ACADEMY
POLICY MANUAL

ACRP

ACADEMY
OF CLINICAL RESEARCH PROFESSIONALS

ACADEMY POLICY MANUAL

Academy 2023 - 2025 Strategic Vision, Mission, Values, and Goals

VISION
Clinical research is performed responsibly, ethically, and professionally worldwide.

MISSION
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.

ORGANIZATIONAL VALUES
Professional Excellence. We exemplify a commitment to ethical practice by conducting our activities in a transparent, professional and responsible manner that promotes workforce excellence.

Integrity. We ensure fairness, accuracy, validity and reliability in the development and administration of the certification program to ensure it meets the highest standards as defined by experts in the field.

Service. We expect excellence, innovation, continual organizational review and improvement in delivering our programs to meet and exceed expectations.

Community and Collaboration. We work together with those whom we lead, serve, and partner with to promote competence and enhance the clinical research community.

STRATEGIC GOALS
The Academy will focus on maintaining the high standards of credentialing programs, enrich awareness of those programs, enhance competency for credentialed professionals in clinical research and sustain the organization's viability.

Goal 1. Continue to develop, maintain, and administer valid and reliable credentialing programs. **[focus on maintaining high standards]**

Goal 2. Promote greater recognition of the value of professionals credentialed by valid and reliable programs **[focus on enriching awareness]** to increase the reach of current certification offerings and expand the scope of credentialing programs for clinical research professionals **[focus on enhancing competency].**

Policy on Governing Authority

MISSION STATEMENT

The mission of Academy of Clinical Research Professionals (Academy) is to 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.

PURPOSE

The Academy of Clinical Research Professionals (Academy) is the separately incorporated certifying body of the Association of Clinical Research Professionals (ACRP). These two bodies share the same initials, but only the Association of Clinical Research Professionals uses the ACRP acronym. The Academy of Clinical Research Professionals, as the governing body of the certification programs, is consistently referred to by its full name or by "Academy" to distinguish it from ACRP.

The Academy serves as an independent and autonomous body with respect to the development, maintenance, and oversight of all certification program policies and procedures. The Academy is solely responsible for all important aspects of the certification program, including, without limitation: policy decisions regarding eligibility for certification; certification maintenance (recertification) standards; development, maintenance, and administration of examinations and other assessment instruments; and program operations. All certification program policies and procedures are developed and approved by the Academy's Board of Trustees and are reported for information to the ACRP Board.

The affairs of the Academy of Clinical Research Professionals shall be managed by its Board of Trustees (BOT). It shall be the Board of Trustees' duty to carry out the objectives and purposes of the Academy; to this end, the BOT may exercise all powers of the Academy, including those in furtherance of the administration of the Academy's certification programs, as described herein. Members of the Academy Board of Trustees (BOT) are selected to represent the diverse demographic characteristics, roles, and settings in which clinical research professionals practice.

The Academy works with contracted testing consultants to develop and administer the certification examinations. Testing consultants are selected for their extensive experience in the development and administration of professional certification examinations that comply with national accreditation standards for certification programs.

Development and maintenance of the Academy's certification examinations are based on Job Analysis Studies that are designed to ascertain, directly from practicing professionals, the frequency with which prerequisite knowledge is applied in practice and the importance or criticality of this knowledge. Content is added to the examinations only after it has been identified through this process and accepted by subject matter experts as required by the examination development policies in this manual.

The Academy is solely responsible for essential decisions related to the development, administration, and ongoing maintenance of the certification programs. The Academy's Board of Trustees ensures that all application and eligibility requirements, examination development and administration, recertification requirements, and all certification program policies and procedures are directly related to the purpose of the certification programs.

STRUCTURE

The Academy of Clinical Research Professionals is a 501(c)(6) not for profit corporation pursuant to the provisions of the Virginia Nonstock Corporation Act. The Academy of Clinical Research Professionals (Academy) is an independent affiliate of the Association of Clinical Research Professionals (ACRP) responsible for administration of certification exams.

The Academy of Clinical Research Professionals is the credentialing agency for the Association of Clinical Research Professionals (ACRP). More than 16,500 members in over 70 countries globally are working in a variety of clinical research practice settings and have taken the Academy's examinations over the past several decades.

The Academy shall be and remains an independent and autonomous entity with respect to all essential professional certification decisions, including eligibility standards, the development, administration, and scoring of assessment instruments, selection of personnel, and operational procedures. The Academy shall conduct its activities in accordance with the Academy of Clinical Research Professionals bylaws, the Master Service Agreement between the Academy and ACRP, and the Academy Policies and Procedures Manual.

AUTHORITY

The Board of Trustees has established eligibility pathways for clinical research certifications in recognition of the diversity in education and experience of qualified applicants. The Academy was established to promote the highest standards for clinical research professionals through the development, implementation, coordination, and evaluation of all aspects of the certification and the maintenance of certification processes and to enhance public protection. The Academy is an independent and autonomous organization unit with the sole authority to develop, evaluate, and administer its certification programs. Individual Trustees have no authority over certification program matters, except as authorized by action of the full Academy Board.

ROLES AND RESPONSIBILITIES

The Board of Trustees is solely responsible for all essential decisions related to the development, administration, scoring, and ongoing maintenance of the certification programs. While the BOT may delegate ongoing program operations to employees, and/or consultants, as needed, these areas of policy level decision-making responsibility may not be subcontracted to any other organization or entity. The certification decisions for which the Board of Trustees is responsible include:

A. Upholding the established mission and principles of the Academy's certification programs;
B. Establishing the policies for granting certification;
C. Establishing the policies for maintaining certification;
D. Establishing policies for suspending or withdrawing certification;
E. Developing, maintaining, administering, and scoring the certification examinations in consultation with a qualified testing consultant/qualified psychometrician and in a manner consistent with generally accepted psychometric practices to ensure that the examinations are both valid and reliable;
F. Exercising fiduciary oversight to ensure the effective management of the certification program operations within the approved budget and financial policies;
G. Providing oversight to examination development and other committees;

H. Attending BOT meetings and serving on committees and/or in roles as requested by the BOT Chair;
I. Monitoring, reviewing, and revising policies, procedures and corresponding materials related to the certification programs;
J. Reviewing and/or approving certification examination detailed test plans, pass/fail standards, appeal dispositions, and other essential certification decisions based on determinations and/or recommendations from testing experts and/or committees.

Annually, all Board of Trustees are required to sign a confidentiality/NDA agreement recognizing the roles and responsibilities for serving as a member of the Academy of Clinical Research Professionals.

LIMITATIONS
Authority
The authority of the Academy is limited to the authority granted in the Academy of Clinical Research Professionals bylaws, the Master Service Agreement between the Academy and ACRP, and the Academy Policies and Procedures Manual.

1. The Board of Trustees shall not develop, sponsor, accredit, approve, or endorse independent review courses or courses of study related to its certification examinations.
2. The Board of Trustees shall not create any new certification, terminate any existing credentials, or create any other business without the approval of the ACRP Board.
3. The Board of Trustees shall not take any action that may put the Academy at risk from legal action without prior full disclosure and the approval of the ACRP Board.

Compensation
The Board of Trustees will serve without compensation or other remuneration. No Board of Trustee will derive any personal profit or gain from his or her participation in the Academy.

Policy on Financial Management

RESOURCES
The Academy will have sufficient and adequate financial resources to conduct effective certification and recertification program activities. To fulfill the mission and objectives of the Academy in the most effective and efficient manner, a detailed Master of Services Agreement with the Association of Clinical Research Professionals has been established. The Academy will be charged for basic services including Accounting and Financial support, Marketing and Communications support, General Administration support, and overall Executive Management support.

EXPENSE REIMBURSEMENT
The Board of Trustees and committee members will be reimbursed for reasonable travel expenses related to attendance at official, required meetings according to the ACRP Corporate Travel Policy which has been adopted by the Academy. This includes expenses such as coach class, roundtrip airfare (or mileage at the currently reimburse rate); ground transportation; lodging; parking; and reasonable meal expenses and gratuities for required meeting and other travel. Board of Trustees and committee members are expensed to utilize the lowest cost travel arrangements available within reasonable limits.

BUDGET

The ACRP Executive Director will prepare a draft budget for Board of Trustees review and approval that provides adequate financial resources to conduct effective certification and recertification activities.

The ACRP Executive Director will provide periodic financial reports to the Board of Trustees for the purpose of monitoring the budget and financial activities of the organization.

The fiscal year of the Academy is the same as the calendar year.

Policy on Disclosure and Management of Conflicts of Interest

PURPOSE

The Conflict-of-Interest Policy supports the expectation that volunteers and employees of the Association of Clinical Research Professionals (ACRP) and its affiliate organization —The Academy of Clinical Research Professionals (Academy) — must act at all times in the best interests of ACRP and not for personal or third-party gain or financial enrichment. Such personal or third-party gain is deemed a conflict of interest.

SCOPE

This policy applies to all volunteers and employees of ACRP and the Academy.

CONFLICT OF INTEREST DIRECTIVE

As an ACRP or Academy Volunteer or Employee, ACRP expects you will act as its fiduciary in all you do on its behalf, especially as to conflicts of interest that may arise during your tenure. To help you understand this fiduciary duty and to avoid even the appearance of any conflict of interest in your tenure with ACRP, we offer the following statement.

First and foremost, please understand that your fiduciary duty includes a duty of loyalty to ACRP/Academy and a duty to act with care in carrying out your ACRP responsibilities. This means that you cannot use your position to benefit yourself to the detriment of ACRP/Academy. You must set aside your personal interests and, as a Volunteer or Employee, act/make decisions on the basis of what's best for ACRP, not what's best for you. ACRP trusts you to do this. In practice, this means you must recognize when your personal/ professional interest and ACRP's interest are in conflict, advise the designated ACRP/Academy official(s) of that conflict, and abstain from voting or acting on the matter that involves the conflict.

You must also not take advantage of an opportunity that belongs to ACRP/Academy by exploiting it for yourself. And most importantly, you must never compete with ACRP/Academy, i.e., you must not take business or customers away from ACRP or take/use its trade secrets or other confidential information for your own personal/professional benefit.

In summary, as a Volunteer and Employee, keep ACRP's interests before your own, act and make decisions in good faith, i.e., fully informed, and with due consideration for the impact of the decision on ACRP/Academy. In doing so, you will likely avoid any difficulty with possible conflicts of interest.

DEFINITIONS
A Conflict of Interest is a transaction or relationship which presents or may present a conflict between a Board member's fiduciary obligation to ACRP/Academy and the Board member's personal, professional, business, or other interests.

Examples of Potential Conflicts of Interest (examples are not all inclusive):

1) You serve on either ACRP's or the Academy's Board of Trustees and also serve on the board of another organization that directly competes with ACRP in the areas of education, training, or certification.

2) You work or consult for a company engaged in the development of marketed educational/training materials or services that directly compete with ACRP.

3) You have a financial/personal interest in an organization with which ACRP/Academy does business and could, therefore, be perceived to be in a position to influence relevant business decisions.

4) ACRP is planning to engage a consultant and you lobby for your relative's company to be awarded the contract.

5) You serve on an advisory board or planning committee for an organization that holds conferences/training sessions that directly compete with ACRP.

6) You submit an abstract, conduct a workshop, or run a training session at a conference that directly competes with a scheduled ACRP event.

7) You present an <u>invited</u> lecture, workshop, or training session at a conference that directly competes with a scheduled ACRP event. Please discuss the specifics with the Executive Director prior to committing.

Finally, the existence of a conflict of interest may not prevent someone from participating in the Association's or its affiliates' programs. However, full disclosure of the relationship will openly identify any potential conflicts of interest which will require management as necessary.

CONFLICT OF INTEREST MANAGEMENT PROCESS
All ACRP/Academy Trustees, Committee Members, and Staff identified by the Executive Director must complete the Conflict-of-Interest Disclosure Form at the start of each calendar year. If a potential conflict of interest should arise after the disclosure form has been submitted, the Executive Director must be promptly notified (within 5 business days) and the nature/specifics of the conflict of interest should be submitted in writing within ten (10) business days.

When a potential conflict of interest is discovered or disclosed the following steps will be taken:
1. The Executive Director will refer it to the Governance Committee if an ACRP conflict or the Academy Board Chair if an Academy conflict.
2. The Governance Committee/Academy Board Chair will collect and consider facts and information surrounding the conflict of interest as needed.

3. After the Governance Committee/Academy Board Chair has fully reviewed and discussed the facts and information about the conflict of interest, it will provide a report and/or a recommended management plan to the ACRP or Academy Board of Trustees as appropriate unless the conflict of interest is determined to be inconsequential.
4. The ACRP or Academy Board of Trustees as appropriate must approve any management plan for the conflict of interest.
5. If time does not allow for the above steps, the Executive Director will share the conflict of interest with the ACRP Board Chair and the Governance Committee Chair or the Academy Board Chair as appropriate to determine any immediate action that must be taken and report it to the appropriate Board of Trustees no later than their next meeting.

Policy on Non-Discrimination

PURPOSE
To state the ACRP policy against discrimination of members, certificants, and applicants for membership or certification.

SCOPE
This policy is applicable to ACRP and its affiliate, the Academy of Clinical Research Professionals.

POLICY
ACRP and the Academy shall not discriminate against any member, certificant, or individual applying for membership or certification based on gender, race, color, national origin, sex, age, religion, marital status, sexual orientation, political affiliation, citizenship status, physical challenge, disability, veteran status or any other status or condition that is protected by applicable law.

Policy on Certification Exam Development

PURPOSE
To establish the procedures for developing and maintaining the certification examinations in a manner consistent with generally accepted psychometric principles to protect the integrity of the certification examinations.

SCOPE
The certification examinations are developed by the Global Examination Committees, one for each certification offered, with the oversight and approval of the Academy Board of Trustees and with qualified psychometric consultation. Subject Matter Experts (SMEs) drawn from a wide variety of practice backgrounds and geographical areas, are enlisted to write and review examination items. The Board of Trustees is ultimately responsible for determining the detailed content outline and the examination specifications, setting the passing score for successful achievement, and establishing eligibility requirements for taking the examination. The Board of Trustees also oversees selection of a testing vendor to provide examination development, analysis, item banking, and test delivery. The Global Exam Committees, in consult with testing vendor/psychometric consultant review and approve the exam items and assemble and approve each form of the exam.

Recruitment of Subject Matter Experts

The Director of Certification has the duty of recruiting Subject Matter Experts (SMEs) as required, aligning with the Academy's present and future needs. Tactful recruitment campaigns will be developed to guarantee the SMEs are representative of the population they are serving. The Academy will ensure that all SME selections are drawn from the latest query of active certificants in the database.

Qualifications for Subject Matter Experts

Subject Matter Experts (SMEs) are drawn from a wide variety of practice backgrounds and geographical areas. All SMEs must be currently certified in the designation for which they are representing and must participate in item writing training.

Item Writers & Training

The Director of Certification will ensure that item writer training is held annually with ACRP's testing partner, to develop well-trained item writers for the Academy. Individuals who complete the item writer training will be added to the Academy's item writer repository for future exam development needs and SME recruitment. Assignments will be issued to "item writers" by the Global Exam Committees based on the needs of each program.

Item Development and Maintenance

The Global Exam Committees will review all item and exam analysis reports and recommendations provided by the test vendor at least annually. Reports will include recommendations for resolving any issues identified during the analysis.

The Global Exam Committees will conduct item writing workshops as needed to ensure sufficient item bank size for the development of new test forms.

Before being administered in an exam, items will be reviewed by the appropriate Global Exam Committee for clarity, content accuracy, bias, and sensitivity. All items appearing on certification exams as scored items will first have been pre-tested.

The Global Exam Committees will work to maintain a sufficient number of usable items in the item bank to ensure that new exam forms can be created in accordance with this policy.

Retired items may be published as sample exam questions for candidates.

Creation of New Exam Forms:

Multiple exam forms will be developed to ensure adequate exam security.

All exam forms will include a block of pre-test questions.

The following are the conditions which will determine when a new form of a particular exam is created:

1. Following a job analysis and creation of a new detailed content outline
2. Changes in the regulations/guidelines that govern the conduct of clinical trials
3. The volume of candidates warrants the creation of a new form according to the following schedule:
    a. Over 100 candidates a new form is created for each offering
    b. From 50 to 100 candidates in a given year, one new form each year
    c. Under 50 candidates in a given year, the exact or modified form of the most recent form will be used

d. Under 50 candidates for a five-year interval, one new form will be created

Exam forms will be approved by the appropriate Global Exam Committee before administration.

Job Analysis

The Academy has determined, based on changes in the profession as reported by the Global Exam Committees and the Board, that a job analysis should be conducted every five - seven years. The job analysis will be conducted in consultation with a qualified psychometrician and in a manner consistent with generally accepted psychometric standards. Exam Specifications are based on the documented findings of the job analysis.

Exam Specifications

After completion of the job analysis, a report detailing the content of the proposed exam specifications, including the relative emphasis to be placed upon each content area and the total test length, will be developed with the test vendor/psychometric consultant. The final exam content outline will be approved by the Board and published and available to applicants and certificants.

Standard Setting

The Academy Board of Trustees will determine the examination passing point based on the recommendations of the test vendor/psychometric consultant, derived from an appropriate cut score study. The modified Angoff method is used for developing a passing point recommendation.

The Academy uses a criterion referenced passing point for all exams.

To ensure fairness for all exam applicants, consistency of the passing point between various forms of the exam will be assured through appropriate equating procedures.

Scores will be reported to candidates as a scaled score on a scale of 200 – 800. 600 will be the necessary scaled passing point.

Global Exam Committee Charge

MISSION

The mission of the Academy's Global Exam Committees is to uphold the integrity of the ACRP's certification programs by using psychometrically sound practices to develop examinations that meet the current test specifications as determined by the most recent Job Task Analysis (JTA).

PURPOSE AND SCOPE

The purpose of this policy is to establish guidelines for the ongoing development of the ACRP-CP®, CCRA®, CCRC®, and CPI® examinations, and applies to all exam committees of the Academy.

Responsibilities

These committees play a crucial role in the exam development process. To ensure the fairness, validity, and integrity of ACRP's examinations, exam committee members will use psychometric best practices to ensure the examinations effectively measure the knowledge, skills, and tasks as identified by ACRP's most recent JTA. Responsibilities typically include:

- Always maintaining the security and confidentiality of examination materials.

- Reviewing and approving items, ensuring each item: tests appropriate skill level; is linked to topics identified in the Exam Content Outline (ECO); has a viable reference; is keyed correctly; is appropriate for all segments of the candidate population in terms of context, setting, language, descriptions, and terminology; is free of bias or stereotyping.
- Developing a repository of items for inclusion on future examinations.
- Issuing assignments to Item Writers by reviewing the item bank and identifying underrepresented topics in the ECO.
- Reviewing and approving examination forms for administration to the candidate population.
- Reviewing and approving retired items to develop ACRP's practice exam item bank.
- Reviewing, revising, and evaluating draft items submitted by Item Writers/Subject Matter Experts for potential inclusion as pre-test items.
- Writing items as necessary for the examination; item references or rationales.
- Serving as a global ambassador to promote ACRP certification.

Committee Composition
- The committee will consist of at least five but not more than eight members.
- The committee will be comprised of subject matter experts (SME's) and include a chair, a vice chair, and a staff liaison.
- Committee members must hold the current certification for the committee they are serving on.
- The demographic makeup of committee members will be based on the relative demographics of exam candidates and shall include a proportionate representation.
  (Multiple representations may be satisfied by one or more committee members.)

Skills and Expertise
- Committee members must keep current with changes and trends in clinical research.
- Committee members must spend at least 50% of their professional time engaged in the practice of clinical research, and in the specialty area for the Global Exam Committee they represent.
- Committee members must be able to meet virtually up to three times per year.
- Committee members will be required to take the certification examination at least once a year.
- Committee members must complete item writer training and demonstrate a proven ability to write good test items.
- Due to the nature of the examination, committee members must have an above average understanding of ICH guidelines.

Roles
- The Chair is responsible for leadership and facilitating meetings and acting as the primary liaison with relevant stakeholders.
- In the absence of the Chair, the Vice Chair is responsible for leadership and facilitating the work of the committee.
- The Staff Liaison provides all necessary support to the Chair, Vice Chair, and all the committee members to facilitate the work of the committee, including setting up meetings and helping to prepare the materials.

Term
- Committee members will serve one, three-year term with an option to serve one additional sequential term of three years.

- Members may return to serving the committee, per the needs of the committee, after a one-year break in service.
- If a committee member has served two three-year terms, they may be appointed for an additional one-year term at the discretion of the Academy Board Chair if it serves the best interest of the program.

Limits
- Committee members will not participate in the development or delivery of any educational or training program designed or intended to prepare individuals to take the certification examinations offered by the Academy during their service or employment and for at least two years afterward.
- Committee members are restricted from taking the certification examination associated with their respective committees, for any purpose other than exam development, during their service or employment and for at least two years afterward.
- The Academy will take measures to prevent any individual or group from exerting undue or disproportionate influence.

Policy on Impartiality Regarding Training

The Academy of Clinical Research Professionals role is in developing and administering certification examinations to determine the qualifications of candidates for certification. The Academy does not require, provide, or endorse any specific study guides, training or review courses.

The Academy, Board of Trustees, certification staff members, certification committee members, and certification subject matter experts will not:
- have involvement in the creation, development, or delivery of examination review courses, preparatory materials, educational programs, or training programs that prepare candidates for the certification examination;
- participate in the development or determination of educational standards, guidelines, or curriculum; and/or
- approve, accredit, endorse, or recommend educational programs designed to prepare individuals for certification.

During their term(s) of service, Board of Trustees will not participate in the development or delivery of any educational program or training designed or intended to prepare individuals to take the certification examinations offered by the Academy.

Board of Trustees who participate in creating and/or reviewing content for the examinations, including serving as item writers and/or item reviewers, may be subject to additional restrictions as established in these policies and procedures.

Policy on Examination and Materials Security

PURPOSE
The Academy's test security policy is in place to maintain the integrity of its certification program, and to adhere to security best practices, in line with accreditation standards. The Academy, any contracted

vendor, test administrator, subject matter expert, candidate, and all testing personnel, are responsible for following procedures outlined in this policy. The Director of Certification is ultimately responsible for keeping the Academy's confidential material secure and ensuring adherence to the test security policy.

SCOPE

Confidential materials are defined as any information the Academy is required to keep confidential and includes: attorney-client communications and attorney work products; proprietary information such as raw or published results of the job analysis, test specifications; exam cut scores and cut score analyses; examination documents including all draft, active or retired items unless expressly removed from the item bank for other uses, draft exam forms, pre-test blocks and item analyses; applicant records including CVs and job descriptions submitted as part of their application, test scores; certificant records including maintenance application materials; disciplinary investigation materials; contracts and agreements; information discussed during executive session of the Board; and any other committee, board or working group, program-related materials not publicly released by the Academy Board of Trustees.

ACCESS CONTROL

All confidential materials will always be retained in a secure manner and disposed of in accordance with the Academy's record retention policy. Access to confidential materials will be limited to the applicant, ACRP staff assigned to work on behalf of the Academy, and volunteers who need to view the information. Academy volunteers are defined as Academy Board members, exam committee members, item writers, subject matter experts, cut score panelists, and any others who are provided with confidential information to review on behalf of the Academy. These individuals will sign a nondisclosure agreement affirming that they have read the Academy's confidentiality policy, before being granted access to any confidential information. Exam materials are held in a secure database, and backups are performed daily for electronically stored data by ACRP and the vendor.

Any information passed between the vendor and the Academy is transmitted using a secure file transfer protocol (SFTP) and passwords are always communicated separately from data transmission.

TEST ADMINISTRATORS

Test administrators or proctors must follow all directions and established procedures as outlined in the test requirement document. TA's will be trained in the proper procedures for administering exams and ensuring they meet all requirements outlined by the Academy. This includes candidate verification for exam entrance, monitoring the testing environment, and reporting any irregularities to the test sponsor.

EDUCATORS

Employees and volunteers who have any responsibility for developing, updating, or evaluating educational programs that are intended to prepare candidates for certification are strictly prohibited to have any access to confidential examination materials.

IDENTIFICATION

Candidates are required to provide the test administrator with identification that is: valid, photo-bearing, unexpired, and government issued to verify their identity. Candidate's first and last name must be an exact match to what the test sponsor and the test administrator have for admission.

MULTIPLE EXAM SECTIONS

Academy exams are divided into three sections: tutorial, examination, and survey. Under no circumstance will a candidate be permitted to return to a section once they have left that section, whether it is complete or not.

BREAKS

Breaks are solely permitted to candidates testing in a test-center based environment, who have pre-approved accommodations. The decision to mandate test center-based accommodations is consistent with NCCA standards on exam security, preventing any compromise of the examination process while accommodating the needs of candidates within the specified guidelines.

SECURITY VIOLATIONS

The Academy ensures that the contracted testing vendor has measures in place to prevent unauthorized access, hacking, or cheating. The following violations may result in the immediate termination of your examination.

- Creating a disturbance
- Giving or receiving help; using notes, papers, or other aids
- Attempting to take the exam for someone else
- Looking somewhere else other than the computer screen. Exam candidates should remain facing toward and looking at the screen during the duration of your exam, so that the proctors can properly monitor your exam session. (For remote proctored exams)
- Possession of communication, surveillance or recording device, including but not limited to cell phones, tablets, smart glasses, smart watches, mobile devices, etc., during the exam administration
- Attempting to share test questions or answers or other information contained in the exam (as such are the confidential information of the Academy); including sharing test questions subsequent to the exam
- Leaving the testing area without authorization. (These individuals will not be allowed to return to the testing room), and
- Accessing items stored in the personal belongings area before the completion of the exam
- Any third-party captured by the Proctor, including children and pets (for remote proctored exams).
- Receiving repeated warnings from the test administrator
- Taking a break or leaving the camera view without a preapproved accommodation

MONITORING AND SURVEILLANCE

The Academy will ensure that the testing vendor has measures in place to monitor the testing environment, including video surveillance (which shall be destroyed 90 days after the candidate has completed their exam).

- The Academy's examinations are reviewed annually by the Certification Director and vendor to address potential security threats.
- The Academy ensures that all technology partners have a procedure in place to address any breach of security. Any breach of security or violation will be reported to the Certification Director within two business days for investigation and/or correction as needed.

Policy on Quality Assurance

PURPOSE

The quality management policy is developed to improve overall certification program performance, promote continued quality monitoring and improvement, establish processes for identifying errors and initiating corrective and preventative actions, and to ensure preventive actions and other proactive measures.

POLICY DEVELOPMENT & MAINTENANCE

The Board of Trustees will regularly develop, evaluate, and update certification program policies to ensure relevance, accuracy, and ongoing conformity with accreditation requirements.

Changes to policies, including the addition or removal of policies, will be reviewed for compliance with relevant accreditation standards and generally accepted psychometric principles (if applicable) before the policy is approved. Any policy revisions, additions, or deletions identified as non-compliant will be subject to further review.

The Director of Certification is responsible for ensuring that the Board of Trustees develops, evaluates, revises, and updates policies and that all policies approved by the BOT are fully and consistently implemented.

The Director of Certification will notify the Board Chair regarding any required and/or recommended revisions to existing policies, the need to develop new policies, or the need to replace or remove existing policies.

PUBLISHED CANDIDATE INFORMATION

The Director of Certification will ensure the review, at least annually, of all published candidate information to confirm this information remains accurate, up-to-date, and consistent with Board of Trustee policies.

Published information includes, but is not limited to, candidate handbooks, recertification handbooks, application forms for certification and recertification, accommodation request forms, summary of certification activities (aggregate data), directory of certificants, and ACRP website content.

Findings of the review process will be presented to the respective departmental directors for corrective and preventative actions. A summary of the findings and corrective and preventative actions will be presented at the next regular meeting of the BOT.

APPLICATION PROCESSING

Applications and corresponding documentation are reviewed in a timely manner by Academy certification staff to ensure all eligibility requirements are fulfilled for the candidate to sit for the respective certification examination.

Applications, corresponding documentation, and fees are only valid for one (1) year after receipt by the Academy.

EXAMINATION DEVELOPMENT

The Board of Trustees is committed to providing the clinical research profession with certification exams of the highest quality, relevance, and accuracy. This commitment requires that the exam development process be highly detailed, time consuming, participatory, and consultative. The test development process employs many of the proven techniques considered as best practices in the industry.

The internal audit will focus on policies and procedures related to conducting the job/practice task analysis (survey development, data analysis), item development and review, exam form assembly and review, standard setting, technical review, and score reporting.

TEST SECURITY

The Director of Certification will be responsible for ensuring that exam content always remains secure. Secure test administrations are contracted to testing agencies; however, the Academy retains oversight and the sole responsibility for all contracted services.

The Board of Trustees will develop, implement, and periodically evaluate a full security program to ensure that:
- Test security issues are prevented, as much as possible, rather than discovered after the fact.
- Test information and material is stored in secure areas, with access limited to authorized individuals.
- Test Administrators/proctors are trustworthy, qualified, trained, and selected from individuals who do not have a vested interest in the outcome of examination results.
- Examination content is protected at all times.
- Possible confidentiality/security violations are investigated, with action taken and corrective and preventative protocols implemented.
- An ongoing system is in place for the prevention, monitoring, and investigation of test irregularities which includes a plan of action in case of violation.

TEST SECURITY INCIDENTS

The Director of Certification will ensure that Academy vendors/contractors consistently follow security protocols. As such, they will report any significant security incidents to the Board of Trustees in a timely manner for review, consideration, and corrective and preventable and action.

Annually, the Director of Certification will provide a summary report to the BOT of all security investigations, irregularities, corrective and preventable actions, and outcomes. This summary will be reviewed and explored for discernable patterns and opportunities to improve current processes.

The Board of Trustees requires all Academy applicants to sign a Non-Disclosure Agreement on the application forms and examination tutorial regarding the examination confidentiality policy and that that Academy reserves the right to make all final decisions about the validity of examination scores.

COMPLAINTS, DISCIPLINARY ACTIONS, & APPEALS

In addition to compliance with the disciplinary/complaints policy, the Director of Certification will present the Board of Trustees with an annual summary of disciplinary complaints, investigations, corrective and preventative actions, and outcomes. This summary will be reviewed and explored by the BOT, or a subcommittee of the BOT, for discernable patterns and opportunities to improve current processes.

RECORD RETENTION

The Director of Certification is responsible for ensuring records are maintained, stored, and disposed of in accordance with the BOT's Document Management Policy.

CONFIDENTIALITY & CONFLICT OF INTEREST

Ensure confidential information, as defined by the Board of Trustees, is maintained appropriately. Individuals with access to confidential information must have current, signed agreements, as per the Confidentiality Policy requirements.

Ensure individuals bound by the conflict-of-interest policy must have current, signed agreements, as per the Conflict-of-Interest Policy requirements.

FINANCIAL

The Academy ensures a full audit every other year and a review of the off years of its financial position by independent accountants at an outside firm.

TRAINING

Training of BOT members, Academy certification staff, examination panels, committees/subject matter experts are integral to the BOT's efforts to consistently implement policies and procedures and prevent error.

STANDARDS FOR CUSTOMER SERVICE

Customer service standards are an integral component of business that are usually defined in terms of accessibility, accuracy, appropriateness, excellence, and timeliness.

ACCESSIBILITY
- Applicants, candidates, and certificants should have easy access to Academy services.
- Documents may be submitted electronically or by mail.
- Inquiries may be submitted via telephone, email, or mail.
- Applicants have access to online certification program information.

ACCURACY
- The processes, policies, and service standards are clearly defined and will be accurately reflected in the content provided on the website and in the candidate handbook.
- Accurate information will be given, to the best of their ability, by certification program employees to potential applicants, candidates, and certificants in response to questions received via telephone, email, or mail.
- Certification program staff will develop tools to monitor and ensure the accuracy of candidates' and certificants' information in the database.

APPROPRIATENESS
- Certification program employees will work to ensure that the expectations of potential applicants, candidates, and certificants are met.
- Employees will uphold high quality standards as expected and set forth by the organization.
- Employees will maintain compliance with BOT policies and procedures.

TIMELINESS
- The Director of Certification will define and implement reasonable response times to certification inquiries and the processing of applications, notifications, and verifications.
- All applications for initial certification, recertification, and verification will be initially reviewed within a 14 business-day timeframe following receipt. Electronic submissions will be sent a receipt via email no later than five business days.
- Any missing or incomplete information in applications for initial certification or renewal will be communicated to the applicant via email, telephone, or mail as soon as noted by certification program staff.
- Phone coverage will be during normal business hours of 9:00 AM – 5:00 PM ET Monday through Friday, except holidays.
- The Director of Certification will work to resolve complaints within one to two weeks of receipt, except where other timelines are established by disciplinary, complaints, and request for reconsideration policies and procedures.
- Certification program staff will acknowledge receipt of correspondence via email, fax, or mail within five business days.

INTERNAL AUDIT

The Academy is committed to ongoing quality review and improvement to:
- Provide high quality services to Academy candidates and certificants;
- Promote public trust and confidence in the certification program;
- Maintain consistency with current national accreditation standards for certification programs;
- Ensure the success of the certification program; and
- Increase the legal defensibility of the certification program.

It is the responsibility of the Board of Trustees to establish policies and procedures for the certification programs, review, and update those policies and provide oversight to ensure the proper and consistent implementation of policies and procedures. The customer service standards, and performance against these standards, will be reviewed with employees on a regular basis.

Policy on Records Retention

PURPOSE

To establish an appropriate scope and timeframe, consistent with the Virginia Public Records Act (VPRA), for the retention, disposal, and destruction of records and documents related to the certification program and the Academy of Clinical Research Professionals (Academy).

SCOPE

This policy covers all records and documents related to the certification programs and the governance and administration of the Academy.

POLICY

The Academy shall maintain the official records of all candidates and certificants, as well as all corporate records for the Academy. The Academy's testing vendor shall maintain copies of candidate examination results for a minimum of ten (10) years. In order to protect the applicant, candidate, certificant, as well as

the Academy Board, no extraneous materials will be retained as part of candidate records. Any notations concerning a candidate's application are discoverable materials and shall be entered into the candidate's record in a formal manner (attached as a PDF or entered into the "Notes" section of the application review screen).

The Director of Certification shall be responsible for annually reviewing the record retention and disposal program. Records will be securely disposed of by appropriate means, including deletion or shredding, after they have been retained until the end of the required retention period. The method of shredding or deletion will be in accordance with approved secure document destruction practices to ensure the irreversible and confidential disposal of sensitive information.

This policy shall cover the following records:

Corporate Records. Incorporation documents and amendments, Bylaws, policies, other organizational documents, governing board and board committee minutes shall be retained permanently.

Tax Records. Filed state and federal tax returns/reports and supporting records, tax exemption determination letter and related correspondence, files related to tax audits shall be retained permanently.

Financial Records. Audited financial statements, attorney contingent liability letters shall be retained permanently.

Intellectual Property Records. Copyright and trademark registrations and samples of protected works shall be retained permanently.

Insurance and Contract/License Records. Vendor, hotel and service agreements, independent contractor agreements, consultant agreements, and all other agreements shall be retained during the term of the agreement and for three years after the termination, expiration, non-renewal of each agreement.

Exam Records. Job analysis documents, test specifications, detailed content outlines, score results files, exam performance reports, eligibility policies shall be retained permanently.

Applicant Files. Applicant records are stored electronically as part of the database. The applicant's contact details, actual application form, and any documents submitted in support of the application, correspondence with the applicant regarding any issues with the application and the response, official notifications of the applicant's status. Applicant files shall be retained for a minimum of five years.

Candidate Files. Applicant files become candidate files once the candidate has been notified of successful eligibility status. Candidate files are stored electronically as part of the database. In addition to the contents of the applicant file, candidate files include examination registrations and dates, pass/fail status, correspondence related to inability to test (no shows or transfers), and any requests and determination regarding Special Accommodations. Candidate files shall be retained permanently.

Certificant Files. Candidate files become the certificant files once an individual has successfully passed the exam and is granted certification status. In addition to the contents of candidate files, certificant files include the date certification became effective and when it expires. Certificant files shall also include applications for maintenance of certification and any subsequent approval or expiration dates. Certificant files shall be retained permanently.

Exceptions. Any exceptions to this policy must be authorized by the Academy Board of Trustees and documented appropriately.

Policy on Eligibility for the ACRP-Certified Professional (ACRP-CP) Program

POLICY

All applicants for the Certified Professional (ACRP-CP) program must meet all of the eligibility requirements stated in the *ACRP Certification Handbook* and on the application form itself in order to be approved to take the ACRP-CP examination.

Applicants are required to submit both
1) a copy of a current curriculum vitae (CV) or resume, and
2) a copy of job descriptions for each of those positions used to demonstrate eligibility with enough detail to sufficiently document and demonstrate achievement of the required minimum number of hours of employment performing the Eligibility Requirements of an ACRP-Certified Professional.

At least one of the ACRP-CP Eligibility Requirements as defined below, in addition to the Detailed Content Outline (DCO) must be met:
- **Planning** – protocol design, feasibility assessment, business operations (budgeting, contracting, billing compliance), site selection activities, regulatory document preparation, collection, and/or submission, site management activities, clinical operations role within site, academic medical centers or CROs.
- **Conducting** – conduct of clinical trials with participants.
- **Overseeing (Management, Administration)** – study site management (Site, CRO, Sponsor, monitoring activities (including in-house, central and remote monitoring), project management, quality control, quality assurance, data management, medical monitoring, safety monitoring (medical safety liaison, pharmacovigilance, IRB professional).

Applicants must document a cumulative, minimum of 3,000 hours of employment performing the eligibility requirement. If the applicant's experience is within 120 hours of the requirement, by the first day of the exam window, full consideration will be given toward eligibility.

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

Academic Qualifications in Clinical Research. The Academy considers applicants who have completed a clinical research degree program that is accredited by the Council for Higher Education Accreditation to have achieved a valid substitution for 1,500 hours (1 year) of professional experience for the CP exam.

If an applicant applies using an educational program as a substitute for 1,500 hours of work experience performing the Essential Duties, then the following information must be included on the applicant's CV and a copy of the degree must also be submitted:

- Name of school
- City and country in which the school is located
- Program title
- Name of organization that accredits the institution providing the program
- Dates attended (From-To)

The Academy reserves the right to verify any and all employment information submitted on an applicant's CV or job description at any time during the process of certification or thereafter. If an applicant is found to have falsified or misrepresented his/her documentation, it is grounds for revocation of eligibility and/or certification status.

Policy on Eligibility for the Certified Clinical Research Associate (CCRA) Program

POLICY

All applicants for the Certified Clinical Research Associate (CCRA) program must meet all the eligibility requirements stated in the *ACRP Certification Handbook* and on the application form itself in order to be approved to take the CCRA examination.

Applicants are required to submit both
1) a copy of a current curriculum vitae (CV) or resume and

2) a copy of job descriptions for each of those positions used to demonstrate eligibility with enough detail to sufficiently document and demonstrate achievement of the required minimum number of hours of employment performing the Essential Duties of a Certified Clinical Research Associate.

The CCRA Essential Duties are defined as:
- Verify that the research site investigator(s) and study personnel are conducting the study according to the clinical protocol, "Good Clinical Practices", and regulatory requirements to ensure protection and ethical treatment of human subjects;

- Ensure identification and reporting of safety issues, when applicable, from research site staff to the sponsor and the IRB/IEC;

- Perform monitoring activities per the monitoring plan (e.g. verification of source documents and eCRF/CRFs, site communications, follow up on data anomalies, etc.)

- Review accuracy and completeness of site records (i.e., essential documents, query resolution, and other data collection tools);

- Ensure accountability of Investigational Product and related supplies are performed, when appropriate;

- Ensure complete reporting and proper documentation of monitoring activities;

- Conduct routine monitoring visits (on site or remotely) independently from the investigative site study staff;

- Ensure the site is identifying issues and implementing corrective and preventive actions to ensure inspection readiness.

- Current Detailed Content Outline (DCO)

Applicants must document a cumulative, minimum of 3,000 hours of employment performing the Essential Duties. If the applicant's experience is within 120 hours of the requirement, by the first day of the exam window, full consideration will be given toward eligibility.

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

Academic Qualifications in Clinical Research. The Academy considers applicants who have completed a clinical research degree program that is accredited by the Council for Higher Education Accreditation to have achieved a valid substitution for 1,500 hours (1 year) of professional experience for the CRA exam.

If an applicant submits an application using an educational program as a substitute for 1,500 hours of work experience performing the Essential Duties, then the following information must be included on the applicant's CV and a copy of the degree must also be submitted:
- Name of school
- City and country in which the school is located
- Program title
- Name of organization that accredits the institution providing the program
- Dates attended (From-To)

The Academy reserves the right to verify any and all employment information submitted on an applicant's CV or job description at any time during the process of certification or thereafter. If an applicant is found to have falsified or misrepresented his/her documentation, it is grounds for revocation of eligibility and/or certification status.

Policy on Eligibility for the Certified Clinical Research Coordinator (CCRC) Program

POLICY
All applicants for the Certified Clinical Research Coordinator (CCRC) program must meet all the eligibility requirements stated in the *ACRP Certification Handbook* and on the application form itself in order to be approved to take the CCRC examination.

Applicants are required to submit both
3) a copy of a current curriculum vitae (CV) or resume and
4) a copy of job descriptions for each of those positions used to demonstrate eligibility with enough detail so as to sufficiently document and demonstrate achievement of the required minimum number of hours of employment performing the Essential Duties of a Certified Clinical Research Coordinator.

The CCRC Essential Duties are defined as:
- Report and document safety issues (e.g. adverse events;)
- Participate in the preparation or review of documents exchanged with the institutional review board (IRB);
- Participate in protocol review or study procedures planning;

- Participate in conducting subject visits;
- Collect accurate, verifiable data, source documents, and essential documents;
- Prepare for and participate in sponsor audits and/or regulatory inspections, if applicable;
- Participate in the informed consent process.
- Detailed Content Outline (DCO)

Applicants must document a cumulative, minimum of 3,000 hours of employment performing the Essential Duties. If the applicant's experience is within 120 hours of the requirement, by the first day of the exam window, full consideration will be given toward eligibility.

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

Academic Qualifications in Clinical Research. The Academy considers applicants who have completed a clinical research degree program that is accredited by the Council for Higher Education Accreditation to have achieved a valid substitution for 1,500 hours (one year) of professional experience for the CRC exam.

If an applicant applies using an educational program as a substitute for 1,500 hours of work experience performing the Essential Duties, then the following information must be included on the applicant's CV and a copy of the degree must also be submitted:

- Name of school
- City and country in which the school is located
- Program title
- Name of organization that accredits the institution providing the program
- Dates attended (From-To)

The Academy reserves the right to verify any and all employment information submitted on an applicant's CV or job description at any time during the process of certification or thereafter. If an applicant is found to have falsified or misrepresented his/her documentation, it is grounds for revocation of eligibility and/or certification status.

Policy on Eligibility for the Certified Principal Investigator (CPI) Program

POLICY

All applicants for the Certified Principal Investigator (CPI) program must meet all the eligibility requirements stated in the *ACRP Certification Handbook* and on the application form itself in order to be approved to take the CPI examination.

Applicants are required to submit documents, as outlined below, to demonstrate that he/she has served as a Principal Investigator for clinical trials for at least two years of the past five years with enough detail so as to sufficiently document and demonstrate achievement of the required minimum experience performing the Essential Duties of a Certified Principal Investigator.

The CPI Essential Duties are defined as:

- 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
- Detailed Content Outline (DCO)

Applicants must document his or her role as a Principal Investigator (PI) during at least two out of the most recent five years by submitting copies of at least one of the following documents for each of those two years.

Requirements	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 or Sub-Investigator who has served in a PI role, as documented below; current license required and must be submitted with application - 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.*

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

Academic Qualifications in Clinical Research. The Academy considers applicants who have completed a clinical research degree program that is accredited by the Council for Higher Education Accreditation to have achieved a valid substitution for 1,500 hours (one year) of professional experience for the PI exam.

If an applicant applies using an educational program as a substitute for 1,500 hours of work experience performing the Essential Duties, then the following information must be included on the applicant's CV and a copy of the degree must also be submitted:

- Name of school
- City and country in which the school is located
- Program title
- Name of organization that accredits the institution providing the program
- Dates attended (From-To)

The Academy reserves the right to verify any and all employment information submitted on an applicant's CV or job description at any time during the process of certification or thereafter. If an applicant is found to have falsified or misrepresented his/her documentation, it is grounds for revocation of eligibility and/or certification status.

Policy on Denial of Eligibility

All applicants who seek eligibility to take one of the Academy's certification exams, the Certified Clinical Research Coordinator (CCRC®), Certified Clinical Research Associate (CCRA®), the Certified Principal Investigator (CPI®), or the ACRP Certified Professional (ACRP-CP®) must satisfy the minimum eligibility requirements as outlined in the appropriate candidate handbook for each designation. Applicant eligibility is reviewed individually. Each applicant is automatically afforded review by three separate reviewers, if necessary, during the eligibility review process.

Eligibility for approval to take an Academy certification exam may be denied when any part of the application and/or disclosure statement is incomplete, illegible or does not contain the correct fees.

Eligibility for approval to take an Academy certification exam may also be denied when an application purporting to represent and demonstrate how the applicant meets the established eligibility requirements is found to be incomplete, and/or does not substantiate or properly demonstrate the applicant's achievement of the minimum eligibility requirements.

When any application for eligibility to take an Academy certification exam is denied, the applicant will be notified in writing, typically via email, and given seven (7) business days to correct and submit that which is necessary to properly complete the application process and verify minimum eligibility requirements as outlined in the Academy's certification handbooks.

If time permits and all documentation is in order, the candidate's application will be processed and eligibility granted for the examination window originally requested by the candidate. Should this process take the applicant within three (3) business days of the start of the examination window he/she requested, the candidate will be granted eligibility for the next available examination window.

Regardless of the items the candidate must supply, or the timeline in which materials are submitted, the candidate's application may only be transferred forward to the next examination window once, based on the examination window for which the candidate originally applied.

If the applicant cannot supply appropriate and sufficient eligibility documentation or an eligible candidate does not take the examination by the start of the next examination window, he/she will forfeit all fees. The applicant will need to reapply and submit all current fees in order to be considered again for eligibility.

Policy on Appeals

The Academy makes every attempt to make fair and accurate decisions based on the information provided by the applicants and certificants. An appeal procedure is available to those who wish to contest any adverse decision affecting his or her application or certification status. Any individual who does not file a request for an appeal within the required time limit shall waive the right to appeal.

The Academy will review appeals of adverse certification decisions from Academy certified individuals ("certificants") and applicants for Academy certification ("applicants").

Candidates are permitted to appeal an adverse certification decision on the grounds that the Academy did not properly apply specified certification eligibility criteria, or the decision was based on a factual error that affected the outcome. Adverse certification decisions include denial of eligibility for initial certification, denial of maintenance of certification, suspension of certification or revocation of certification.

No appeal may be taken from an adverse decision based on an individual's receipt of a failing score on an Academy certification examination absent extraordinary circumstances, as determined solely by the Academy. Individuals cannot appeal (1) the passing score, or actions taken in setting a passing score; (2) establishment of eligibility criteria; (3) individual test items; and (4) test content validity.

Privileged Information, including the nature, format, content, and results of examinations administered by the Academy are considered privileged information. Due to the importance of exam security and item banking, neither exam forms nor answer keys will be disclosed or made available for review by candidates or any other unauthorized third party.

Appeal Process
Upon receipt of notice of an adverse decision, the applicant or certificant has the option to submit a written notice of appeal to the Academy no more than fifteen days following notice of the adverse decision.

In the written appeal, the applicant or certificants shall detail the nature of the request for appeal and the specific facts and circumstances supporting the request, and all reasons why the action or decision should be changed or modified. The applicant or certificant must provide additional written, factual documentation to support his/her appeal. The applicant shall bear the burden of proving the adverse decision was based on erroneous factual determination. There is no appeal based on an incomplete application.

Applicants or certificants submitting a request for review to the Academy shall receive notification of the results within fifteen days of receipt of the request. Should the candidate not be satisfied with the decision rendered, the candidate may submit a written appeal to the Academy within fourteen days.

The Academy will review the appeal submission and accompanying documents and make a determination. Candidates will be notified of the Academy's decision within 45 days of receipt of the request. The Academy's decision is final.

This policy does not apply to certificants who have had their certification or recertification denied, suspended or revoked for fraud, misrepresentation, violation of testing procedures or other conduct in violation of the ACRP Uniform Code of Ethics and Professional Conduct. Such candidates may have their case processed through the appeal rights described in the Discipline and Complaints Policy.

Policy on No Shows, Refunds, Cancellation, and Transfers

POLICY

When an applicant is granted eligibility to take an Academy certification exam, that eligibility is granted for the exam period for which application was made. All eligible candidates are expected to schedule an exam appointment for, and take the examination during, the exam period for which eligibility was granted. The Academy does recognize that occasionally circumstances may prevent a candidate from testing in the originally scheduled exam period. Under certain circumstances, the Academy will grant eligibility for one additional exam period beyond the original period for which the candidate has applied. Eligibility will not be granted for an additional exam period in the event that the certification program eligibility requirements have changed from the most recent application period.

No Shows and Missed Appointments. 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 appointments due to lateness are not eligible for a refund.

Refunds will not be given for exams that are missed because a candidate was not able to locate the testing center or arrived late.

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 fee, allowing you to retest during the same testing period. Contact ACRP at certification@acrpnet.org as soon as possible with the completed Missed Exam Appointment Form.

Refunds. Exam Refunds are issued to candidates who are ineligible or candidates who request a cancellation. The application fee covers the cost associated with reviewing the application and therefore is nonrefundable. The examination fee is fully refundable granted 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 only, 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 fee. 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 48 hours 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 a Candidate choose to transfer to the next exam window for one of the two reasons above, they must submit a request to transfer before the end of the exam window for which they had originally applied. The candidate must cancel any previously scheduled appointments with the testing agency in order to take advantage of this option.

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 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 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 acrpnet.org/contact if you didn't 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*.*

No Testing Appointment Scheduled. If a candidate does not schedule an appointment for, or take, the exam in the original exam period for which he or she was approved, and the candidate does not request a transfer before the close of the original exam period for which he or she was approved, the candidate will not be refunded the exam fee. Candidates will need to 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.

Emergencies. If a candidate is unable to keep his or her exam appointment due to an emergency that arises within the 48 hours prior to his or her exam appointment, the candidate is required to notify ACRP and provide official documentation to the Academy in order to avoid forfeiting fees. This information must be received by the Academy within seven business days after the candidate's scheduled exam appointment. The following situations will be considered with documentation:

- Emergency room visit or hospitalization
- Severe medical condition requiring hospitalization (e.g., spouse, child/dependent, parent, grandparent, sibling)
- Death of an immediate family member (e.g., spouse, child/dependent, parent, grandparent, sibling)
- Jury duty
- Call to active military duty

Policy on Name Change

To avoid the potential for confusion or misrepresentation, a certificant should apply for and hold certification in his/her legal name.

An individual wishing to change his/her name on their eligibility notice, certificate, or database record may do so with proper legal documentation.

The Academy will make a name change only if the individual provides the following:
- Written request for name change (via email or letter)
- Copy of the legal document showing the name change (marriage certificate, divorce decree, court order, etc.)
- Copy of a current government issued identification showing new or former name

The above-named documents do not need to be notarized copies. Copies of these documents will be attached to the individual's electronic database record.

If a current certificant wishes a new certificate reflecting the name change, he/she must also submit the Duplicate Certificate Form and the appropriate fee.

Policy on Retesting

PURPOSE
The Academy's Policy on Retesting protects the security and integrity of ACRP examinations by preventing item over-exposure. It is the Academy's policy to maintain an adequate number of unique tests forms, update test items annually to reduce over exposure, and enforce a waiting period for candidates looking to retake the examination. The time between testing windows provides a sufficient amount of time for candidates to adequately prepare for their retest examination.

TESTING WINDOWS

The Academy 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, the Academy 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.

APPLICATION & FEES

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, he or she 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 his or her first examination opportunity and, subsequently, does not pass, he or she 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.

Policy on Special Accommodations

The Academy is committed to ensuring that qualified candidates with a disability are not deprived of the opportunity to take an ACRP examination by providing reasonable accommodations in accordance with the Americans with Disabilities Act (ADA).

A candidate requesting special accommodation must do so in writing by completing the *Request for Special Accommodations Form – Parts 1 and 2*, and the request must accompany a completed application for certification. The request must include proper documentation from a licensed professional or certified specialist who diagnosed the disability condition AND the specific accommodations being requested. Accommodation, if approved, will be provided at no additional charge.

The decision as to whether a medical condition that is not covered by the ADA is a "qualifying medical condition" is at the sole discretion of The Academy. All special accommodation forms and related documentation are confidential and will not be released without the written consent of the candidate.

Documentation Requirements. It is the responsibility of the candidate to ensure that all required forms and supporting documentation are submitted to the Academy. A request for special testing accommodation will not be reviewed until all documentation is received.

Required documentation includes:
- A completed Request for Special Accommodations form. This form consists of two sections—one to be completed by the candidate, and one to be completed by the healthcare professional.
- Evaluation of the candidate's disability, to be completed by the healthcare professional. Note: The healthcare professional must be a licensed or otherwise qualified practitioner whose credentials are appropriate to diagnose and evaluate the specific disability. Candidates requesting accommodations for learning disorders or mental disabilities must be diagnosed by a psychiatrist, psychologist, or other professional with a minimum of a Master's degree, with credentials recognized as competent to diagnose a mental disorder or learning disability.

Policy on Testing Experience Issues

POLICY

All the Academy's certification exams are administered via a network of computer-based testing centers. These centers are administered by the Academy's contracted testing partner and administer a wide variety of tests. Very rarely do any issues arise at the test center that may be perceived as having a negative effect on a candidate's performance. However, the Academy takes these issues very seriously.

For the Academy to be able to investigate any problems thoroughly, all issues must be reported to the Testing Center Administrator (TCA) before leaving the test center. Issues can be reported on the exam exit survey but must be brought to the attention of the TCA during the exam/before leaving the test center. Problems reported later than the day of testing will not be considered.

Technical Issues. The Academy expects a candidate to be responsible for immediately notifying the proctor at the testing center should the candidate believe there to be a technical problem with the computer or related equipment during their exam. It may be possible for the TCA to resolve the program and restart the candidate's exam or reschedule the candidate for later the same day.

Any complaints regarding technical issues should be reported immediately and must be reported to the Testing Center Administrator (TCA) before leaving the testing center. The candidate must also report the issue to the Academy the same day. If it is over a weekend, a voice mail or email message must be sent to the Academy on the same day the candidate is tested.

The Academy will investigate all reported technical issues and report back to the candidate within two weeks of receiving the report. Based on the results of the investigation of the reported issue, the Academy may choose to offer a subsequent opportunity to retest.

Disruptive Issues. Candidates should expect an environment suitable for testing but should also understand that they will be testing with other individuals who may be taking exams of varying length or requiring use of the keyboard. Noise cancelling headphones are available to each candidate, upon request, at the testing center.

Should there be a disruption that the candidate believes is affecting his or her performance on the exam, the situation should be reported to the TCA immediately. Should the candidate believe that his or her performance is hindered by the disruption, the candidate may choose to end the test and inform the TCA of the reason. The candidate must also report the issue to the Academy the same day. If it is over a

weekend, a voice mail or email message must be sent to the Academy on the same day the candidate is tested.

The Academy will investigate all reported disruption issues and report back to the candidate within two weeks of receiving the report. Based on the results of the investigation of the reported issue, the Academy may choose to offer a subsequent opportunity to retest.

Candidate requests for a review of the fairness or accuracy of an exam due to equipment or software failure, or disruptive conditions in a testing center, shall result in the Academy working with its testing vendor to review relevant incident or discrepancy reports, technical data, and analyses.

Exam Content. Candidates who have an issue with a particular test question are welcome to put their concerns in writing to the Academy. Such information will be shared with the appropriate exam committee. However, given the security of the exam, the candidate will not receive any response regarding the content of the question, the correct answer, or the rationale for the item.

Candidates are permitted to appeal the appropriateness of content on the exam through its *Policy on the Appeal of Denial of Eligibility* but cannot be granted access to test questions or an answer key.

Policy on Release of Certificant Information

Certification is a voluntary credentialing process with the goal of protecting the public. The purpose of certification is to assure the public that Academy certificants have met all eligibility criteria and mastered knowledge to perform the duties essential to their role in clinical trials safely and effectively.

Names of individuals holding Academy certifications, which have not opted out, shall be available to the public via the Academy's online Certification Registry or inquiry to Academy staff. This publicly available information shall be limited to confirming an individual is "currently certified" or individual is "not certified". No contact information or employer details will be released.

Any further details regarding an individual's certification status will only be released upon receipt of a signed released signed by the individual about whom information is being sought. Upon receipt of the signed release the Academy will release the following information only:

- Name of the individual
- Name of the certification program
- Initial certification date
- Certification expiration date
- Certification number

Confidential information that will not be released, even if a signed release is provided, includes names of candidates for certification; names of individuals who are not successful on the examination; and individual test scores.

Based on certification status, the following information will be released following receipt of a signed release form.

Never Certified: "Individual is not currently certified."

Applicant/Candidate for Certification: "Individual is not currently certified." No other information, including confirmation of the individual's status as an application or candidate, will be released.

Currently Certified: Name of the certification program (CCRC, etc.), Initial certification date, Certification expiration date, Certification number

Expired/Decertified: Name of the certification program (CCRC, etc.) Initial certification date, Certification expiration date, Certification number

Policy on Use of the Certification Mark

PURPOSE

The Academy will confer certification when a candidate has successfully completed all certification requirements, including passing the examination. The Academy will send an official certificate verifying certification status. Certificants are then authorized to use the credential on business cards, letterhead, directory listings, and other marketing materials (e.g. press releases). The Academy's credentials may be used as long as the certificant remains in good standing and keeps his or her certification valid through the maintenance of certification process.

The Academy of Clinical Research Professionals offers the following four programs to certify various job roles within the clinical research industry:
- Certified Clinical Research Associate (CCRA®)
- Certified Clinical Research Coordinator (CCRC®)
- Certified Principal Investigator (CPI®)
- ACRP-Certified Professional (ACRP-CP®)
- ACRP-Project Manager (ACRP-PM®)
- ACRP-Medical Device Professional (ACRP-MDP®)

PROPER USE OF CREDENTIALS

The Academy grants limited permission to individuals who have met all the certification eligibility criteria, passed the applicable exam(s), maintained certification per the Academy's maintenance requirements, and received notification of certification from the Academy to use the CCRA®, CCRC®, ACRP-CP®, CPI®, ACRP-PM®, or ACRP-MDP® designations.

Proper uses of the designations include:
- Jane J. Smith, CCRA®
- John R. Smith, CCRC®
- Jane D. Doe, ACRP-CP®
- John Doe, CPI®
- Jane Doe, CCRC®, ACRP-PM®
- John Doe, CPI®, ACRP-MDP®

CERTIFICATES

A non-transferable certificate shall be issued only to individuals found to meet all certification requirements. Each Academy certificant receives a certificate that includes:

- the certificant's name
- certification type
- date of initial certification
- expiration date **or** statement that the certification must be renewed

DIGITAL BADGES

A non-transferable digital badge shall be awarded only to individuals who have successfully met all the prescribed requirements for certification. These digital badges serve as a visual and verifiable representation of an individual's certified status, providing a convenient and portable way to showcase their achievements in the digital realm. They are designed to enhance recognition and facilitate easy verification of a certificant's credentials.

Digital badges will remain valid as long as the certificant complies with the maintenance requirements established by the Academy. Failure to do so may result in the expiration or revocation of the badge.

OWNERSHIP OF THE MARK AND LOGO

The certification mark and logo are the property of the Academy of Clinical Research Professionals. Permission to use the certification mark or logo is granted to credentialed persons at the discretion of the Board of Trustees, for permissible uses only. The CCRA®, CCRC®, ACRP-CP®, CPI®, ACRP-PM®, or ACRP-MDP® designations are registered trademarks in the United States, Canada, and India (CPI® only) and their use is protected by applicable trademark law.

AUTHORIZED USE OF THE MARKS

Limited permission allows only individuals who are currently in good standing with the Academy to use the designations as part of one's professional title.

Use of the CCRA®, CCRC®, ACRP-CP®, CPI®, ACRP-PM®, or ACRP-MDP® designations by individuals who are not currently in good standing with the Academy (e.g. have not been granted certification, have failed to properly maintain certification), is prohibited. Improper use of the designations or certification trademarks may result in disciplinary or legal action.

An Academy credential holder has the responsibility to report the unauthorized use, misuse, or other violation of this Policy to the Academy in a timely manner. This reporting responsibility includes any circumstance where the use of an Academy granted certification mark is related to an individual or organization that's not an Academy credential holder, or where a certification mark is used improperly by an Academy credential holder.

Suspected improper use of the CCRA®, CCRC®, ACRP-CP®, CPI®, ACRP-PM®, or ACRP-MDP® designations should be reported in writing via email to the Academy of Clinical Research Professionals at certification@acrpnet.org. A report of improper use must include a copy of the materials showing the misuse (i.e., copy of a CV, email signature line, business card, online profile, etc.). The complainant must include his or her name and contact details when lodging a complaint. However, such information will be held as confidential.

Within seven business days upon receipt of a report of suspected misuse, the Academy will verify the certification status of the individual reported to have been misusing the designation. If the individual is currently in good standing with the Academy, the complainant will be notified as such.

If the individual purportedly misusing the designation is not currently certified in good standing with the Academy, the Academy shall contact the individual through a written letter, via a traceable method.

The letter shall inquire regarding the use of credential and a request made that the respondent forward any evidence of current certification (copy of certificate or award of certification letter) to the Academy within 15 days of receipt of the notification. The respondent may also reply acknowledging the improper use with evidence that corrective action has been taken (i.e., removal of the designation from business cards, website, CV, etc.) or with an application to take the appropriate examination to achieve the designation.

If no response is received within the stipulated time frame, the Academy shall then request legal counsel to send a cease-and-desist letter to the individual, demanding a response and applicable mandatory corrective action.

If the individual is a current ACRP member, a copy of the cease-and-desist letter shall be forwarded to the ACRP Ethics Committee for review regarding possible further action. The ACRP Ethics Committee will coordinate its review in accordance with the ACRP Discipline and Complaints Policy.

If the individual is not a current ACRP member and does not respond to the letter from legal counsel, the Board of Trustees shall receive notice of the failure to respond to legal counsel to determine what further action is warranted.

Policy on Continuing Competency and Maintenance for the CCRC, CCRA, and ACRP-CP Programs

POLICY
The goal of the Certification process is to ensure, as much as possible, the continuing competence of each certificant and maintain the professional standard of those engaged in clinical research. There are a number of professional activities that can contribute to that goal.

The purpose of the Continuing Competency requirements established by the Academy are that CCRCs, CCRAs, and CPs continue to:
- obtain current professional development information;
- explore new knowledge in specific content areas;
- master new clinical research-related skills and techniques;
- enhance approaches to effective clinical research, both within their specified job role and beyond;
- further develop professional judgment;
- conduct clinical research in a safe and ethical manner.

The Academy expects that clinical research professionals will engage in lifelong development to maintain and improve knowledge and skills for competent practice. This includes continuous self-assessment to identify professional strengths and learning needs, establishment of short- and long-term goals for

individual professional development, and selection of appropriate professional development to meet these goals.

Candidates for Maintenance should choose those professional development activities that provide them with the most benefit, keeping in mind that the length and rigor of a program contribute to its value. Planning for Professional Development enables candidates to choose more appropriate courses and to control expenses more effectively. Professional development programs provide one of the main methods for keeping up with professional practice.

Maintenance of Certification is required every two years. Each candidate for Maintenance must demonstrate that he/she meets the current requirements to successfully recertify and be permitted to continue to use the designation.

To successfully maintain Certification, each candidate must submit 24 points as part of the Maintenance application. At least 12 of those 24 points must come from participation in research-related professional development programs.

REPORTING PERIOD FOR POINTS

Applicable activities to satisfy the Maintenance requirements must fall within the appropriate timeframe for a candidate's maintenance period.

Certification Expiration Date	24 Month Reporting Period
May 31	June 1 (year 1) – May 15 (year 2)
November 30	December 1 (year 1) – November 15 (year 2)

PROFESSIONAL DEVELOPMENT PROGRAM TOPIC AREAS

Candidates for Maintenance can take professional development offerings in two areas:
- Research Topics
- Disease/Bodily System/other Healthcare Topics

RESEARCH PROGRAM TOPICS

For Maintenance purposes, Research Topics are defined those that cover the actual "practice" of clinical research and follow topics covered on the Detailed Content Outline (DCO) for your designation. These topics should cover transferable knowledge and skills, not those specific to your workplace, such as company SOPs or specific software. Examples of Research Topics include, but are not limited to:
- Trial Management
- Investigational Product Management
- Protocol Development
- Safety
- Human Subject Protection
- Document Management
- Trial Oversight
- Ethics
- Adverse Events
- Informed Consent

- Good Clinical Practice (GCP)
- ICH Guidelines
- Regulatory Issues
- Monitoring
- Statistics

DISEASE/BODILY SYSTEM/HEALTHCARE/OTHER PROGRAM TOPICS

Disease/Bodily System/Healthcare Topics are those that deal with the prevention, treatment, and management of illness and the preservation of physical well-being. Training to gain access or query a specific database or software, even if healthcare related, is not acceptable. Consideration is also given to specific skills that, while not clinical research or healthcare related, are acknowledged as an advanced set of skills invaluable to the work of clinical research. These specifically include project management, grant writing, medical writing, and soft skills.

Courses pertaining to a particular disease are generally considered to be Disease/Bodily System/Healthcare Topic hours. Examples include, but are not limited to:
- Pharmacology
- Medical devices
- Palliative / Hospice care
- Psychiatry
- Oncology
- Endocrinology
- Cystic Fibrosis
- Results of clinical trial studies
- Advanced Cardiac Life Support (ACLS)
- Project Management
- Soft Skills

For general participation in workshops, seminars, conferences and in-service training, points are awarded according to the actual amount of time spent under instruction at a ratio of 1:1. For instance, 45 – 60 minutes of instruction = one education point; one semester credit = 15 points.

Points are not awarded for sessions that are fewer than 45 minutes in length but can be prorated for sessions exceeding 60 minutes (i.e., a session one hour and fifteen minutes in length = 1.25 points)

All web-based training to be applied to the requirements must result in a certificate that indicates the number of hours awarded for successful completion. The Academy cannot determine the number of points for web-based training for a candidate. The Academy reserves the right to request certificates of attendance and/or transcripts from any and all courses.

Activity	Time Spent	Contact Hours	Points on *Maintenance* Application
Professional Development Session *(non-accredited programs)*	< 45 minutes 45-60 minutes 90 minutes	No points awarded 1 contact hour 1.5 contact hours	0 points 1 contact hour = 1 point 1.5 contact hour = 1.5 points
Activity Awarding CMEs	60 minutes	1 CME	1 CME = 1 point
Course Awarding CEUs	60 minutes	1 CEU	1 CEU = 1 point
University Course	1 semester	1 semester credit	1 semester credit = 15 points

ACCREDITED PROFESSIONAL DEVELOPMENT PROGRAMS

It is anticipated that most programs that a candidate for Maintenance of Certification will submit in support of his/her application will come from programs that have some sort of accreditation. If the program does not have accreditation from a known accrediting body, the applicant should submit the program for approval prior to submitting it as part of the Maintenance Application process.

EXAMPLES OF ACCEPTABLE PROVIDERS OF ACCREDITED PROFESSIONAL DEVELOPMENT CONTACT HOURS:

- ACRP
- All state and national nursing associations (e.g. ANCC, CBRN)
- Accreditation Council for Pharmacy Education (ACPE)
- Accreditation Council for Continuing Medical Education (ACCME) (e.g. CME and AMA Category I credits)
- Other national healthcare-related associations offering professional development contact hours
- College/university courses in healthcare and clinical research
- Regulator-sponsored educational programs
- In-company training on research topics with specific learning objectives awarding a certificate/proof of attendance and specifying the number of hours (SOP training is not acceptable.)

CONTINUING INVOLVEMENT

Continuing Involvement is another area in which a candidate for Maintenance can earn points toward the stated Maintenance requirements. These are activities other than attending a professional development educational activity.

Continuing Involvement Activities CCRC /CCRA/ ACRP-CP applicants may document **up to 12 points** in this category from activities listed below. These points **DO NOT** satisfy the required points form participation in research-related professional development programs				
Activity Name	**Points per activity**	**Maximum times it can be claimed**	**Maximum Points for this activity**	**Examples of Documentation**
Continuing Education developer or presenter in clinical research or related topic (to both research and non-research audiences)	2	4	8	Copy of program with speakers and objectives or presentation abstract including organization, location and dates (not required for ACRP Global Conference speakers)
Authorship of journal paper on clinical research (cannot be self-published)	2	4	8	Journal citation including authors
Participate in or present at investigator meeting (in-person or virtual)	2	2	4	Documentation of meeting date, time and proof of participation and/or presentation
Participate in a site initiation visit	2	2	4	Documentation of meeting date, time and proof of participation and/or presentation
Active participation in regulatory authority meeting (does not include an audit)	2	2	4	Proof of attendance
Involvement in a New Marketing Application process (specifically compiling a section or writing a clinical study report)	2	2	4	Supervisor documentation of specifically compiling a specific section or writing a clinical study report (signature page or supervisor letter confirming role)
Authorship of protocol	2	2	4	Supervisor documentation of role
Inclusion on a 1572 (or equivalent regulatory authority document) as active investigator or sub-I	2	2	4	Copy of 1572 (both sides) or equivalent regulatory authority document
Service as a peer reviewer for scientific articles	4	per 12 months of service	8	Confirmation of appointment as peer reviewer that includes dates
Service as a peer reviewer of clinical research-related papers or clinical research grants	4	per 12 months of service	8	Confirmation of appointment as a peer reviewer that includes dates
Service on DSMB/IDMC or equivalent	4	per 12 months of service	8	Letter from DSMB/IDMC chair outlining level of participation and # of meetings attended
Volunteer service on IRB/IEC	4	per 12 months of service	8	Letter from IRB/IEC chair outlining level of participation and # of meetings attended

Service on healthcare-related exam committee	4	per 12 months of service	8	Copy of certificate/proof of participation
Service as a clinical research exam item writing writer	0.50	per question submitted	12	Proof of participation
Service on an association's clinical research-related committee (Editorial Advisory Board, Conference Session Review, Regulatory Affairs Committee permitted) (Membership, Nominating or General board service is not permitted)	4	per 12 months of service	8	Proof of participation
Planning (ACRP-CP Only) Examples include business operations, feasibility assessment, site selection activities, regulatory document participation	2	4	8	Letter/Email from management confirming participation
Overseeing (ACRP-CP Only) Examples include management and administration	2	4	8	Letter/Email from management confirming participation

- Other activities may be approved on a case-by-case basis by the Academy Board.
- Presentation Development and Delivery: A single presentation can be claimed only once per year. The same presentation can be counted a second time the following year only if the presentation required significant updates prior to being presented again.
  - Certificants are permitted to include presentations they were paid to develop and present to the extent allowed by the above chart. Certificants cannot claim participation points for programs that they present.
- Authorship of an article pertaining to Clinical Research
  - Certificants are not required to be the primary author to be able to claim points for a published article.
  - Presentations and articles must be in clinical research-related topics in order to be considered for points.
  - An article must be published within the appropriate time frame for the current Maintenance cycle.

TAKING THE EXAM FOR MAINTENANCE

Taking and passing the current form of the exam for a specific designation's Maintenance is acceptable and satisfies all point requirements (all 24 points). The exam must be taken and passed BEFORE the candidate's Certification expires. A candidate must then submit a copy of their score report with their Maintenance application. This would include taking another Academy Certification exam to obtain an additional credential (i.e., a CCRC taking the CCRA exam to also achieve the CCRA designation.)

When being used for Maintenance, candidates are expected to apply for the exam, using the Examination for Maintenance Form in accordance with the regular exam window deadlines. Once they are successful on the exam, a candidate must then apply for Maintenance in accordance with the regular process and deadlines and submit a copy of his/her score report.

If a candidate wishes to use the exam for another Academy designation, as in the example above, for Maintenance he or she must still apply for and be deemed eligible for that program. In this instance, the Examination for Maintenance Form cannot be used.

If a candidate is unsuccessful on the examination, he or she may still submit the necessary 24 points to satisfy the Maintenance requirements.

NON-COMPLIANCE OF THE MAINTENANCE REQUIREMENTS
Candidates for Maintenance are expected to apply for Maintenance that fulfills all the necessary requirements no later than his/her certification expiration date. A candidate will be considered non-compliant if:

- no application for Maintenance was submitted;
- if the application submitted does not meet the stipulated requirements and the candidate has not rectified any deficiencies; or
- if randomly selected, the candidate has not satisfied the requirements of the Document Verification Process.

If compliance is not achieved within the stipulated timeframe, the candidate's certification will expire, and the designation will be permanently removed from his/her record. The individual must stop using the designation and/or representing him or herself as certified.

Once a candidate's certification has been removed from his/her record, the only way to regain use of the credential is to apply to the program as a candidate for initial certification and to take and pass the current form of the examination.

Policy on Continuing Competency and Maintenance for the CPI Program

POLICY
The goal of the Certification process is to ensure, as much as possible, the continuing competence of each certificant and maintain the professional standard of those engaged in clinical research. There are a number of professional activities that can contribute to that goal.

The purposes of the Continuing Competency requirements established by the Academy are that CPI's continue to:
- obtain current professional development information;
- explore new knowledge in specific content areas;
- master new clinical research-related skills and techniques;
- enhance approaches to effective clinical research, both within their specified job role and beyond;
- further develop professional judgment;

- conduct clinical research in a safe and ethical manner.

The Academy expects that clinical research professionals will engage in lifelong development to maintain and improve knowledge and skills for competent practice. This includes continuous self-assessment to identify professional strengths and learning needs, establishment of short- and long-term goals for individual professional development, and selection of appropriate professional development to meet these goals.

Candidates for Maintenance should choose those professional development activities that provide them with the most benefit, keeping in mind that the length and rigor of a program contribute to its value. Advance planning for Professional Development enables candidates to choose more appropriate courses and also to control expenses more effectively. Professional development programs provide one of the main methods for keeping up with professional practice.

Maintenance of Certification is required every two years. Each candidate for Maintenance must demonstrate that he/she meets the current requirements to successfully recertify and be permitted to continue to use the designation.

To successfully maintain Certification, each candidate for CPI Maintenance must submit 24 points as part of the Maintenance application. The point requirements are broken down below. At least 8 of those 24 points must come from participation in research-related professional development programs AND at least 12 of those 24 points must come from Continuing Involvement activities.

REPORTING PERIOD FOR POINTS
Applicable activities to satisfy the Maintenance requirements must fall within the appropriate timeframe for a candidate's maintenance period.

Certification Expiration Date	24 Month Reporting Period
May 31	June 1 (year 1) – May 15 (year 2)
November 30	December 1 (year 1) – November 15 (year 2)

PROFESSIONAL DEVELOPMENT PROGRAM TOPIC AREAS
Candidates for Maintenance can take professional development offerings in two areas:
- Research Topics
- Disease/Bodily System/other Healthcare Topics

RESEARCH PROGRAM TOPICS
For Maintenance purposes, Research Topics are defined those that cover the actual "practice" of clinical research and follow topics covered on the Detailed Content Outline (DCO) for your designation. These topics should cover transferable knowledge and skills, not those specific to your workplace, such as company SOPs or specific software. Examples of Research Topics include, but are not limited to:
- Trial Management
- Investigational Product Management
- Protocol Development
- Safety
- Human Subject Protection

- Document Management
- Trial Oversight
- Ethics
- Adverse Events
- Informed Consent
- Good Clinical Practice (GCP)
- ICH Guidelines
- Regulatory Issues
- Monitoring
- Statistics

DISEASE/BODILY SYSTEM/HEALTHCARE/OTHER PROGRAM TOPICS

Disease/Bodily System/Healthcare Topics are those that deal with the prevention, treatment, and management of illness and the preservation of physical well-being. Training to gain access or query a specific database or software, even if healthcare related, is not acceptable. Consideration is also given to specific skills that, while not clinical research or healthcare related, are acknowledged as an advanced set of skills invaluable to the work of clinical research. These specifically include: project management, grant writing, medical writing, and soft skills.

Courses pertaining to a particular disease are generally considered to be Disease/Bodily System/Healthcare Topic hours. Examples include, but are not limited to:
- Pharmacology
- Medical devices
- Palliative / Hospice care
- Psychiatry
- Oncology
- Endocrinology
- Cystic Fibrosis
- Results of clinical trial studies
- Advanced Cardiac Life Support (ACLS)
- Project Management
- Soft Skills

For general participation in workshops, seminars, conferences and in-service trainings, points are awarded according to the actual amount of time spent under instruction at a ratio of 1:1. For instance, 45 – 60 minutes of instruction = one education point; one semester credit = 15 points.

Points are not awarded for sessions that are fewer than 45 minutes in length but can be pro-rated for sessions exceeding 60 minutes (i.e., a session one hour and fifteen minutes in length = 1.25 points)

All web-based training to be applied to the requirements must result in a certificate that indicates the number of hours awarded for successful completion. The Academy cannot determine the number of points for web- based training for a candidate. The Academy reserves the right to request certificates of attendance and/or transcripts from any and all courses.

Activity	Time Spent	Contact Hours	Points on *Maintenance* Application
Professional Development Session *(non-accredited programs)*	< 45 minutes 45-60 minutes 90 minutes	No points awarded 1 contact hour 1.5 contact hours	0 points 1 contact hour = 1 point 1.5 contact hour = 1.5 points
Activity Awarding CMEs	60 minutes	1 CME	1 CME = 1 point
Course Awarding CEUs	60 minutes	1 CEU	1 CEU = 1 point
University Course	1 semester	1 semester credit	1 semester credit = 15 points

ACCREDITED PROFESSIONAL DEVELOPMENT PROGRAMS

It is anticipated that the majority of programs that a candidate for Maintenance of Certification will submit in support of his/her application will come from programs that have some sort of accreditation. If the program does not have accreditation from a known accrediting body, the applicant should submit the program for approval prior to submitting it as part of the Maintenance Application process.

EXAMPLES OF ACCEPTABLE PROVIDERS OF ACCREDITED PROFESSIONAL DEVELOPMENT CONTACT HOURS:

- ACRP
- All state and national nursing associations (e.g. ANCC, CBRN)
- Accreditation Council for Pharmacy Education (ACPE)
- Accreditation Council for Continuing Medical Education (ACCME) (e.g. CME and AMA Category I credits)
- Other national healthcare-related associations offering professional development contact hours
- College/university courses in healthcare and clinical research
- Regulator-sponsored educational programs
- In-company training on research topics with specific learning objectives awarding a certificate/proof of attendance and specifying the number of hours (SOP training is not acceptable.)

CONTINUING INVOLVEMENT

Continuing Involvement is another area in which a candidate for Maintenance can earn points toward the stated Maintenance requirements. These are activities other than attending a professional development educational activity.

Continuing Involvement Activities All applicants MUST document 12 points in this category from activities listed below				
Activity Name	**Points per activity**	**Maximum times it can be claimed**	**Maximum points for this activity**	**Examples of Documentation**
Continuing Education developer or presenter in clinical research or related topic (to both research and non-research audiences)	2	4	8	Copy of program with speakers and objectives or presentation abstract including organization, location and dates (not required for ACRP Global Conference speakers)
Participate in or present at investigator meeting (in-person or virtual)	2	2	4	Documentation of meeting date, time and proof of participation and/or presentation
Participate in a site initiation visit	2	2	4	Documentation of meeting date, time and proof of participation and/or presentation
Participate in close out visit	1	3	3	Report signature page
Active participation in regulatory authority meeting (does not include an audit)	2	2	4	Proof of attendance
Authorship of journal paper on clinical research (cannot be self-published)	2	4	8	Journal citation including authors
Authorship of journal paper on a therapeutic topic (cannot be self-published)	2	4	8	Journal citation including authors
Authorship of protocol	2	2	4	Supervisor documentation of role
Authorship/review of clinical study report (sole or co-authorship)	2	2	4	Report signature page that includes protocol # or study name
Inclusion on a 1572 (or equivalent regulatory authority document) as active investigator or sub-I	2	3	6	Copy of 1572 (both sides) or equivalent regulatory authority document
Medical Monitor for clinical research trial	1	3	3	Name listed on protocol title page (sponsor)
Clinical research compliance officer for institution	12	1	12	Copy of appointment letter
Director of research center	12	1	12	Copy of appointment letter
Involvement in a New Marketing Application process (specifically compiling a section or writing a clinical study report)	2	2	4	Supervisor documentation of specifically compiling a specific section or writing a clinical study report (signature page or supervisor letter confirming role)
Investigational New Drug or Device Application/Clinical Trial Exemption Application	2	2	4	Supervisor documentation of authoring the application (signature page; supervisor letter confirming role)

Service as a peer reviewer for scientific articles	4	per 12 months of service	8	Confirmation of appointment as peer reviewer that includes dates
Service as a peer reviewer of clinical research-related papers or clinical research grants	4	per 12 months of service	8	Confirmation of appointment as a peer reviewer that includes dates
Service on DSMB/IDMC or equivalent	4	per 12 months of service	8	Letter from DSMB/IDMC chair outlining level of participation and # of meetings attended
Volunteer service on IRB/IEC	4	per 12 months of service	8	Letter from IRB/IEC chair outlining level of participation and # of meetings attended
Service on healthcare-related exam committee	4	per 12 months of service	8	Copy of certificate/proof of participation
Service as a clinical research exam item writing writer	0.50	per question submitted	12	Proof of participation
Service on an association's clinical research-related committee (Editorial Advisory Board, Conference Session Review, Regulatory Affairs Committee permitted) (Membership, Nominating or General board service is not permitted)	4	per 12 months of service	8	Proof of participation

- Other activities may be approved on a case-by-case basis by the Academy Board.
- Presentation Development and Delivery: A single presentation can be claimed only once per year. The same presentation can be counted a second time the following year only if the presentation required significant updates prior to being presented again.
  - Certificants are permitted to include presentations they were paid to develop and present to the extent allowed by the above chart. Certificants cannot claim participation points for programs that they present.
- Authorship of an article pertaining to Clinical Research
  - Certificants are not required to be the primary author to be able to claim points for a published article.
  - Presentations and articles must be in clinical research-related topics in order to be considered for points.
  - An article must be published within the appropriate time frame for the current Maintenance cycle.

TAKING THE EXAM FOR MAINTENANCE

Taking and passing the current form of the exam for a specific designation's Maintenance is acceptable and satisfies all point requirements (all 24 points). The exam must be taken and passed BEFORE the candidate's Certification expires. A candidate must then submit a copy of their score report with their

Maintenance application. This would include taking another Academy Certification exam to obtain an additional credential (i.e., a CCRC taking the CCRA exam to also achieve the CCRA designation.)

When being used for Maintenance, candidates are expected to apply for the exam, using the Examination for Maintenance Form in accordance with the regular exam window deadlines. Once they are successful on the exam, a candidate must then apply for Maintenance in accordance with the regular process and deadlines and submit a copy of his/her score report.

If a candidate wishes to use the exam for another Academy designation, as in the example above, for Maintenance he or she must still apply for and be deemed eligible for that program. In this instance, the Examination for Maintenance Form cannot be used.

If a candidate is unsuccessful on the examination, he or she may still submit the necessary 24 points to satisfy the Maintenance requirements.

NON-COMPLIANCE OF THE MAINTENANCE REQUIREMENTS
Candidates for Maintenance are expected to submit an application for Maintenance that fulfills all the necessary requirements no later than his/her certification expiration date. A candidate will be considered non-compliant if:
- no application for Maintenance was submitted;
- if the application submitted does not meet the stipulated requirements and the candidate has not rectified any deficiencies; or
- if randomly selected, the candidate has not satisfied the requirements of the Document Verification Process.

If compliance is not achieved within the stipulated timeframe, the candidate's certification will expire, and the designation will be permanently removed from his/her record. The individual must stop using the designation and/or representing him or herself as certified.

Once a candidate's certification has been removed from his/her record, the only way to regain use of the credential is to apply to the program as a candidate for initial certification and to take and pass the current form of the examination.

Policy on Maintenance Applications for Global Exam Committee Members, Board Members, and Certified Staff

All members of the Academy's Global Exam Committees are required to hold a current Certification with the Academy. As part of the recognition of their service to the clinical research profession and the Academy through their service on a Global Exam Committee, members are awarded Continuing Education and Continuing Involvement points for participating in each meeting toward the fulfillment of their Certification Maintenance requirements.

In addition, the Academy also waives the Maintenance application fee for each Global Exam Committee member, Academy Board member, and certified ACRP staff members if that individual is due to maintain his/her Certification during a year of service on the Committee or employed as ACRP staff.

The Academy Board does require that each Committee, Board, and/or certified staff member apply for Maintenance of his/her Certification by the appropriate deadlines and demonstrate that he/she meets all

necessary Maintenance requirements. Failure to properly maintain his/her designation by the required deadlines will result in expiration of the designation.

Policy on Certification Reinstatement

POLICY

The goal of the maintenance of certification process is to ensure, as much as possible, the continuing competence of each certificant and maintain the professional standard of those engaged in clinical research. The Academy recognizes that circumstances may prevent one from meeting maintenance requirements. As such, an individual may apply for reinstatement.

An individual may request reinstatement of ACRP certification after voluntary relinquishment and/or failure to renew within two years of the most recent certification expiration date. A reinstatement application must be submitted with a non-refundable reinstatement fee.

An individual may reactivate a lapsed certification by fulfilling one of the following requirements.

Option One:
- CCRA, CCRC, ACRP-CP: 24 hours of continuing education (minimum 12 research specific)
- CPI: 24 hours of continuing education (minimum four research and 12 continuing involvement)

Option Two:
Taking and passing the current form of the exam for a specific designation's reinstatement is acceptable and satisfies all point requirements (all 24 points).

If a candidate is unsuccessful on the examination, he or she must submit the necessary 24 points to satisfy the Reinstatement requirements. Upon review of the application, the candidate will be notified of their status within two weeks.

Policy on Maintenance Verification

To maintain the integrity of the Maintenance program, and to ensure compliance when recertifying, the Academy will randomly select up to 5% of the applicants in each Maintenance cycle for verification.

Any individual that applies to maintain their designation is eligible for selection to verify their application submission. The selection process is randomly generated for each application period, Spring and Fall. Candidates selected for verification will be notified informing them that they have been selected and requesting that all required information be submitted by a specified deadline.

To comply with the verification, a selected candidate will need to supply documentation to support all continuing education hours and continuing involvement points submitted on his/her application for Maintenance. Documentation should: prove the applicability of the content of the activities; confirm the candidate's participation in the activity; validate the dates/times of participation; and prove the activity occurred within the specified Maintenance cycle. Examples of acceptable documents for each activity can be found in the Maintenance Handbook for each designation.

If submitted hours/points cannot be sufficiently verified, the candidate will have the opportunity to substitute another activity. Upon successful verification of all claimed hours/points, the candidate will be successfully recertified for two years.

Failure to submit the necessary documentation to successfully complete the verification process within the stipulated timelines will result in denial of Maintenance of the candidate's Certification designation. To regain use of the credential, the candidate will have to reapply to take the exam as a candidate for initial Certification.

Academy Certification Forms
- ACRP Certification Reinstatement Application
- ACRP Maintenance by Examination Form
- Request for Special Accommodations Form
- Missed Certification Exam Appointment Form