the application and submit a **Special Accommodations Form**. This must be signed by a licensed health professional approving the request as accurate and reasonable. This form MUST be submitted at the time of application.

EXAM BREAKS

Breaks are NOT permitted without a pre-approved accommodation, as outlined in the Academy's Policy on Examination And Materials Security. Under no circumstance will candidates be allowed leave the testing room or camera view without pre-approval. Candidates who violate any of the established security measures will result in the immediate termination of their examination with a result of "fail". To request an accommodation, please review the Academy's Policy on Special Accommodations and **download the applicable form** to submit with your application.

RESOURCES

The following resources can be made available:

- On-screen abbreviations list
- On-screen calculator
- Noise canceling headset (test center exams only)
- White board and dry-erase markers (test center exams only)
- Two pieces of paper and two pens/pencils (remote exams only)

PART V

EXAM SCORING

The passing scaled score for the exam is 600. A candidate scoring below 600 has not been successful on the exam and will not be certified. The highest possible score is 800.

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." ACRP 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 scoring, please contact **ACRP Customer Care**.

EXAM RESULTS AND NOTIFICATION

The test result will be displayed at the end of the exam and the Score Report will be emailed to the address that was provided to PSI within 48 hours. An email address is a required field when scheduling online and by phone. You will receive official confirmation of your ACRP Certification status via email approximately three weeks after testing.

Candidates who pass the exam will have their ACRP account updated to reflect their certification status. A copy of the certification can be downloaded from the user's ACRP Profile. Certificates are not mailed. They will also have the option to opt-in to ACRP's Certification Registry so their certification status can be verified online. The Registry will be updated within 30 days following the close of the testing window and can be accessed **here**.

Candidates are not considered certified until official notification of certification status is received from ACRP.

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 any future exam. 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.

PART VI

RESCHEDULING AND CANCELLATION FEES

You can make changes to your appointment up to 48 hours in advance. **Fees apply** for appointment rescheduling or cancellations made within within three to 29 days prior to an appointment date and do not include transfer fees paid to ACRP. Cancellations made 30 days or more prior to the exam appointment are not subject to additional fees from PSI.

Rescheduling and cancellations are not permitted less than 48 hours prior to an appointment.

NO SHOWS AND MISSED EXAMS

If a candidate schedules an exam appointment and fails to take the exam, they will forfeit all fees. If a candidate arrives late for a scheduled exam appointment, they may not be allowed to test and, subsequently, will not be eligible for a refund. Missed appointments due to lateness are not eligible for a refund. If you missed your appointment due to unforeseen circumstances, and there is ample time left in the testing window, ACRP may be able to reset your eligibility for a $100 fee, allowing you to retest during the same testing period. **Contact ACRP** as soon as possible with the completed **Missed Appointment Form**.

RETESTING

ACRP offers its examinations each year during two testing windows. Candidates who do not achieve a passing score on the certification examination will only be allowed to retest during the next available examination period.

In cases where the gap between testing opportunities can potentially jeopardize a candidate's employment, ACRP will grant special consideration to individuals who formally seek a retest within the same testing window. To initiate such a request, candidates are required to submit a written appeal to the Director of Certification.

Candidates retesting during the immediate testing window after their initial examination need only cover the examination fee.

If the candidate is not successful on this retest examination, they will need to complete a new application and pay all fees in place at the time for any subsequent exams.

If a candidate chooses to transfer their first examination opportunity and, subsequently, does not pass, they will need to complete a new application, meet all eligibility criteria in effect at that time, and pay all fees in place at the time for any subsequent exams.

Candidates who do not achieve a passing score on their second attempt or who are unable to test again during the next examination period must submit a new application, together with all current fees, to continue their pursuit of certification. Such reapplications will be subject to all eligibility criteria in effect at that time.

REFUNDS

Refunds are issued to candidates who are ineligible or who request a cancellation. The application fee covers the cost associated with reviewing the application and is nonrefundable. The examination fee is fully refundable when the candidates has:

- not taken the examination and;
- provided a written request to ACRP and;
- cancelled their exam appointment with PSI more than 48 hours before the original appointment (if applicable)

No one other than the candidate may request a cancellation or refund. To receive a refund, the cancellation request must be received at least five calendar days BEFORE an exam appointment. Requests within five days of an exam appointment will not be honored. 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.

INELIGIBILITY
Ineligible applicants will receive a refund of the examination fee within three weeks of the final ineligibility notification.

TRANSFERS
ACRP offers a one-time transfer from the current exam window to the next for a $50 fee. There are two situations in which candidates may take advantage of this:

- If a candidate is determined ineligible for the current exam window, but will have met the eligibility requirements by the next exam window.
- If an eligible candidate withdraws from taking the original exam for any reason (up to 48 hours before a scheduled exam appointment).

Transfers are applied toward the next exam window 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 before the end of the exam window for which you had originally applied. To submit a transfer request, you must access your online application and select Request Exam Window Transfer. If you have an exam appointment scheduled, you must first cancel it directly with PSI before submitting your online request to transfer to the next exam window. 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. When a transfer request has been approved, all application and exam fees are applied automatically at the start of the next application period. All eligible tranfer candidates will receive an email Notice of Eligibility when the Eligibility ID has been reactivated and an exam appointment can be scheduled. Contact **ACRP Customer Care** 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 the **Academy's Policy on No Shows, Refunds, Cancellation, and Transfers**.

MAINTAINING YOUR CERTIFICATION
Maintenance of Certification is required every two years. Each candidate for Maintenance must demonstrate that the current requirements are met to successfully re-certify and be permitted to continue to use the designation.

There are two options for meeting the requirements prior to your Certification expiration date:

1. Earn 24 points and pay the maintenance fee
2. Pass the current Certification exam and pay the maintenance fee

See the **Maintenance of Certification Handbook** for information.

PART VII

ACRP CODE OF ETHICS AND PROFESSIONAL CONDUCT

The Association of Clinical Research Professionals (ACRP) is a US registered nonprofit, tax-exempt corporation that functions as a global association of clinical research professionals. ACRP's vision is that clinical research is performed ethically, responsibly, and professionally everywhere in the world. ACRP's mission is to promote excellence in clinical research. The Academy of Clinical Research Professionals (Academy) is a nonprofit, tax-exempt organization that advances and promotes the professional interests of clinical research professionals and provides certification for such professionals.

This Code of Ethics and Professional Conduct (the "Code") serves as a code of professional conduct for ACRP members and/or Academy Certificants. ACRP members and Academy Certificants are expected to adhere to this Code in all professional activities and relationships with each other, organizations where they work, research participants, and society in general. The core values of Integrity, Courage, Excellence, Dedication, and Collaboration are manifest in the ACRP Code. The Code also applies to individuals who seek membership in and/or certification by ACRP and the Academy.

This Code is a summary of what ACRP and the Academy define as essential ethical behavior for clinical research professionals. Compliance with the Code is a requirement for initial and continued ACRP membership and/or certification through the Academy. ACRP members and Academy Certificants affirm their endorsement of the Code and acknowledge their commitment to uphold its principles by joining and subsequently renewing their membership in ACRP and/or by applying for and maintaining certification from the Academy. Violations of the Code may result in sanctions imposed under the Discipline and Complaints Policy (the "Policy") adopted by ACRP and the Academy. This Policy was adopted to provide clarity of expected behavior and description of due process accorded to ACRP members and Academy Certificants necessary to protect the integrity, and ensure the efficacy, of the Code.

This Code is intended to be used by current and prospective ACRP members and Academy Certificants in conjunction with applicable national and international frameworks that govern the practice of clinical research, such as professional license requirements, ethical principles, guidelines, and laws and regulations applicable to clinical research, including, but not limited to, principles of the Declaration of Helsinki, Belmont Report, ICH GCP, US Codes of Federal Regulations, WHO "Ethical Standards and Procedures for Research with Human Beings," and UK Research Governance Framework.

The term "Clinical Research Professional" as used herein encompasses many job titles, disciplines, and duties within the profession of clinical research. For the purpose of this Code, the term shall include anyone involved in the design, conduct, reporting, review, and oversight of clinical research who is an ACRP member or Academy Certificant or applicant for membership or certification, and those who represent ACRP in any elected or volunteer capacity (e.g. Chapter President, Treasurer, etc. or volunteers to serve on a local or national committee, speakers at a conference or event).

Read the **ACRP Code of Ethics and Professional Conduct** for detailed information.

COMPLAINTS

Please review ACRP's **Discipline and Complaints Policy** before submitting a complaint regarding a potential violation of ACRP's Code of Ethics and Professional Conduct.

ACADEMY POLICY MANUAL

Download the **Academy Policy Manual** for comprehensive details regarding the specifics of ACRP Certification programs.