



Candidate Handbook

CCRP[®] Certification Program

Purpose of the CCRP Certification Program Candidate Handbook

The purpose of this Candidate Handbook is to provide clinical research professionals with a guide for earning and maintaining the Certified Clinical Research Professional (CCRP) credential from the Society of Clinical Research Associates (SOCRA).

The Society of Clinical Research Associates (SOCRA)
5034 Thoroughbred Lane,
Brentwood, TN 37027 USA

Phone: 423.424.2814
Email: socra@parthenonmgmt.org Web: SOCRA.org

Version Date: 5/14/2026

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Overview

Introduction

The Certified Clinical Research Professional (CCRP®) certification program is governed by the SOCRA CCRP Certification Committee, which operates with complete authority regarding essential decisions related to certification to protect against undue influence that could compromise the integrity of the certification process. The certification committee operates for the benefit of the public and outside stakeholders such as government, regulatory agencies, academic research institutions, and industry.

The CCRP® Certification Examination is offered in various locations throughout the U.S. and Canada, as well as some international locations. Examinations are scheduled throughout the year. Please visit the certification page of the SOCRA website at www.SOCRA.org for information about exam application and scheduling.

Responsibility of the Candidate

It is the responsibility of each candidate to read and understand the contents of this handbook before applying for the CCRP certification examination. This handbook contains current information about the policies and procedures of the certification program, eligibility criteria, exam content outline, and the reference materials used to develop examinations. It is essential that each candidate keep this handbook readily available for reference until the entire certification process, including score reporting, is completed. **The 2025 Candidate Handbook supersedes all previous versions of this handbook.**

History/Background

The “Certified Clinical Research Associate” (CCRA) examination was successfully implemented in August of 1995. In January of 2000, the certification designation changed from “Certified Clinical Research Associate” (CCRA) to “Certified Clinical Research Professional” (CCRP®). The purpose of this change was to embrace the diversity of the candidate population, recognizing that all may have different job titles, but all are clinical research professionals (CRPs). The certification continues to reflect a common, strong foundation of knowledge and practice in research regulations and Good Clinical Practice (GCP).

Purpose

The purpose of the certification program is to provide an internationally accepted Certification Program for Clinical Research Professionals that defines a basic level of knowledge and experience for the conduct of clinical research as governed by the principles of good clinical practice by which certified clinical research professionals will be recognized by the medical research community. Those individuals so approved may use the designation, “Certified Clinical Research Professional” or “CCRP®.”

Scope/Standards of Practice

The standards upon which this certification program is based have been set forth by the certification committee to promote recognition and continuing excellence in the ethical conduct of clinical trials and to ensure the protection of human research subjects and the general public.

The Certified Clinical Research Professional Certification program was created to acknowledge a CRP’s knowledge, understanding, and application related to the conduct of clinical investigations involving humans in accordance with the International Council for Harmonisation (ICH) Guideline for Good Clinical Practice (E6R3), ICH Clinical Safety Data Management: Definitions and Standards for Expedited Reporting (E2A), the United States Code of Federal Regulations (CFR) and the ethical principles that guide clinical research consistent with the principles of the Nuremberg Code, the Belmont Report and the Declaration of Helsinki.

Accreditation

The SOCRA CCRP certification program is accredited by the National Commission for Certifying Agencies (NCCA). Accreditation status is granted for five years. NCCA is the standard-setting body of the Institute for Credentialing Excellence (I.C.E.) for professional certification programs. The *NCCA Standards for the Accreditation of Certification Programs* were developed to help ensure the health, welfare, and safety of the public. They highlight the essential elements of a high-quality program with accreditation awarded to certifications that meet all NCCA Standards.

Goals of Certification

Candidates for certification should possess an understanding of, and demonstrate an application of basic concepts of Good Clinical (Research) Practice, including:

- The Nuremberg Code
- The Belmont Report
- The Declaration of Helsinki
- 21 U.S. Code of Federal Regulations - Parts 11, 50, 56, 312, 812
- 45 U.S. Code of Federal Regulations - Part 46
- ICH Harmonised Guideline for Good Clinical Practice (E6R3), and
- ICH Clinical Safety Data Management: Definitions and Standards for Expedited Reporting (E2A)
- FDA Form 482: Notice of Inspection
- FDA Form 483: Inspectional Observations
- FDA Form 1572: Statement of the Investigator
- FDA Form 3454: Certification – Financial Interests and Arrangements of Clinical Investigators
- FDA Form 3455: Disclosure – Financial Interests and Arrangements of Clinical Investigators
- FDA Form 3500: For Voluntary Reporting of Adverse Events and Product Problems
- FDA Form 3500A: For Use by User-Facilities, Distributors, and Manufacturers for Mandatory Reporting

This credential is not intended for those professionals working exclusively under Good Laboratory Practice (GLP) and/or Good Manufacturing Practice (GMP) regulations.

FDA regulations and ICH guidelines constitute the scope of the certification program. Additionally, clinical research professionals are expected to adhere to national, state, local and provincial regulations and institutional policies.

CCRP® Certification

Examination Background Information

Clinical research professionals are guided by a common framework of regulations, guidelines and ethical principles, despite their varied backgrounds and job descriptions. The examination is designed to assess the candidate's ability to apply the basic concepts of Good Clinical Research Practice, as specified in the scope and standards of practice.

Earning the CCRP Certification

The CCRP® certification is awarded after two criteria are met:

1. successful application (includes meeting the Eligibility Criteria)
2. passing examination score

Individuals that meet these criteria earn the CCRP Certification and may use the “Certified Clinical Research Professional” and “CCRP” designations.

Examination Development

The CCRP® Certification Examination has been developed by clinical research professionals who have demonstrated expertise in the development, management, and administration of clinical trials. These clinical research subject matter experts (SMEs) have varying backgrounds and job descriptions that reflect the diversity of a clinical research professional's scope of activity. Examination questions are written and reviewed by committees of CCRP certified professionals. This is to ensure that item content is accurate and reflective of current practice. Prior to writing questions, all new committee members are trained in question writing best practices, which include avoiding unnecessarily long question stems, unclear question queries, and the use of sensitive content that may lead to bias in questions.

Newly written questions are assigned to a test committee for review. A subgroup of the committee first reviews and revises each question virtually. Next, the questions are reviewed, revised, and approved by the committee at either an in-person or virtual meeting. During this review, questions considered problematic are deleted. Only questions that are approved by the committee as being accurate and important to test are moved to the next step of the approval process. After committee approval, each question is given final approval by staff editors who standardize question style, format, and terminology; correct grammar; and eliminate ambiguity and technical flaws.

Once the process is complete, approved questions are made available for selection in future exams. All approved questions are reviewed periodically for accuracy, currency, and relevance. This review also includes any questions that have been previously used on an exam.

Question Format

The CCRP certification exam is composed of multiple-choice questions, each with one correct response. This is the most widely used format in the testing industry as it allows for greatest coverage of content within a specified amount of time. Most exam questions include a clinical stem that provides information about a scenario, with a question that asks candidates to analyze the scenario and apply their knowledge to determine the best answer from the options provided. Each question is followed by four response options, one of which is the correct answer. Part of the question review process is to ensure that the designated answer is clearly correct, uncontroversial, evidence-based, and that the other options are incorrect responses to the question. The other options (“distractors”) are designed to reflect plausible responses likely to be selected by less knowledgeable candidates.

Examination Format

The CCRP® certification exam includes 130 multiple choice questions: 100 scored and 30 unscored questions. The scored items determine if a candidate passes or fails the exam, while data collected on the unscored items is used to evaluate the psychometric soundness of each CCRP® test item to determine if it is a good item for use on future exams. Each question is weighted equally. The questions are formulated to be straight-forward and easily understood.

The certification examination is offered in the English language. Candidates have the option to take the exam at an approved Prometric testing center through computer-based testing (CBT) with in-person proctors, or on their own computer at home via ProProctor with live remote proctoring (LRP).

Examination Validation

The Certification Committee evaluates the results from statistical/psychometric evaluations and updates the exam as needed.

Certification Program Eligibility

Eligibility

SOCRA is not able to consider candidates who are unable to provide the supporting documentation requested regarding their clinical research experience.

Minimum Experience:

| | Minimum Work Experience | Minimum Education |
|-------------------|---|---|
| Category 1 | 2 years of full-time experience* as a Clinical Research Professional within the past five years <i>*Equal to 3,500 part-time hours</i> | not required |
| Category 2 | 1 year of full-time experience* as a Clinical Research Professional within the past two years <i>*Equal to 1,750 part-time hours</i> | Degree** in "Clinical Research" from an Associate, Undergraduate or Graduate Degree Program |
| Category 3 | 1 year of full-time experience* as a Clinical Research Professional within the past two years <i>*Equal to 1,750 part-time hours</i> | Undergraduate or Graduate Certificate** in "Clinical Research" AND Associate or bachelor's Degree in a science, health science, pharmacy or related field |

**see Clinical Research Degree/Certificate Requirements

Work Experience

To be considered for CCRP® certification, the candidate must be able to provide documentation of the minimum work experience as a clinical research professional, working with GCP guidelines under IRB/EC/REB approved (or specifically exempted) protocols. For more details, review the Definition of a Clinical Research Professional.

Clinical Research Degree/Certificate Requirements

Candidates who have completed educational degrees and certificate programs with a specific focus in clinical research management and related fields may qualify under eligibility categories 2 or 3. These paths were designed specifically for candidates who have completed programs developed to educate the student in clinical research operations, including Good Clinical Practice regulations and guidelines. Certification eligibility does not allow for substitution of coursework completed that is not a part of a curriculum in clinical research.

The course of study must be related to clinical research, designed to educate the student in clinical research regulations and operations, including ICH Good Clinical Practice regulations and guidance.

- Degree/Certificate issued by an accredited academic institution of higher learning (community college, college or university).
- Candidates must have successfully completed all program requirements and have been issued a degree prior to applying for certification.
- Certificate programs must include a minimum of 12 semester (credit) hours (or minimum of 144 credit hours)

Questions?

Any questions regarding the eligibility requirements should be directed to the SOCRA Administrative Office, certification@socra.org.

Job Task Analysis Overview

The aim of the Society of Clinical Research Associates (SOCRA) Certified Clinical Research Professional (CCRP) certification examination is to evaluate if eligible candidates have the requisite knowledge and skills to perform the job tasks that are critical for successful practice as a clinical research professional. To ensure that the SOCRA CCRP certification stays relevant and current, every five to seven years SOCRA conducts a Job Task Analysis (JTA) with current CCRPs to review and validate the job requirements for safe practice as a certified clinical research professional. The JTA was facilitated by a psychometrician with expertise in statistics specific to certification, licensure, and educational measurement, as well as certification program and examination development.

In 2024, SOCRA conducted the most recent JTA for the SOCRA Certified Clinical Research Professional program to identify the duties and tasks performed by clinical research professionals, and to update the Exam Outline which serves as the blueprint for the SOCRA CCRP examination. The first phase of this JTA involved a panel of clinical research subject matter experts (SME) meeting to review and update the purpose, job role, target audience, eligibility criteria, and requirements for certification as a CCRP. The SME panel then reviewed and updated the job tasks performed by clinical research professionals developed in 2017, and grouped them into three phases of research (Research Study Start-Up, Research Study Maintenance, and Research Study Closure) considered to be primary job duties for CCRPs. The updated tasks and phases were assembled into an updated CCRP Certification Exam Content Outline that would be further reviewed and validated during the next phase of the JTA. The SME panel that performed this first phase of the JTA was composed of nine (9) clinical research professionals from the United States, Canada, and the United Kingdom, serving as a representative sample of the total CCRP population.

During the second phase of the JTA, the 18 job tasks defined by the SME panel in phase 1 were assembled into an online survey and distributed to clinical research professionals who practice throughout the world. The survey asked respondents to rate the importance of each task on a five point scale ranging from “1. Not Important at all” to “5. Extremely Important” as it relates to successful job performance as a clinical research professional. Participants were also asked to rank the order of importance of each task, and estimate the frequency with which they perform each of the job tasks. The survey was sent to more than 50,000 clinical research professionals, with a total of 1,188 providing job task data and another 607 providing only demographic questions. While the response rate was low, the 1,188 useable responses provided more than enough statistical power for all analyses.

The final phase of the JTA involved another meeting with the original SME panel to review the results of the validation survey to establish a test blueprint for the CCRP certification examination. The psychometrician presented results from the validation survey and lead a discussion with the SME panel to determine the final weights of each task in the CCRP Exam Content Outline. Demographic data from the group of respondents to the 2024 JTA validation survey was largely similar to the demographic data from respondents to the 2017 JTA validation survey, with the panel deciding that the sample was representative of the population of clinical research professionals. The panel then reviewed seven write-in responses to a question asking, “Are there any tasks or activities performed by clinical research professionals that were not listed and that you feel are important to successful practice as a clinical research professional,” ultimately deciding that the responses were either not relevant for candidates newer to the profession, out of scope for clinical research professionals, or already covered in the CCRP Exam Content Outline.

The validation survey data confirmed the tasks defined by the SME panel to be important to the role of the clinical research professional, with the mean rating of all 18 tasks being considered “Important” or more, and 14 out of 18 tasks having a mean rating considered to be “Very Important” or more. This supported the inclusion of all 18 tasks in the final CCRP Certification Exam Content Outline.

The panel then reviewed the importance ratings of the job tasks, as well as the importance and percentage of time ratings of the three research phases to establish the final Exam Outline (a.k.a., test blueprint) for the CCRP certification examination. This data was utilized to establish the percentage “weight” and associated job tasks assigned to each research phase, resulting in the final Exam Outline for the CCRP Certification Exam. The detailed CCRP Examination Outline is available to help candidates prepare for the CCRP Certification Exam. It can be found starting on the next page of this Candidate Handbook, as well as on the SOCRA website (<https://www.socra.org/assets/Certification/2501.1-Major-Content-Outline-241007.pdf>).

CCRP Certification Exam

Examination Content

The CCRP® certification examination is organized into Three major content areas. The content outline is derived from the 2024 Job Task Analysis and Validation Survey. Over 4,000 clinical research professionals participated in the 2024 survey, validating the relevance and weighting of the exam content outline for the clinical research professional job role.

Three Content Areas and Percent of Scored Test Items (Range) in Each Area

This table shows the percent of scored test questions that are included in each major content area.

| Three Content Areas | Brief Description | Percent of Scored Test Items (Range) |
|--------------------------------------|--|--------------------------------------|
| Research Study Start-Up | Regulatory Requirements of IRB/IEC, sponsors and investigators related duties/task related to study start-up | 40% |
| Research Study Implementation | Regulatory Requirements of IRB/IEC, sponsors and investigators related duties/task related to conduct of the study | 50% |
| Research Study Closure | Regulatory Requirements of IRB/IEC, sponsors and investigators related duties/task related to study close out and record maintenance | 10% |

Detailed CCRP® Examination Outline

The CCRP certification examination content is arranged into three major content areas (listed below). The detailed examination outline is expanded to be more descriptive of the topics that are included within the major content areas of the exam. It is our hope that these descriptions will further assist you in your study process.

| MAJOR CONTENT AREA | TOPICS AREAS |
|---|---|
| 1. RESEARCH STUDY START-UP: 40% | |
| a. Coordinate the development of initial research study protocol | <p>Determine if a research study design involves human subjects Develop Standard Operating Procedures (SOPs) for sponsors, clinical investigators, and IRBs</p> <p>Coordinate the expedited review of research study protocol Coordinate the development of emergency use research study protocol</p> <p>Coordinate the development of a research study protocol involving vulnerable subjects</p> <p>Coordinate the development of a research study protocol involving investigational products (e.g., pharmaceutical, biologic or device)</p> |

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Detailed CCRP® Examination Outline (*continued*)

| MAJOR CONTENT AREA | TOPICS AREAS |
|--|---|
| <p>a. Coordinate the development of initial research study protocol</p> | <p>KNOWLEDGE OF:</p> <p>Roles and responsibilities of the sponsor, clinical investigator and IRB in determining the applicable regulatory pathway for a clinical study (e.g. IND, IDE)</p> <p>Ethical concepts with foundation in:</p> <ul style="list-style-type: none"> - Nuremberg Code - Belmont Report - Declaration of Helsinki <p>Roles and responsibilities of the sponsor, clinical investigator and IRB in determining the applicable regulatory pathway for a clinical study (e.g. IND, IDE)</p> <ul style="list-style-type: none"> - Development of Standard Operating Procedures (SOPs) for IRB/IECs, Sponsors and Clinical Research Sites <p>Roles and responsibilities of IRB/IEC review and approval of clinical studies including:</p> <ul style="list-style-type: none"> - Emergency use of a research product - Expedited Review clinical studies - Significant risk determination for medical device clinical studies <p>Development of protocols (including study design with consideration of methods to reduce bias, objectives, endpoints, data safety monitoring)</p> <ul style="list-style-type: none"> - Clinical trial phases (e.g. drug trials- phase 1, 2, 3 and medical devices- feasibility, pivotal) - Study design characteristics (e.g. Randomization and blinding) - Study objectives and purpose - Inclusion/exclusion criteria - Description of procedures - Statistical plan <p>Roles and responsibility for protection of human subjects including:</p> <ul style="list-style-type: none"> - Safeguards for children in clinical trials - Protection of vulnerable subjects - Emergency Use Research |
| <p>b. Create or obtain research study documents (e.g., informed consent, essential documents, case report forms, financial disclosure statements)</p> | <p>Develop informed consent & informed assent documents</p> <p>Obtain financial disclosure from clinical investigators and sub investigators</p> <p>Develop case report forms</p> <p>Preparing a delegation log</p> <p>Identify the need to develop and submit an IND/IDE</p> <p>Obtain clinical investigator agreements for device trials</p> <p>Develop regulatory documents (i.e. essential documents)</p> |

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Detailed CCRP® Examination Outline (continued)

| MAJOR CONTENT AREA | TOPICS AREAS |
|--|--|
| <p>b. Create or obtain research study documents (e.g., informed consent, essential documents, case report forms, financial disclosure statements)</p> | <p>KNOWLEDGE OF:</p> <p>Informed consent/assent process including development, content, review, approval</p> <p>Submission (obtain approval) of informed consent documents to reviewing IRB/IEC-original</p> <p>Informed consent essential and optional elements/information to be provided to subjects</p> <p>Requirements for documentation and reporting financial disclosure for clinical investigators including:</p> <ul style="list-style-type: none"> - Form FDA 3454 and 3455 - Definition of significant equity interest and significant payments in clinical trials - Definition of covered clinical trial - Record maintenance <p>Investigational product brochure/Investigator’s brochure</p> <p>IDE Significant Risk Determination</p> <p>Regulatory requirements related to essential documents for clinical studies (IRB/IEC, sponsor and clinical sites)</p> <p>Roles, responsibilities and obligations of the sponsor</p> <p>Roles, responsibilities and obligations of the investigator</p> <p>Delegation of duties</p> <p>Investigational New Drug (IND) development and submission to applicable authorities</p> <p>Investigational Device Exemption (IDE) development and submission to applicable authorities</p> <p>IDE Significant Risk Determination</p> <p>Regulatory requirement for protocol(s) and protocol related document(s) (e.g., informed consent)</p> <p>Essential study related documents (paper/electronic) Clinical investigator agreements (e.g FDA Form 1572, investigator agreement)</p> |
| <p>c. Obtain research study approval from necessary stakeholders (e.g., IRB, research study sponsor, and relevant regulatory authorities)</p> | <p>Obtain research study sponsor approval</p> <p>Obtain IRB/IEC approval</p> <p>Obtain relevant regulatory authority approval</p> |

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Detailed CCRP® Examination Outline (continued)

| MAJOR CONTENT AREA | TOPICS AREAS |
|--|--|
| <p>c. Obtain research study approval from necessary stakeholders (e.g., IRB, research study sponsor, and relevant regulatory authorities)</p> | <p>KNOWLEDGE OF:</p> |
| | <p>Regulatory requirements for submission of protocol(s) to applicable authorities, sponsor and IRB/IEC</p> <p>Regulatory requirement for protocol(s) and protocol related document(s) (e.g., informed consent documents, recruitment materials, safety reports, continuing review reports) development, review, and submission to reviewing authorities</p> |
| <p>d. Obtain research study product, related materials, equipment, tools and aids</p> | <p>Develop research study tools/aids</p> <p>Requirements for data management systems</p> |
| | <p>KNOWLEDGE OF:</p> <p>Development of data collection tools (e.g., essential documents such as case report forms, product accountability logs, delegation logs) Regulatory requirement for essential document development (electronic or paper based)</p> |
| <p>e. Select research study sites</p> | <p>KNOWLEDGE OF:</p> |
| | <p>Evaluating a clinical site to conduct a clinical study</p> |
| <p>f. Train research study staff members</p> | <p>Evaluate research study staff member qualifications (e.g., clinical investigator, research coordinator, study monitors)</p> <p>Develop training program for all personnel involved in the study Administer training program</p> |
| | <p>KNOWLEDGE OF:</p> <p>Clinical site and personnel for qualifications to conduct a clinical study</p> <p>Site/investigator training (GCP, investigational product, study, reporting requirements, compliance with protocol)</p> |
| <p>g. Evaluate research study's compliance with relevant local, state and provincial laws</p> | <p>Evaluate IRB compliance with applicable regulations</p> <p>Submit relevant studies to clinicaltrials.gov</p> <p>Evaluate compliance with relevant local, state and provincial laws</p> |

continued >>

Detailed CCRP® Examination Outline (*continued*)

| MAJOR CONTENT AREA | TOPICS AREAS |
|--|---|
| <p><i>(continued)</i></p> <p>g. Evaluate research study's compliance with relevant local, state and provincial laws</p> | <p>KNOWLEDGE OF:</p> <p>Roles and responsibilities of the IRB/IEC for review and approval of study</p> <p>Standard operating procedure development and implementation for the IRB/IEC</p> <p>IRB/IEC membership requirements</p> <p>IRB/IEC protocol review requirements</p> <p>IRB/IEC protocol amendment review requirements</p> <p>IRB/IEC expedited protocol review requirements</p> <p>IRB evaluation of significant risk/non-significant medical device study determination</p> <p>Requirements for documentation of IRB/IEC meeting minutes, reviews and decisions</p> <p>Communication of IRB/IEC decisions</p> <p>Record retention for IRB/IEC documentation</p> <p>Regulatory requirements for clinicaltrials.gov</p> <ul style="list-style-type: none"> - Applicable studies - Elements required in informed consent document <p>Determine applicable requirements of regulatory agencies and any local (institution), state and provincial requirements Data Safety Monitoring Board (DSMB) responsibilities</p> |
| <p>2. RESEARCH STUDY IMPLEMENTATION: 50%</p> | |
| <p>a. Execute Research Strategy</p> | <p>Follow research study protocol</p> <p>Follow Standard Operating Procedures (SOPs) (e.g., IRB/IEC, study and sponsor)</p> <p>Evaluate research study protocol</p> <p>Develop & submit continuing review submissions</p> <p>Develop & submit research study protocol amendments to IRB/IEC sponsor and regulatory authorities</p> |

continued >>

Detailed CCRP® Examination Outline (continued)

| MAJOR CONTENT AREA | TOPICS AREAS |
|--|---|
| <p><i>(continued)</i></p> <p>a. Execute Research Strategy</p> | <p>KNOWLEDGE OF:</p> <p>Roles and responsibilities of IRB/IEC, sponsor and clinical investigator in the conduct of clinical research</p> <p>Regulatory requirements to conduct a study in accordance with an investigational plan</p> <ul style="list-style-type: none"> - Investigator agreement, and applicable regulations <p>Evaluating clinical site and personnel for ability to conduct a clinical study</p> <p>Implementation of Standard Operating Procedures (SOPs) for:</p> <ul style="list-style-type: none"> - IRB/IECs - Sponsors - Clinical Sites <p>Requirements for documentation, reporting and maintenance of financial disclosure for clinical investigators including:</p> <ul style="list-style-type: none"> - Form FDA 3454 - Form FDA 3455 <p>Regulatory requirements for Investigational site study reports and development and submission to reviewing authorities (e.g., progress reports, safety reports, final reports protocol changes, protocol deviations)</p> <p>Submission and review of protocol amendment(s)</p> <p>Regulatory requirements for submission of protocol amendment(s) to applicable authorities, IRB/IEC</p> |
| <p>b. Assure regulatory compliance</p> | <p>Comply with relevant local, state and provincial laws Comply with applicable privacy laws</p> <p>KNOWLEDGE OF:</p> <p>Regulatory requirements for confidentiality of a research subject's information</p> |
| <p>c. Manage research study product (e.g., treatment, procedure, medication, medical device, questionnaire)</p> | <p>Prepare research study product(s)</p> <p>Dispense research study product(s)</p> <p>Administer research study products(s)</p> <p>Store research study product(s)</p> <p>Verify research study product(s)' use</p> |

continued >>

Detailed CCRP® Examination Outline (continued)

| MAJOR CONTENT AREA | TOPICS AREAS |
|--|---|
| <p><i>(continued)</i></p> <p>c. Manage research study product (e.g., treatment, procedure, medication, medical device, questionnaire)</p> | <p>KNOWLEDGE OF:</p> <p>Sponsor’s roles and responsibilities for Investigational product accountability:</p> <ul style="list-style-type: none"> - Regulatory requirements related to shipment and disposition of investigational products including: - Investigational product (e.g., package insert, report of prior investigations, Investigator’s Brochure) - Documentation of randomization of investigational product - Investigational product accountability - Packaging and labeling of investigational products - Evaluation and documentation of investigational product compliance (e.g., protocol, standard operating procedures, local governance) <p>Clinical Investigator’s roles and responsibilities related to receipt and distribution of investigational product and other supplies at study site</p> <p>Regulatory requirements related to receipt and distribution of investigational product and other supplies at study site:</p> <ul style="list-style-type: none"> - Documentation of randomization of subjects and investigational product - Packaging and labeling of investigational products - Evaluation and documentation of Investigational product compliance (i.e., according to protocol) - Documentation of Investigational Product Accountability and Subject training for the use of study agents |
| <p>d. Identify, document & report research study anomalies</p> | <p>Identify, document & report protocol deviations/violations</p> <p>Identify, document & report unanticipated problems</p> <p>Identify, document & report unanticipated adverse events and adverse device effects</p> <p>Identify, document & report adverse events/effects</p> <p>Identify, document & report serious adverse events/effects</p> <p>Identify, document & report research misconduct</p> |

continued >>

Detailed CCRP® Examination Outline (continued)

| MAJOR CONTENT AREA | TOPICS AREAS |
|---|--|
| <p><i>(continued)</i> d. Identify, document & report research study anomalies</p> | <p>KNOWLEDGE OF:</p> <p>Sponsors and Clinical Investigator’s roles and responsibilities for identification, documentation and reporting of unanticipated problems, unanticipated adverse device effects, adverse drug events, serious adverse events/effects.</p> <p>Requirements for informing subjects of safety concerns and any relevant changes to the study</p> <p>Subject safety issues—definitions, documentation, and reporting of adverse events, serious adverse events/serious adverse drug reactions, and unanticipated adverse device effects including the following:</p> <ul style="list-style-type: none"> - Documentation - Expected or unexpected results associated with investigational products - Investigator’s plan/protocol of action or management of adverse event (e.g., stop investigational product; call, retest, treat subject) - Follow-up to determine resolution of adverse events - Definition/classification of: adverse event, adverse drug reaction, serious adverse event, and unanticipated adverse device effects <p>Documentation of serious adverse events/serious adverse drug reactions, and unanticipated adverse device effects and relevant information in source documents and CRFs</p> <p>Regulatory requirements for reporting serious adverse event/serious adverse drug reaction, and unanticipated adverse device effects to Sponsor/CRO and IRB/IEC</p> <p>Regulatory requirements for documenting reasons for subject discontinuation/termination</p> <p>Regulatory requirements for documenting follow-up medical care for study subjects</p> <ul style="list-style-type: none"> - Safety monitoring/reporting activities - Un-blinding <p>Regulatory reporting and Medwatch [3500 and 3500A] requirements</p> <p>Identification and reporting of research misconduct: - Clinical Investigator Disqualification and debarment - Ethical concepts with foundation in:</p> <ul style="list-style-type: none"> * Nuremberg Code * Belmont Report * Declaration of Helsinki |

continued >>

Detailed CCRP® Examination Outline (continued)

| MAJOR CONTENT AREA | TOPICS AREAS |
|---|--|
| <p>e. Manage subjects Recruit subjects</p> | <p>Recruit subjects</p> <p>Evaluate subject eligibility</p> <p>Assess the capacity for consent of vulnerable populations</p> <p>Document subject eligibility</p> <p>Explain a research study methodology to subjects and associated family members and caregivers</p> <p>Obtain informed consent</p> <p>Obtain informed assent</p> <p>Document informed consent</p> <p>Document reasons for subject discontinuation</p> <p>Coordinate subject interactions with associated family members and caregivers</p> <p>Document subject and associated family members and caregiver interactions</p> <p>Communicate with subjects and associated family members and caregivers</p> <hr/> <p>KNOWLEDGE OF:</p> <hr/> <p>Regulatory requirements for IRB review and approval of subject requirement materials</p> <p>Subject Scheduling, Screening, Recruitment, and Retention including:</p> <ul style="list-style-type: none"> - Recruitment plan/strategies (including regulatory requirements for recruitment materials) - Subject compliance - Subject visits - Subject retention - Subject discontinuation/study termination <p>Regulatory requirements and ethical concepts related to protection of vulnerable subjects</p> <ul style="list-style-type: none"> - Children - Prisoners - Pregnant Women - Human Fetuses and Neonates |

continued >>

Detailed CCRP® Examination Outline (continued)

| MAJOR CONTENT AREA | TOPICS AREAS |
|---|---|
| <p>e. Manage subjects Recruit subjects</p> | <p>KNOWLEDGE OF:</p> <p>Regulatory requirements related to source documentation (paper/electronic) – completion and review of</p> <p>Source documentation and case report forms (CRFs) of subject participation in a study including:</p> <ul style="list-style-type: none"> - Subject eligibility - Informed consent (e.g., vulnerable subjects, legally authorized representative, and short form) - Safety-adverse events, adverse drug reactions, serious adverse effects, unanticipated adverse device effects - Study related visits, procedures, and assessments - Discontinuation/termination of study subjects - Maintenance of essential study related documents (paper/electronic) |
| <p>f. Maintain the research study</p> | <p>Maintain training documentation</p> <p>Maintain research study equipment</p> <p>Maintain the delegation log</p> <p>Maintain essential documents</p> <p>Maintain medical records (source documents)</p> <p>Maintain information in clinicaltrials.gov</p> <p>Manage all regulatory documents (e.g., essential documents)</p> <p>Develop, initiate, and resolve data queries</p> <p>Verify the accuracy and completeness of site records</p> <p>Prepare for or perform for a site audit, a monitoring visit and a regulatory inspection</p> <p>KNOWLEDGE OF:</p> <p>Regulatory requirements for maintenance and retention of study related essential documents, sources documents and equipment including:</p> <ul style="list-style-type: none"> - Investigator qualification and financial disclosure - Research staff qualification and training - Informed consent documents - Study related visits, procedures, and assessments - Safety-adverse events, adverse drug reaction, serious adverse effect, unanticipated adverse device effect |

continued >>

Detailed CCRP® Examination Outline (continued)

| MAJOR CONTENT AREA | TOPICS AREAS |
|--|---|
| <p><i>(continued)</i> f. Maintain the research study</p> | <p>KNOWLEDGE OF:</p> <p>Regulatory requirements related to clinical.trials.gov</p> <ul style="list-style-type: none"> - Informed consent documents - Covered studies <p>Review of accuracy and completeness of site records including monitoring source documentation/case report forms: eligibility, product dosing and accountability, adverse events, study related visits and follow up care, and informed consent documentation Review of accuracy and completeness of site records including monitoring source documentation/case report forms: eligibility, product dosing and accountability, adverse events, study related visits and follow up care, and informed consent documents Preparation and follow-up for study site, IRB/IEC and sponsor regulatory agency inspections (including FDA Forms 482 and 483)</p> <p>Knowledge of principles of Quality Assurance and Corrective and Preventive Action Plans (CAPA)</p> |
| <p>g. Communicate with research study stakeholders</p> | <p>Communicate with the IRB Communicate with research study sponsor Communicate with Data Safety Monitoring Board (DSMB) Communicate with regulatory authorities Communicate with study sites Complete case report forms</p> <p>KNOWLEDGE OF:</p> <p>Regulatory requirements for communication with IRB/IEC, sponsor, investigational site and regulatory authorities including:</p> <ul style="list-style-type: none"> - Annual progress reports - Safety reporting - Withdrawal of IRB approval - Deviations from the investigational plan - Use of investigational product without informed consent - Protocol amendments - IND/IDE amendments - Study/protocol termination/discontinuation - Recall of investigational product <p>IRB/IEC communication with sponsor, clinical investigator and regulatory authorities</p> <p>Role and Responsibilities of Data Safety Monitoring Boards (DSMB)</p> <p>Regulatory requirements related to study documentation (paper/ electronic) – completion/review</p> <p>Development and maintenance of accurate, current and complete records relating to clinical studies.</p> |

continued >>

Detailed CCRP® Examination Outline (continued)

| MAJOR CONTENT AREA | TOPICS AREAS |
|---|--|
| h. Perform/participate a research study audit | Regulatory requirements for maintenance and retention of study related essential documents, sources documents Quality Control and Quality Assurance Preparation and follow-up for study site, IRB/IEC and sponsor regulatory agency inspections Research |
| 3. RESEARCH STUDY CLOSURE: 10% | |
| a. Perform/participate a research study closeout visit | KNOWLEDGE OF: Study closeout visit <ul style="list-style-type: none"> - Essential documents, verification of study documentation - Resolution of monitoring queries - Accountability of investigational product |
| b. Develop & submit research study closure reports | Develop & submit closure report to IRB Develop & submit final report to research study sponsor Develop & submit final report to relevant regulatory authorities Develop & submit final report to clinicaltrials.gov |
| c. Archive/retrieve research study records | |

How to Apply

SOCRA provides candidates with an easy to use online application in the Certification section of the SOCRA website (www.SOCRA.org). Selecting “Apply Online” from under “CCCRP Certification Exam” in the left-hand column of the Certification page will open the online application with instructions. Here candidates can enter their information, submit documentation verifying that they meet eligibility requirements, pay exam fees, and request testing accommodations. The application and all the supporting documents must be included and forwarded to the SOCRA administrative offices a minimum of six weeks prior to the test date you would like. Once the application is approved, fees are not refundable.

Application Fee

PAYMENT IN FULL

| | Member Rate | Non-Member Rate |
|--------------|---|---|
| Exam Fee | \$395 (includes 3 year complimentary SOCRA membership)* | \$450 (includes 3 year complimentary SOCRA membership)* |
| 3 Year Total | \$395** | \$450** |

*beginning upon successful completion of the exam

**CBT is an additional \$115 (USA, Canada, Mexico), \$175 (other countries)

RETEST FEE: \$275

3 YEAR INSTALLMENT PLAN

| | Member Rate | Non-Member Rate |
|--------------|------------------------|------------------------|
| Exam Fee | \$250 initial payment* | \$300 initial payment* |
| Year 2 | \$100** | \$100** |
| Year 3 | \$100** | \$100** |
| 3 Year Total | \$450*** | \$500*** |

*includes SOCRA membership upon successful completion of the exam

**includes complimentary SOCRA membership

**CBT is an additional \$115 (USA, Canada, Mexico), \$175 (other countries)

RETEST FEE: \$275

**CBT-Computer Based Testing

Application Review

- Applications will be reviewed within 3-5 business days of receipt.
- Applicants may be contacted by e-mail or phone if additional information is needed to complete their application.
- NO REFUNDS will be issued after the application is approved.

Application Determination

Applicants will be notified via email when their application has been accepted or denied.

Accommodation Policy

SOCRA (Society for Clinical Research Associates) provides reasonable and appropriate ADA accommodation for those taking our examinations who make a timely request and demonstrate a need. This guide describes the information that you will need to apply for a *new or revised ADA accommodation in accordance with the Americans with Disabilities Act Amendments Act (ADAAA)*. Please use it to help you collect and submit the information required to request test accommodation. If you still have questions after reading this guide, please email us at certification@socra.org.

Candidates can describe their need for testing accommodations and upload supporting documentation when completing the online application on the SOCRA website (www.SOCRA.org). To access the application, select “Apply Online” from under “CCCRP Certification Exam” in the left-hand column of the Certification page.

If you have a disability covered under the ADA and require test accommodation, you must notify SOCRA every time you apply for an exam.

Fairness in Testing Policy

The purpose of this policy is to ensure that the certification examination process is fair, impartial, valid, and consistently applied. The SOCRA is committed to providing equal opportunity to all candidates and to maintaining the integrity and credibility of its certification decisions.

Scope

This policy applies to all applicants and candidates worldwide seeking certification through SOCRA, including application review, examination administration, scoring, and appeals.

- 1. Equal Access and Global Eligibility**

The certification program is open to qualified candidates worldwide. All certification activities are conducted impartially and without discrimination on the basis of nationality, geographic location, or other non-certification-related characteristics. Policies and procedures are designed to support fairness and consistency across all candidates.

- 2. Consistent Screening Criteria**

All applicants are screened using the same eligibility requirements and evaluation criteria. Screening decisions are based solely on established standards set by the Certification Committee and listed in the Policies and Procedures and documented on the website to ensure consistency and fairness across all candidates.

- 3. Fairness of Test Content**

Subject Matter Experts are trained in fairness and bias in testing. Certification examination content is developed and maintained through a structured and documented process to ensure fairness, relevance, and alignment with the certification blueprint. Test questions are developed, reviewed, and maintained to ensure they are fair, unbiased, and directly related to the knowledge, skills, and abilities being assessed. Items are evaluated to minimize cultural, linguistic, or other forms of unintended bias.

- 4. Criterion-Referenced Scoring**

Candidates must meet or exceed a criterion-referenced passing score based on clearly defined test blueprints and performance standards. Scores reflect mastery of required competencies rather than comparison to other candidates.

- 5. Equated Passing Scores Across Exam Forms**

Passing scores are equated across different versions (forms) of the exam to maintain consistency and comparability over time. This ensures that no candidate is advantaged or disadvantaged by the specific exam form they receive.

- 6. Appeals Process**

Applicants who are denied approval to test or who do not pass an assessment may submit an appeal. The appeals process allows candidates to provide additional relevant documentation or materials for review. Appeals are evaluated objectively and in accordance with established procedures.

Review and Compliance

This policy is reviewed periodically to ensure alignment with best practices in testing and assessment, as well as applicable laws and professional standards. All personnel involved in testing and evaluation are expected to comply fully with this policy.

Policy of Non-Discrimination

SOCRA does not discriminate on the basis of gender, race, color, age, marital status, sexual orientation, national origin, religion, or disability.

Certification of Honesty

Falsification or misrepresentation of application information will invalidate the applicant's certification status. This would include disapproval of the application or revoking of certification.

Application Portfolio

Application portfolios must include documentation to substantiate sufficient experience to demonstrate minimum eligibility. The applicant must submit the following, along with payment:

| | Description | Category 1 | Category 2 | Category 3 |
|--|--|---------------|---------------|---------------|
| Application Form | A completed certification application form (if applying online, this form is completed online) | yes | yes | yes |
| Resume/CV | The applicant's resume or CV documenting their employment in clinical research | yes | yes | yes |
| Employment Documentation* | A letter on organizational letterhead signed by a supervisor or human resources representative, documenting: <ul style="list-style-type: none"> - Position titles - Dates of employment - Full time/part time status | yes | yes | yes |
| | The applicant's official job description issued by the institution or employer | yes | yes | yes |
| Education Documentation** | Form 1011 completed | n/a | yes | n/a |
| | Form 1022 completed | n/a | n/a | yes |
| | Applicant's transcript documenting graduation with an Undergraduate or Graduate Certificate in "Clinical Research" | n/a | n/a | yes |
| | Applicant's transcript documenting graduation with an associate or bachelor's Degree in a science, health science, pharmacy or related field. | n/a | n/a | yes |
| | Applicant's transcript documenting graduation with an Associate, Undergraduate, or Graduate degree in "Clinical Research." | n/a | n/a | yes |
| | Education program information, showing program meets requirements. | n/a | yes | yes |
| Special Needs/ Disability Request | For applicants who have a disability or special need that prohibits them from taking the examination under standard conditions, a written request, along with written confirmation from a physician, must accompany the application form. Such requests will be reviewed/ approved by the Certification Committee. | if applicable | if applicable | if applicable |

*If the minimally required experience spans multiple positions, each position must be substantiated through submitted documentation and letters of reference.

**See Clinical Research Degree/Certificate Requirements. If applying using a degree or certificate program for eligibility purposes, appropriate forms and documentation (including transcripts) must be included (see www.socra.org for details).

The certification program reserves the right to verify any information submitted in a candidate's application portfolio. It is the obligation of the candidate to provide documentation to substantiate the included information that supports their eligibility.

Applicants must agree to the Certification of Honesty.

Registering for the CCRP Certification Exam

What to Expect Once a Candidate is Accepted

- Upon approval of the application, the applicant will receive the CCRP Candidate Approval Letter via email from SOCRA and access to the CCRP® Certification Program Reference Manual. Within 5-7 business days of receiving the CCRP Candidate Approval Letter, candidates will receive a Preregistration Letter via email with instructions on how to schedule an exam at a computer-based testing (CBT) center or at home with live remote proctoring (LRP).
- After an application has been approved, fees are not refundable.
- Candidates will be able to select a date and time within the authorized testing dates to sit for the CCRP certification exam at a proctored test center of their choice or at home via ProProctor with live online proctoring.
- After scheduling the certification exam, the candidate will be emailed an Admission Letter that includes certification exam and appointment information, instructions on what's needed to test, and other pertinent information.
- If a candidate fails to appear at the designated time and location for an exam, candidate will forfeit a \$115 CBT fee.
- The applicant MUST bring a government photo ID to be admitted to the examination site.

Refund Policy

The fee is refundable if the application is unsuccessful. For qualified applicants who apply for an examination, the fee is not refundable.

Rescheduling

A candidate wishing to cancel or reschedule must do so at least fifteen (15) days prior to the scheduled exam date to not forfeit the \$115 fee. Without an approved excuse, which includes death of an immediate family member, active military orders, jury duty, or a doctor's excuse (on the medical facility letterhead) candidates wishing to cancel or reschedule with 15 or fewer calendar days prior to their scheduled exam session will be required to pay \$25. Candidates are not permitted to reschedule or cancel a scheduled examination less than five (5) calendar days prior to their scheduled examination, without an approved excuse. If a candidate fails to appear for their scheduled examination, comes to the test site without proper ID, and/or the proper admission letter, the candidate will forfeit \$115 of the exam fee.

Prometric Testing Centers Policies and Procedures

Candidate Admission Letter

You MUST present this letter to the testing center in order to be admitted for your exam. Also, the Candidate UserID and Passcode printed on this letter are required for you to login and start your examination.

Arriving for Your Appointment

Please arrive at the testing center A MINIMUM OF 30 MINUTES BEFORE YOUR APPOINTMENT TIME. If you have any doubts about the location of the testing center, Prometric IQT strongly recommends that you review directions to the location prior to your exam day to gauge your travel time; or you may wish to drive to the center in advance (the evening prior, for example), to ensure you know where it is located.

Identification

You must present a VALID GOVERNMENT ISSUED PHOTO ID WITH SIGNATURE in order to be admitted to the examination. Approved forms for ID are: Driver's License, Government Issued ID Card (must have photo and signature), Passport, Military ID Card. No other forms of identification will be accepted. The name on your admission letter must match the name on your photo ID.

Food and Drink

No food or drink will be permitted in the examination room for any reason.

Breaks During The Exam

All candidates have the opportunity to take a brief break at the midpoint of the examination. After completing questions 1-65, candidates will submit the first half of the exam and will not be able to go back to those questions once submitted. After submitting questions 1-65, candidates may take a brief break. Please note that the exam time will not stop during the break, so candidates are encouraged to take only a brief lavatory break or, if not needed, skip the break and continue with the second half of the exam. This is the only break available to candidates during the CCRP certification exam; no other breaks are permitted. Any candidate that elects to use the restroom is not permitted to take anything with them (e.g., no pocketbooks, cell phones, or other personal items). Outside communication is strictly prohibited, including use of cell phones and/or other communication devices. After submitting questions 1-65, the second half of the exam will be available for completion, no additional login is required. Candidates can begin with questions 66-130 immediately after submitting the first half of the exam, or right after a brief break.

Examination Security

Failure to follow candidate instructions will result in your application being voided and forfeiture of your application fee. Conduct that results in violation of security or disrupts the administration of the examination could result in cancellation of your examination and dismissal from the testing center. In addition, your examination will be considered void and will not be scored. Examples of misconduct include, but are not limited to, the following: looking at another candidate's computer monitor, or talking with other candidates anytime during the entire examination period. You are particularly cautioned not to do so after you have completed the examination, as other candidates in the area might be taking a break and still not have completed the examination. You may not attend the examination only to review or audit test materials. You may not copy any portion of the examination for any reason. No examination information may leave the test room under any circumstances. No unauthorized persons will be admitted into the testing area. Please be further advised that all examination content is strictly confidential. You may only communicate about the test, or questions on the test, using the appropriate forms provided within the examination delivery system. At no other time, before, during or after the examination, may you communicate orally, electronically or in writing with any person or entity about the content of the examination or individual examination questions.

Examination Site

While the site climate is controlled to the extent possible, be prepared for either warm or cool temperatures at the testing center in the event that you become uncomfortable. Cellular phones and beepers are prohibited in the testing area. The use of headphones inside the testing area is prohibited. Electrical outlets will not be available for any reason. Earplugs for sound suppression are allowed. No smoking or use of tobacco products will be allowed inside the testing area. You must vacate the testing area after you have completed the examination. If you require special assistance, you must contact IQT at least one week in advance of the examination date and appropriate arrangements will be made. Due to limited parking facilities at some testing centers, please allow ample time to park and reach the testing area.

Inclement Weather Policy

If your area is experiencing inclement weather, it is your responsibility to contact your testing center to confirm if it is closed or delayed in opening. Most likely there will be a voice message on the testing center's phone system to notify candidates of any change in business hours during the inclement weather. There are no additional costs for such reschedules.

Home Testing via ProProctor Policies and Procedures

Candidate Admission Letter

You **MUST** present this letter to the remote proctor in order to be admitted for your exam. Also, the Candidate UserID and Passcode printed on this letter are required for you to login and start your examination.

Prior to Your Exam Date

Review the [ProProctor User Guide](#) and follow the instructions to ensure your computer and internet are prepared for the test administration.

Arriving for Your Appointment

Please log in to ProProctor following the link provided in your Candidate Admission Letter (email) A MINIMUM OF 15 MINUTES BEFORE YOUR APPOINTMENT TIME.

Check in and Testing Environment Scan

You will first connect with a Readiness Agent who will check you in, validate your ID, and conduct a 360-degree scan of your testing environment. The Readiness Agent will also run a check of the ProProctor system on your device to ensure that all test administration requirements are met. They may ask you to turn off programs or features for the test administration.

Identification

You must present a VALID GOVERNMENT ISSUED PHOTO ID WITH SIGNATURE to be admitted to the examination. Approved forms for ID are: Driver's License, Government Issued ID Card (must have photo and signature), Passport, Military ID Card. No other forms of identification will be accepted. The name on your admission letter must match the name on your photo ID.

Remote Proctor

Once you have passed the ID validation and room scan, you will be transitioned to the Remote Proctor. The Remote Proctor will launch the exam and then monitor you during your exam and provide technical assistance, as necessary.

Food and Drink

No food or drink will be permitted in the examination room for any reason.

Breaks During The Exam

All candidates have the opportunity to take a brief break at the midpoint of the examination. After completing questions 1-65, candidates will submit the first half of the exam and will not be able to go back to those questions once submitted. After submitting questions 1-65, candidates may take a brief break. Please note that the exam time will not stop during the break, so candidates are encouraged to take only a brief lavatory break or, if not needed, skip the break and continue with the second half of the exam. Any candidate that elects to use the restroom is not permitted to take anything with them (e.g., no pocketbooks, cell phones, or other personal items). Outside communication is strictly prohibited, including use of cell phones and/or other communication devices. After submitting questions 1-65, the second half of the exam will be available for completion, no additional login is required. Candidates can begin with questions 66-130 immediately after submitting the first half of the exam, or right after a brief break.

Examination Security

Failure to follow candidate instructions will result in your application being voided and forfeiture of your application fee. Conduct that results in violation of security or disrupts the administration of the examination could result in cancellation of your examination and dismissal from the testing center. In addition, your examination will be considered void and will not be scored. Examples of misconduct include, but are not limited to, the following: using any unauthorized study aids (e.g., textbooks, smartphones, internet), having other individuals in the testing room, talking with other individuals in the exam setting, or leaving the visual monitoring area of the proctor. If the proctor notices any unauthorized behaviors, they will stop your exam and require you to perform another 360-degree scan of the testing area. You may not attend the examination only to review or audit test materials. You may not copy any portion of the examination for any reason. No examination information may leave the testing area under any circumstances. No unauthorized persons will be admitted into the testing area. Please be further advised that all examination content is strictly confidential. You may only communicate about the test, or questions on the test, using the appropriate forms provided within the examination delivery system. At no other time, before, during or after the examination, may you communicate orally, electronically or in writing with any person or entity about the content of the examination or individual examination questions. If the proctor notices any unauthorized behaviors, they will stop your exam and require you to perform another 360-degree scan of the testing area. If the unauthorized behaviors are severe, or if they continue after investigation and additional room scans, your exam may be terminated.

Examination Site

The room that you select for your exam must meet the following requirements:

- The testing location must be indoors, in a well-lit room free from background noise and disruptions
- No one other than the exam candidate may be present in the room for the duration of the exam. If someone enters the room, your exam may be terminated and/or your results invalidated
- Your workstation and surrounding area must be free of pens, paper, electronic devices, etc. No content that could potentially provide an unfair advantage during your exam, including that posted on walls or within your immediate area, should be present during your exam
- Two tissues are permitted
- Two tissues are permitted at the workstation, but must be inspected by the Proctor prior to the start of your exam.
- If taking an exam from a company office, windows and/or glass doors must be covered or contain frosted glass to eliminate distractions and prevent outside viewing. If testing from a personal space (e.g., home office, hotel room, etc.) candidates should cover windows and/or glass doors to eliminate distractions – if possible.

Examination Results

Receiving Your Results

Candidates will receive a score report with their exam results upon completion of their examination at a computer-based testing (CBT) center or via ProProctor with live remote proctoring (LRP). Test results for candidates that pass the CCRP certification exam will include the candidate's score and the Exam Result: PASS. Test results for candidates that fail the CCRP certification exam will include the candidate's score, the Passing Score required, the Exam Result: FAIL, and the percentage of questions the candidate answered correctly for each content area of the CCRP certification exam.

Exam Scores

The examination pass/fail score, or "cut score", is determined by a panel of experts and is validated by a psychometric testing analysis. A candidate's pass/fail result is determined by comparing their score (i.e., total questions answered correctly) to the cut score. If a candidate's score is equal to or greater than the cut score, they pass the exam. All scores below the cut score result in a failed exam.

Awarding Certification

Candidates that successfully pass the examination will receive a CCRP® certificate approximately four weeks after the score report has been received. Exam results will not be disclosed by phone. SOCRA considers test scores to be confidential and will not publish or release this information to anyone other than the candidate.

Retesting

- When retesting within one year of the original test date, an applicant may not need to resubmit supporting documentation (job description(s), employment verification letter(s), etc.)
- There is a 15-day waiting period before you can re-test. If you are unsuccessful in passing the exam 3 times, you must provide proof of 6 hours of GCP education/training before retesting for the 4th time
- To register, complete an application form and submit with payment to the SOCRA administrative office, including "Retest" if this is within one year of the original test date.

Retest fee - \$275.00

Appeals

SOCRA will accept appeals for the following:

1. **Eligibility Appeals** – Individuals who have their certification application denied can appeal for reconsideration by submitting a written appeal with additional information and/or documentation to support their application.

2. **Certification Decision Appeals** – Candidates wishing to appeal their CCRP certification decision may appeal their exam score, or request to have their exam hand scored for a \$50 fee. Appeals requesting to see specific exam questions and/or answers will be denied as that could compromise the integrity of the exam.
3. **Recertification Appeals** – Certificants who have their recertification application denied can appeal the acceptability of denied continuing education (CE) toward their recertification CE requirement. They can also appeal if their application was denied due to insufficient CE by providing an updated CE log with additional information and/or CE credits. Individuals who let their CCRP Certification expire but have the required CE can recertify within two months of their expiration date ("Grace period") at no additional cost, or can renew their certification from the Grace period up to 12 months after their expiration date by paying a reinstatement fee along with the recertification fee.
4. **Disciplinary Appeals** – Candidates and certified CCRPs have the option to appeal disciplinary decisions, including revocation of certification. Individuals who submit a disciplinary appeal should reference the action being appealed, explain why they are requesting the decision be reconsidered, and submit supporting evidence.

All appeals must be sent in writing to SOCRA "Re: Certification Appeal" by e-mail at: certification@socra.org, mail: 5034-A Thoroughbred Lane, Brentwood, TN 37027.

SOCRA follows a similar approach in reviewing all appeals:

1. SOCRA certification staff evaluate the appeal and determine if it is appropriate due to an error, in which case they can approve it, or if it needs to go to the CCRP Certification Committee for review.
2. The CCRP Certification Committee will review appeals that it receives within 30 days and make a decision. If they have questions about the appeal, they can reach out to the individual for clarification or additional information.
3. Once a final determination is made by the Certification Committee, no further appeal will be accepted.

Recertification

Purpose

The recertification of certificants is based on a continuing process of professional development. The recertification program provides recognition of the professional growth of the individual “CCRP®” to the healthcare and clinical research community. The purpose of the CCRP recertification process is to prompt certificants to maintain and enhance their competence throughout their professional careers. In order to demonstrate continued competence, certificants must maintain their knowledge of regulations and stay current on changes to regulatory requirements and issues in the clinical research environment and enhance their knowledge of clinical research practice.

Timeframe

The timeframe for initial certification and recertification is three years. The certification period begins on the date of certification and ends 3 years thereafter. The regulatory requirements and issues in clinical research change frequently enough that CCRPs must complete the Recertification Continued Competency Learning Module and at least 22 hours related to clinical research regulations, policies, etc., every three years to stay current. This rationale supports the requirement for CCRPs to renew their certifications every three years.

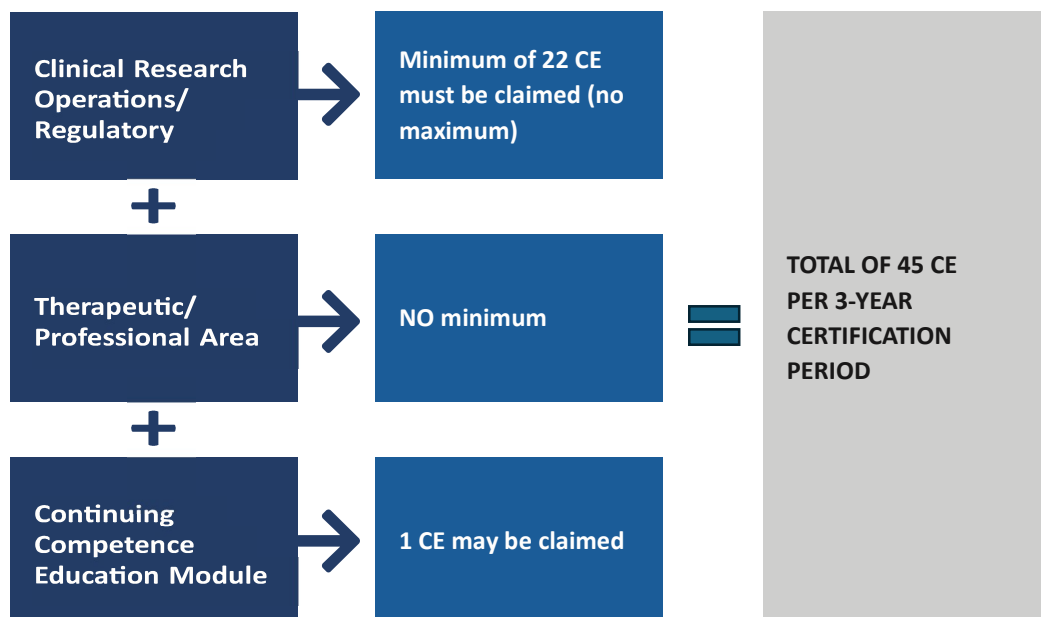
Maintenance of Certification

Term of Certification/Certification Period

The certification period is three years, beginning on the date of the most recent certification and ending on the certification expiration date. All continuing education (CE) must be accrued during this time.

Continuing Education (CE) Requirements

CCRP® certification is based on a continuing process of professional experience and education. This program is dedicated to providing recognition and validation of the professional growth of the individual CCRP® to the healthcare community. Certificants must have completed 45 hours (45 credits) of CE during their certification period. A minimum of 22 CE must be related to Clinical Research regulations, policy, etc. The remaining CE may relate to their Therapeutic or Professional Area. 1 CE will be awarded for the successful completion of the required online regulatory educational module. Only educational hours may be claimed for CE.



Because of the diversity of activities of clinical research professionals, a specific listing of approved CE programs will not be developed. Certificants applying for re-certification will be asked to sign an affidavit that verifies an accumulation of 45 hours of Continuing Education applicable to their work in clinical research. Only educational hours may be claimed for CE. **CE credit for work hours, and protocol specific SOPs may NOT be claimed.**

It is the responsibility of the certificant to maintain copies of program descriptions or agendas, and some form of verification of attendance such as a certificate of completion or letter of attendance or notice of grade, or class completion certificate. A random audit of programs submitted for CE credit will be conducted each year.

CE Tracking

To renew the CCRP Certification, certificants must provide documentation showing that they completed at least 45 CE that meet the CE Requirements. SOCRA created a CE Tracking Log that certificants can download from the SOCRA website to record and track CE completed during each three-year certification period. The online recertification application has a section where certificants can upload their "Completed CE Log." To download a copy of the CE Tracking Log, select "CE Recordkeeping Requirements" from under "Maintenance of Certification" in the left-hand column of the "Certification" page of the SOCRA website (www.SOCRA.org), then find the instructions for downloading the CE Tracking Log under "CE Tracking Tool."

Examples and Descriptions of Acceptable CE

| Type of Activity | Description of Activity | Supporting Documentation Required (submit ONLY if audited) | Maximum CE Allowed | |
|---|--|--|--|--|
| SOCRA Conference/ Workshop/Chapter Meeting | Programs developed by SOCRA and SOCRA Chapter Meetings offering CE | Certificate of attendance | No Maximum | |
| Workshops at Research Facilities/ Sites | Workshops at research facilities/ sites or pharmaceutical company meetings encompassing subjects appropriate to clinical research. | Agenda AND Certificate of attendance and/or letter signed by supervisor | No Maximum | |
| Web Based/Online Coursework | Education related to clinical research or therapy | Agenda AND Certificate of attendance and/or letter signed by supervisor | No Maximum | |
| Other Seminars/ Conferences | Seminars, conferences, programs (applying to clinical research) that contribute to education or professional advancement | Agenda AND Certificate of attendance and/or letter signed by supervisor | No Maximum | |
| University/College Coursework | College, university, or accredited independent study courses relevant to work in clinical research. | Transcript showing completion of course, AND Syllabus/course description | No Maximum | |
| Grand Rounds, Tumor Boards, and IRB/IEC Meetings | Grand rounds, tumor boards, and Institutional Review Board (IRB)/ Independent Ethics Committee (IEC) meetings | Agenda, AND Letter signed by supervisor stipulating learning hours | Maximum: 2 CE from all of these areas combined, per year | Maximum: 6 CE per certification period |

continued >>

Examples and Descriptions of Acceptable CE (*continued*)

| Type of Activity | Description of Activity | Supporting Documentation Required (submit ONLY if audited) | Maximum CEU Allowed | |
|---|---|--|--|---|
| Investigator/Site Initiation Meetings | CE can be claimed for the GCP training given at investigator meetings and site initiation visits (not for protocol specific training) | Agenda, AND Letter signed by supervisor stipulating learning hours NOTE: Only the GCP training sections of the meetings may be counted | Maximum: 2 CE from all of these areas combined, per year | Maximum: 6 CE per certification period |
| Audio/Video | Audio and video recordings of CE programs related to clinical research (state, chapter or association meetings, area or local chapter meetings, etc.). Recordings must be one hour in length for each hour claimed. | Summary of studied material (minimum 250 words) | Maximum: 5 CE per year | Maximum: 15 CE per certification period |
| Self-Study/Journal Articles | Reading of journal articles and self study programs may be claimed in one-hour increments for each hour spent on the activity. 1 hour of this activity = 1 CE | Summary of studied material (minimum 250 words). Self-Study Articles with completed self-test exams do not require | Maximum: 5 CE per year | Maximum: 15 CE per certification period |
| | SOCRA Source Self Study article(s) period offers 1 CE each. You may use articles from issues published during your certification period only 12 issues are published during a 3-year certification period. | A copy of the completed SOCRA self-test exam for each article. | | |
| Active SOCRA officer, committee chair/member | Active participation in SOCRA as an elected officer, committee chair or active committee member for SOCRA or a SOCRA chapter. | No documentation required Note: One year of such participation = one CE hour | Maximum: 1 CE per year | Maximum: 3 CE per certification period |

SOCRA's requirements for recertification CE credit are quite general, as they pertain to research regulations, operations and management, and yet are also specific to the therapeutic area of the research in which the candidate participates. We, therefore, leave it to the candidate to determine whether a course or program is acceptable for the individual's CE requirement, and do not "validate" individual training courses/workshops/presentations.

Any question regarding the appropriateness of a program for CE credits may be e-mailed to SOCRA at: certification@SOCRA.org directed to the attention of the Certification Committee. More information can be found on the SOCRA website at www.SOCRA.org.

Renewal of Certification

To maintain active certification status, the CCRP® must apply to SOCRA for renewal of certification every three years. Those wishing to renew their CCRP® certification must successfully complete an online regulatory learning module and provide documentation of 45 hours of validated continuing education credit.

| Recertification Fee Options | |
|---------------------------------|--|
| Payment in Full for Three Years | \$350 |
| Three Year Installment Plan | Initial payment = \$200 Year 2 = \$100 Year 3 = \$100 |

The requirements for recertification include:

- Completion of the recertification application and CE log, indicating the required forty-five (45) contact hours of continuing education, applicable to work in clinical research, during the period since the most recent certification date,
- Completion of the SOCRA online regulatory learning module
- Submission of the recertification processing fee in U.S. Funds to the SOCRA administrative office.

How to Renew a CCRP Certification

SOCRA provides certificants with an easy to use online application in the Recertification section of the SOCRA website (www.SOCRA.org). Selecting “Apply Online” from the left-hand column of the Recertification page will open the online application with instructions. Here certificants can enter their information, submit documentation verifying that they meet CE requirements, and pay the full recertification fee or select the three year installment plan and make the initial payment.

Recertifying within the Grace Period

If a certificant submits their properly completed recertification application with supporting documentation including the required 45 CE accumulated during the three-year certification period, the certificate of completion from the SOCRA continuing competence learning module, and the recertification fee within two months of their expiration date (the grace period), they will be considered certified continually and their recertification will become effective with their certification renewed for three years and their expiration date updated to three years from the prior expiration date.

Reinstating a Certification within 12 months after the Recertification Date

If a certificant submits their properly completed recertification application with supporting documentation including the required 45 CE accumulated during the three-year certification period, a certificate of completion from the SOCRA continuing competence learning module, and the recertification fee plus a reinstatement fee within twelve months of their expiration date, they will be reinstated and with their certification renewed from three years from the previous expiration date.

Removal of CCRP® Credential

Removal/Suspension

The CCRP® credential will be automatically suspended/removed if the certificant:

- Fails to apply for renewal of certification at the end of their certification period
- Fails to submit timely installment plan payment(s)
- Fails to meet all the requirements for recertification
- Misrepresents the CCRP® (SOCRA) credential
- Debarment by the FDA

Revocation

The CCRP® credential will be automatically revoked for any of the following reasons:

- Falsification of the certification / recertification application
- Falsification of any information requested by SOCRA

Appeals

Certificants that have their CCRP Certification revoked can appeal the decision. Additional appeals information is found earlier in this document following information about “Retesting.”

All appeals must be sent in writing to SOCRA “Re: Certification Appeal” by e-mail: certification@socra.org or mailed to 5034-A Thoroughbred Lane, Brentwood, TN 37027 USA.