FOR CLINICAL RESEARCH EXCELLENCE

Candidate Handbook

CCRP® Certification Program

Certification Program Overview

Introduction

The CCRP® certification program is governed by the SOCRA Certification Committee, which operates with complete authority regarding essential decisions related to certification in order 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 the most updated listing of exam sites and dates.

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 (E6R2), 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.

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

Scope / Standards of Practice, cont'd

- 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 (E6R2), 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.

Definition of a Clinical Research Professional

CRPs come from a wide variety of backgrounds.

CRPs may have backgrounds in nursing, pharmacy, medical technology, business administration, health record management, statistics, science, education, or other areas.

CRPs work in various settings, including private practice; cooperative research groups; public and private academic institutions; pharmaceutical, device, and biotechnology companies; Clinical Research Organizations (CROs); Site Management Organizations (SMOs); independent research and development organizations; and organizations otherwise involved in the management of clinical trials.

A clinical research professional's (CRP) practice is guided by one or more aspects of the principles of Good Clinical Practice (GCP).

A CRP may function as a:

- clinical investigator
- sub-investigator
- clinical researcher
- research nurse
- pharmacist
- administrator
- coordinator
- consultant
- data manager
- quality assurance manager
- regulatory affairs manager
- educator in clinical trial management

Definition of a Clinical Research Professional

The duties of a CRP may include:

- data collection
- analysis, or monitoring
- case management of protocol participants
- recruitment and enrollment of human subjects
- protection of subjects and subjects' rights
- development of informed consent documents
- preparation of adverse event experience reports
- construction or monitoring of case report forms
- maintenance of drug accountability records;
- development of grants and budgets
- preparation of reports
- educating other healthcare professionals, patients or families about clinical trials
- protocol development;
- program administration
- auditing research program

This definition does NOT include professionals working exclusively under Good Laboratory Practice (GLP) and/or Good Manufacturing Practice (GMP) regulations.

CCRP® Certification Examination

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.

The CCRP® certification is awarded after two criteria are met:
1) successful application and
2) a passing examination score.

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

The test questions are designed to be straightforward and easily understood. The questions are reviewed for fairness and readability by experts in test question development.

The Certification Examination is evaluated and updated at least annually in order to assure that content is up-to-date and reflective of the current regulatory environment in which clinical trials are performed.

The certification program periodically conducts a Job Task Analysis in order to validate the examination content. A copy of the Job Task Analysis summary report is available by request through the SOCRA administrative office.

Examination Format

The CCRP® exam includes 130 multiple choice questions; 100 scored and thirty (30) unscored questions.*

The data collected on the unscored items is used to evaluate the psychometric soundness of each CCRP® test item.

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, in two formats: paper and pencil format and computer based testing at approved testing centers and via home proctoring.

Examination Validation

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

Examination Content

The CCRP® certification examination is organized into Three major content areas. The content outline is derived from the 2017 Job / Task Survey and Analysis. Over 4,000 clinical research professionals participated in the 2017 survey

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	45%
Research Study Closure	Regulatory Requirements of IRB/IEC, sponsors and investigators related duties/task related to study close out and record maintenance	15%

Detailed CCRP® Examination Outline

The CCRP certification examination content is arranged into three major content areas (listed below). The examination outline has been 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	Determine if a research study design involves human subjects
	Develop Standard Operating Procedures (SOPs) for sponsors, clinical investigators, and IRBs
	Coordinate the expedited review of research study protocol
	Coordinate the development of emergency use research study protocol
	Coordinate the development of a research study protocol involving vulnerable subjects
	Coordinate the development of a research study protocol involving investigational products (e.g., pharmaceutical, biologic or device)
	KNOWLEDGE OF:
	Roles and responsibilities of the sponsor, clinical investigator and IRB in determination the applicable regulatory pathway for a clinical study (e.g. IND, IDE)
	Ethical concepts with foundation in:
	- Nuremberg Code
	- Belmont Report
	- Declaration of Helsinki
	Roles and responsibilities of the sponsor, clinical investigator and IRB in determining the applicable regulatory pathway for a clinical study (e.g. IND, IDE)
	- Development of Standard Operating Procedures (SOPs) for IRB/IECs, Sponsors and Clinical Research Sites
	Roles and responsibilities of IRB/IEC review and approval of clinical studies including:
	- Emergency use of a research product
	- Expedited Review clinical studies
	- Significant risk determination for medical device clinical studies
	Development of protocols (including study design with consideration of methods to reduce bias, objectives, endpoints, data safety monitoring)
	- 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
	Roles and responsibility for protection of human subjects including:
	- Safeguards for children in clinical trials
	- Protection of vulnerable subjects
	- Emergency Use Research
b. Create or obtain research study documents (e.g., informed consent, essential documents, case report forms, financial disclosure statements)	Develop informed consent & informed assent documents
	Obtain financial disclosure from clinical investigators and sub investigators
	Develop case report forms
	Preparing a delegation log
	Identify the need to develop and submit an IND/IDE
	Obtain clinical investigator agreements for device trials
	Develop regulatory documents (i.e., essential documents)

Detailed CCRP® Examination Outline, Cont'd.

MAJOR CONTENT AREA	TOPICS AREAS
1. RESEARCH STUDY START-UP - 40%	
(continued) b. Create or obtain research study documents (e.g., informed consent, essential documents, case report forms, financial disclosure statements)	KNOWLEDGE OF:
	Informed consent/assent process including development, content, review, approval
	Submission (obtain approval) of informed consent documents to reviewing IRB/IEC- original
	Informed consent essential and optional elements/information to be provided to subjects
	Requirements for documentation and reporting financial disclosure for clinical investigators including:
	- Form FDA 3454 and 3455
	- Definition of significant equity interest and significant payments in clinical trials
	- Definition of covered clinical trial
	- Record maintenance
	Investigational product brochure / Investigator's brochure
	IDE Significant Risk Determination
	Regulatory requirements related to essential documents for clinical studies (IRB/IEC, sponsor and clinical sites)
	Roles, responsibilities and obligations of the sponsor
	Roles, responsibilities and obligations of the investigator
	Delegation of duties
	Investigational New Drug (IND) development and submission to applicable authorities
	Investigational Device Exemption (IDE) development and submission to applicable authorities
	IDE Significant Risk Determination
	Regulatory requirement for protocol(s) and protocol related document(s) (e.g., informed consent)
	Essential study related documents (paper/electronic)
	Clinical investigator agreements (e.g FDA Form 1572, investigator agreement)
c. Obtain research study approval from necessary stakeholders (e.g., IRB, research study sponsor, and relevant regulatory authorities)	Obtain research study sponsor approval
	Obtain IRB/IEC approval
	Obtain relevant regulatory authority approval
	KNOWLEDGE OF:
	Regulatory requirements for submission of protocol(s) to applicable authorities, sponsor and IRB/IEC
	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
d. Obtain research study product, related materials, equipment, tools and aids	Develop research study tools/aids
	Requirements for data management systems
	KNOWLEDGE OF:
	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)
e. Select research study sites	KNOWLEDGE OF:
	Evaluating a clinical site to conduct a clinical study

Detailed CCRP® Examination Outline, Cont'd.

MAJOR CONTENT AREA	TOPICS AREAS
1. RESEARCH STUDY START-UP - 40%	
f. Train research study staff members	Evaluate research study staff member qualifications (e.g., clinical investigator, research coordinator, study monitors)
	Develop training program for all personnel involved in the study
	Administer training program
	KNOWLEDGE OF:
	Clinical site and personnel for qualifications to conduct a clinical study
	Site/investigator training (GCP, investigational product, study, reporting requirements, compliance with protocol)
g. Evaluate research study's compliance with relevant local, state and provincial laws	Evaluate IRB compliance with applicable regulations
	Submit relevant studies to clinicaltrials.gov
	Evaluate compliance with relevant local, state and provincial laws
	KNOWLEDGE OF:
	Roles and responsibilities of the IRB/IEC for review and approval of study
	Standard operating procedure development and implementation for the IRB/IEC
	IRB / IEC membership requirements
	IRB / IEC protocol review requirements
	IRB / IEC protocol amendment review requirements
	IRB / IEC expedited protocol review requirements
	IRB evaluation of significant risk/non significant medical device study determination
	Requirements for documentation of IRB/IEC meeting minutes, reviews and decisions
	Communication of IRB/IEC decisions
	Record retention for IRB/IEC documentation
	- Regulatory requirements for clinicaltrials.gov
	- Applicable studies
	Elements required in informed consent document
	Determine applicable requirements of regulatory agencies and any local (institution), state and provincial requirements
	Data Safety Monitoring Board (DSMB) responsibilities
2. RESEARCH STUDY IMPLEMENTATION - 45%	
a. Execute Research Strategy	Follow research study protocol
	Follow Standard Operating Procedures (SOPs) (e.g., IRB/IEC, study and sponsor)
	Evaluate research study protocol
	Develop & submit continuing review submissions
	Develop & submit research study protocol amendments to IRB/IEC sponsor and regulatory authorities
	KNOWLEDGE OF:
	Roles and responsibilities of IRB/IEC, sponsor and clinical investigator in the conduct of clinical research
	Regulatory requirements to conduct a study in accordance with an investigational plan
	- Investigator agreement, and applicable regulations
	Evaluating clinical site and personnel for ability to conduct a clinical study

Detailed CCRP® Examination Outline, Cont'd.

MAJOR CONTENT AREA	TOPICS AREAS
2. RESEARCH STUDY IMPLEMENTATION - 45%	
(continued) a. Execute Research Strategy	Implementation of Standard Operating Procedures (SOPs) for:
	- IRB/IECs
	- Sponsors
	- Clinical Sites
	Requirements for documentation, reporting and maintenance of financial disclosure for clinical investigators including:
	- Form FDA 3454
	- Form FDA 3455
	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)
	Submission and review of protocol amendment(s)
	Regulatory requirements for submission of protocol amendment(s) to applicable authorities, IRB/IEC
b. Assure regulatory compliance	Comply with relevant local, state and provincial laws
	Comply with applicable privacy laws
	KNOWLEDGE OF:
	Regulatory requirements for confidentiality of a research subject's information
c. Manage research study product (e.g., treatment, procedure, medication, medical device, questionnaire)	Prepare research study product(s)
	Dispense research study product(s)
	Administer research study product(s)
	Store research study product(s)
	Verify research study product(s)' use
	KNOWLEDGE OF:
	Sponsor's roles and responsibilities for Investigational product accountability:
	- 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)
	Clinical Investigator's roles and responsibilities related to receipt and distribution of investigational product and other supplies at study site
	Regulatory requirements related to receipt and distribution of investigational product and other supplies at study site:
	- 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

Detailed CCRP® Examination Outline, Cont'd.

MAJOR CONTENT AREA	TOPICS AREAS
2. RESEARCH STUDY IMPLEMENTATION - 45%	
d. Identify, document & report research study anomalies	Identify, document & report protocol deviations/violations
	Identify, document & report unanticipated problems
	Identify, document & report unanticipated adverse events and adverse device effects
	Identify, document & report adverse events/effects
	Identify, document & report serious adverse events/effects
	Identify, document & report research misconduct
	KNOWLEDGE OF:
	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.
	Requirements for informing subjects of safety concerns and any relevant changes to the study
	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:
	- 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
	Documentation of serious adverse events/ serious adverse drug reactions, and unanticipated adverse device effects and relevant information in source documents and CRFs
	Regulatory requirements for reporting serious adverse event/ serious adverse drug reaction, and unanticipated adverse device effects to Sponsor/CRO and IRB/IEC
	Regulatory requirements for documenting reasons for subject discontinuation/ termination
	Regulatory requirements for documenting follow-up medical care for study subjects
	- Safety monitoring/reporting activities
	- Un-blinding
	Regulatory reporting and Medwatch [3500 and 3500A] requirements
	Identification and reporting of research misconduct:
	- Clinical Investigator Disqualification and debarment
	- Ethical concepts with foundation in:
	* Nuremberg Code
	* Belmont Report
	* Declaration of Helsinki
e. Manage subjects	Recruit subjects
	Evaluate subject eligibility
	Assess the capacity for consent of vulnerable populations
	Document subject eligibility
	Explain a research study methodology to subjects and associated family members and Caregivers
	Obtain informed consent

Detailed CCRP® Examination Outline, Cont'd.

MAJOR CONTENT AREA	TOPICS AREAS
2. RESEARCH STUDY IMPLEMENTATION - 45%	
(continued) e. Manage subjects	Obtain informed assent
	Document informed consent
	Document reasons for subject discontinuation
	Coordinate subject interactions with associated family members and caregivers
	Document subject and associated family members and caregiver interactions
	Communicate with subjects and associated family members and caregivers
	KNOWLEDGE OF:
	Regulatory requirements for IRB review and approval of subject requirement materials
	Subject Scheduling, Screening, Recruitment, and Retention including:
	- Recruitment plan/strategies (including regulatory requirements for recruitment materials)
	- Subject compliance
	- Subject visits
	- Subject retention
	- Subject discontinuation/ study termination
	Regulatory requirements and ethical concepts related to protection of vulnerable subjects
	- Children
	- Prisoners
	- Pregnant Women,
	- Human Fetuses and Neonates
	Regulatory requirements related to source documentation (paper/electronic) –completion and review of
	Source documentation and case report forms (CRFs) of subject participation in a study including:
	- Subject eligibility
	- Informed consent (e.g. vulnerable subjects, legally authorized representative, & 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)

Detailed CCRP® Examination Outline, Cont'd.

MAJOR CONTENT AREA	TOPICS AREAS
2. RESEARCH STUDY IMPLEMENTATION - 45%	
(continued) f. Maintain the research study	KNOWLEDGE OF:
	Regulatory requirements for maintenance and retention of study related essential documents, sources documents and equipment including:
	- 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
	Regulatory requirements related to clinical.trials.gov
	- Informed consent documents
	- Covered studies
	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)
	Knowledge of principles of Quality Assurance and Corrective and Preventive Action Plans (CAPA)
g. Communicate with research study stakeholders	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
	KNOWLEDGE OF:
	Regulatory requirements for communication with IRB/IEC, sponsor, investigational site and regulatory authorities including:
	- 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
	IRB/IEC communication with sponsor, clinical investigator and regulatory authorities
	Role and Responsibilities of Data Safety Monitoring Boards (DSMB)
	Regulatory requirements related to study documentation (paper/electronic) -completion/review. Development and maintenance of accurate, current and complete records relating to clinical studies.

Detailed CCRP® Examination Outline, Cont'd.

MAJOR CONTENT AREA	TOPICS AREAS
3. RESEARCH STUDY CLOSURE - 15%	
a. Perform / participate a research study closeout visit	KNOWLEDGE OF:
	Study closeout visit
	- Essential documents, verification of study documentation
	- Resolution of monitoring queries
	- Accountability of investigational product
b. 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
c. 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
	KNOWLEDGE OF:
	Regulatory requirements for development and submission of study closure reports to IRB/ IEC, sponsor and regulatory authorities:
	- Termination/discontinuation
	- Study completion
	Regulatory requirements related to clinical.trials.gov
	- Informed consent documents
	- Covered studies
	- Reporting
d. Archive / retrieve research study records	KNOWLEDGE OF:
	Regulatory requirements for maintenance and retention of study related essential documents, sources documents

Certification Program Eligibility

Eligibility

The certification committee 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 *equal to 3500 part-time hours	not required
Category 2	1 year of full-time experience* as a Clinical Research Professional within the past two years *equal to 1750 part-time hours	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 *equal to 1750 part-time hours	Undergraduate or Graduate Certificate** in "Clinical Research" AND Associate or Bachelor Degree in a science, health science, pharmacy or related field

**see Clinical Research Degree / Certificate Requirements

Work Experience

In order 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 / Certification 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 guideances.

- 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 the degree prior to applying for certification.
- Certificate programs must include a minimum of 12 semester (credit) hours (or minimum of 144 credit hours)

Choosing an Exam Site

The SOCRA CCRP® Exam is offered at SOCRA sponsored sites and at approved computer based testing centers

SOCRA sponsored exam sites	Computer based testing centers
Paper and Pencil Format	Computer Based Testing Centers (CBT) or home proctoring*
Prescheduled - see the exam calendar for dates and locations.	Over 700 computer based testing centers worldwide and you can schedule your exam at your convenience, Anytime, Anywhere.
See pages 24-27 for policies and procedures related to SOCRA sponsored exam sites.	See pages 28-29 for policies and procedures related to computer based testing centers.
Exam Fee: Member Rate: $395* Non-Member Rate $450* *includes complimentary SOCRA membership upon successful completion of the exam	Exam Fee plus additional $115 fee
Retest Fee = $200	Retest Fee = $275

* Candidate device must meet system requirements

SOCRA sponsored exam site - How to Apply

The application and all of the supporting documents must be included and forwarded to the SOCRA administrative offices a minimum of six weeks prior to the test date for US and Canadian exam locations or eight weeks prior to the desired test date for non- US/non- Canadian locations. Upon approval of the application, the applicant will receive a notice of approval and access to the Certification Program Reference Manual. Once the application is approved, fees are not refundable.

A complete application packet must be received by the deadline date as stated on the examination schedule. Applications received after the deadline will be considered for an alternate examination date designated by the applicant. The certification program is not responsible for lost or misdirected applications.

SOCRA sponsored exam site - Choosing an Exam Site /Date

- Select an exam date from the exam schedule on the website, www.socra.org/certification
- Register early. Applications received after the deadline will be considered for an alternate examination date designated by the applicant.
- Exam sites and dates are added throughout the year, and the online exam schedule is updated as exam sites are confirmed.
- Enrollment in specific exam venues may be limited due to room size and may require enrollment to be closed prior to the registration deadline. Therefore, please apply early to secure a space.
- Please do not book non-refundable travel prior to confirmation of enrollment.

SOCRA sponsored exam site - Application Deadlines

- Registration deadlines can be found on the exam schedule page of the website.
- All of the materials must be submitted a minimum of six weeks prior to the test date for US or Canadian exam locations or eight weeks prior to the test date for non-US/non-Canadian locations.
- Enrollment at specific exam venues may be limited due to room size, this may require enrollment to be closed prior to the registration deadline. Therefore, please apply early to secure a space.

SOCRA sponsored exam site - Application Fee (Payment Options)

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

Retest Fee = $200

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

Retest Fee = $200

Computer Based Test Center Application Procedure - How to Apply

The application and all of 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.

The certification program is not responsible for lost or misdirected applications.

Computer Based Test Center - Choosing a Location/Date

- Visit https://www.prometric.com/site-openings for a list of test centers
- You should apply to SOCRA 6 weeks prior to the date you wish to test. Choose Computer Based Testing on the CCRP® application under Testing Information, Exam Format for both test center or home proctoring.
- Allow 3-5 days for application processing. Once your application is approved, you will be able to schedule your exam at a testing center or at home via Pro-Proctor. Exam sessions are available at least 6 weeks in advance. You will have the best opportunity to schedule your preferred date if you schedule your exam date 4-6 weeks prior to your preferred date.

Computer Based Test Center - Application Fee (Payment Options)

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

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: ❖ 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	yes	n/a
	Applicant's transcript documenting graduation with an Associate's or Bachelor's Degree in a science, health science, pharmacy or related field.	n/a	yes	n/a
	Applicant's transcript documenting graduation with an Associate, Undergraduate, or Graduate degree in "Clinical Research."	n/a	yes	n/a
	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.

Clinical Investigators

For clinical investigators who are working independently, the following documentation may be submitted to show eligibility. This applies only to investigators named as the clinical investigator on FDA Form 1572, or a comparable Investigator Agreement.

This does NOT apply to sub-investigators.

	Description
Application Form	A completed certification application form (if applying online, this form is completed online)
Resume / CV	The applicant's resume or CV documenting their employment in clinical research.
Documentation of participation in at least five clinical trials over the past five years	Required documentation for each trial includes: ❖ 1572 or a comparable Investigator Agreement. ❖ IRB approval letter

Clinical Investigators

- ❖ Before submitting an application portfolio, applicants must review the eligibility requirements, application procedures, and certification program policies and procedures.
- ❖ The certification application may be downloaded by visiting the Application and Fee section of the SOCRA website.
- ❖ A complete application portfolio must be received by the deadline date as stated on the examination schedule. Applications received after the deadline will be considered for an alternate examination date designated by the applicant. SOCRA is not responsible for lost or misdirected applications.
- ❖ SOCRA will NOT be able to consider candidates who are unable to provide the requested supporting documentation regarding their experience in clinical research.
- ❖ The submitted application should be fully and legibly completed. Incomplete or illegible applications will not be accepted.
- ❖ Applications and corroborating documentation must be completed in the English language.
- ❖ Payment must accompany the application portfolio, in order for it to be reviewed.
- ❖ If payment is by personal or company check, the application packet and check must be mailed together and received by the SOCRA administrative office on or before the registration deadline.
- ❖ If submitting an application portfolio by e-mail, please combine the complete application packet into a single PDF attachment (including the completed application, payment and supporting documentation) and email to: certification@socra.org.
- ❖ If a candidate has a disability or a special need that prohibits them from taking the examination under standard conditions, please contact the SOCRA administrative office prior to submitting the application to confirm what documentation must accompany the application.

Application Review

- Applications will be reviewed within five business days of receipt.
- Applicants may be contacted by e-mail or phone if additional information is needed to complete their application.
- Enrollment is NOT confirmed until the application is complete and has been approved. Space will NOT be held for a specific exam site/ date for pending applicants.
- 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.

Computer Based Test Center - 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.
- 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, at a test center of their choice
- 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 exam, candidate will forfeit the $115 CBT fee.
- The applicant MUST bring photo ID in order to be admitted to the examination site.

Questions?

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

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

SOCRA sponsored site: If the applicant is unable to take the examination on the date specified, the applicant must email certification@socra.org that they will be unable to sit for the examination. The applicant will then have one year, from the originally scheduled examination date, to take the examination at another site. If the applicant fails to take the exam within that specified period, he/she will forfeit the examination fee and must submit a new application and fee when reapplying.

CBT Format: 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 the full $115 testing fee.

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.). Contact SOCRA by e-mail to confirm, certification@socra.org.
- No waiting period is required for retesting.
- 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 - $200 paper & pencil | $275 CBT

Appeals

All appeals must be sent in writing to SOCRA "Re: Certification Appeal" by e-mail at: certification@socra.org, mail: 530 West Butler Avenue, Suite 109 Chalfont, PA 18914 USA, or fax: (215) 822-8633

Preparing for the Exam

How to Prepare for the Examination

Content areas on the Examination that deal with topics concerning your daily job requirements should not require extensive study on your part; it is anticipated that this is part of your working knowledge. Content areas appearing on the Examination that are not part of your daily job requirements may require some research and study. For instance, if you do not deal with Institutional Review Boards (IRB), you will want to study the requirements of this aspect of clinical research. If you are from a country other than the United States, you will need to study the United States Federal Regulations concerning clinical trials. If you work in the United States, you will need to study the International Conference on Harmonisation (ICH) Guidelines. (Most of these guidelines cross national borders; however, this examination will relate specifically to United States federal regulations, and ICH guidelines.)

Please remember that the Examination assesses knowledge and understanding of the United States Code of Federal Regulations and the International Conference of Harmonisation (ICH) E6 & E2A Guidelines. It does not assess state, local, provincial, Ministry of Health, or institutional policy.

Explanation of Hierarchy of Federal Food, Drug, and Cosmetic Act vs. Regulations vs. Guidance

The Federal Food, Drug, and Cosmetic Act (FD&C Act) is United States (US) federal law enacted by Congress (statutory law). It and other federal laws establish the legal framework within which the US Food and Drug Administration (FDA) operates. The FD&C Act can be found in the United States Code (U.S.C), which contains all general and permanent U.S. laws, beginning at 21 U.S.C. 301.

The FDA develops regulations based on the laws set forth in the FD&C Act or other laws under which FDA operates. FDA follows the procedures required by the Administrative Procedure Act, another federal law, to issue FDA regulations. FDA regulations are also federal laws, but they are not part of the FD&C Act. The regulations are legally binding (administrative law).

FDA guidance describes the agency's current thinking on a regulatory issue. Guidance is not legally binding on the public or FDA. The Good Guidance Practice regulation can be found at 21 CFR 10.115

21 CFR 10.115 (b) What is a guidance document? (1) Guidance documents are documents prepared for FDA staff, applicants/sponsors, and the public that describe the agency's interpretation of or policy on a regulatory issue.

Please note: The examination assesses your knowledge and understanding of the FDA regulations. You will not be tested on FDA guidance. However, some of these documents published by the FDA may be helpful in explaining regulatory concepts.

Certification Reference Manual

The purpose of this reference manual is to help one prepare for the Examination. It is a resource to assist with preparation however; it is not an all-inclusive resource. See the Examination Content section of this handbook for a detailed description of the concepts included in the examination.

Additional Resources

Applicants are encouraged to consider information provided in applicable journal articles, textbooks, manuals, workshops, or meetings specific to clinical trials and investigational products.

Disclaimer: The additional resources listed below may be helpful for study. However, please take note of the publication dates, as these references may contain outdated material. Please remember that the Examination assesses knowledge and understanding of the United States Code of Federal Regulations and the International Conference of Harmonisation (ICH) E6 and E2A Guidelines.

The following is a list of additional resources that may be included in study:

- Guide to Clinical Trials, Spilker, B., (Lippencott-Raven Publishers, 1991)
- Foundation of Clinical Research, Center for Clinical Research Practice, Inc., (Center for Clinical Research
- Practice, Inc., 2001)
- Investigator's Handbook, Manual for Participation in Clinical Trials of Investigational Agents Sponsored by the Division of Cancer Treatments, National Cancer Institute (1986).
- http://ctep.cancer.gov/investigatorResources/ investigators_handbook.htm (Updated January 24, 2012)
- Protecting Study Volunteers in Research, Cynthia McGuire Dunn, M.D, Gary Chadwich, PharmD
- The CRC's Guide to Coordinating Clinical Research. Karen E. Woodin, Ph.D.
- Conducting Clinical Research, Judy Stone, MD.

The following is a list of websites that may be included in study:

- FDA Website: www.fda.gov
- CFR: www.ecfr.gov
- ICH Website: www.ich.org
- OHRP Website: www.hhs.gov/ohrp/
- Information Sheet Guidance for Institutional Review Boards (IRBs), Clinical Investigators, and Sponsors.

Website: www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/GuidancesInformationSheetsandNotices/ucm113709.htm (There have been new FDA Regulations enacted since the publication of these documents and the documents have not been updated to reflect the new regulations however, they may be helpful in clarifying concepts)

- 21 CFR Part 314- Applications for FDA Approval to Market a New Drug: www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=314
- 21 CFR Part 814- Premarket Approval of Medical Devices: www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=814
- CITI website: www.citiprogram.org
- NIH Protecting Human Research Participants Course: http://phrp.nihtraining.com

Sample Questions

The correct answers are **highlighted**.

1. A subject has been enrolled on a study and was randomized to the non-treatment arm. The protocol outlines study procedures for all subjects to be performed within one week of enrollment. Which of the following statements about this case is correct?

a. This subject does not need to undergo any of the study procedures since the subject is enrolled on the non-treatment arm

b. This subject should undergo all study procedures as outlined in the protocol

c. This subject only needs to undergo the study procedures that pertain specifically to the subject

d. This subject can undergo the study procedures whenever it is convenient

2. Informed consent documents must contain which of the following?

a. A description of the scientific background for conducting the investigation

b. An explanation of the purpose of the investigation

c. Contact information for the sponsor of the investigational drug/device

d. A description of the investigator's responsibilities

3. With respect to IRB/IEC membership, both the FDA and the ICH require that

a. A majority of the members' primary area of interest is in a scientific area

b. At least one member holds a Ph.D. degree or equivalent

c. At least one member's primary area of interest is in a nonscientific area

d. A majority of the members are from or have ties to the institution of record

4. Which of the following is the proper way to make a correction to a CRF?

a. Completely blacken the incorrect entry and then enter the correct information.

b. Back date the corrected entry with the date of the original entry

c. Initial using the initials of the sponsor's representative who reviewed the change

d. Add the initials of the person making the change, the date of the change, and, if necessary, a brief explanation of the change

5. A purpose of monitoring clinical trials is to verify that:

a. The rights, safety, and well-being of human subjects are protected

b. Investigators receive adequate payment for their participation in the clinical trial

c. The investigator has received annual reports from the sponsor

d. The regulatory agency has received all case history information of subjects enrolled on the clinical trial

CCRP Certification Program Policies and Procedures

Ethics Statement

As a clinical research professional, I recognize and affirm my responsibility to abide by the following basic ethical principles inherent in clinical research:

1. I will respect the human dignity of research participants with regard to self-determination and full disclosure of information throughout the research process.
2. I believe that research participants should be free from harm and exploitation in accordance with the risks and benefits of the research project.
3. I believe that research participants should have the right to receive fair and confidential treatment during the selection process and throughout the research project.
4. Additionally, I will be accountable for adhering to the standards for scientific integrity recognized around the world. This mandates honest, truthful behavior on behalf of myself and others with whom I deal while engaged in clinical research. I recognize my right and responsibility as a clinical research professional to question suspected falsified data, and if necessary, proceed with appropriate reporting procedures as mandated by the regulatory agencies.

Note: The ethical principles above are based upon the Office for Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research, Report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research.

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.

Confidentiality Statement

The SOCRA Certification Committee (the "Committee") will take all reasonable measures to ensure that any material, reports, proceedings, and/or hearings related to the certification process shall remain confidential between the Committee and the candidate except as required by law, authorized in writing by the candidate, or as otherwise provided in the Committee's Policies and Procedures.

Policy on Non-Discrimination

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

Special Needs / Disability Accommodation

The CCRP® certification program supports the intent of, and complies with the Americans with Disabilities Act ("ADA"). The certification committee will take steps reasonably necessary to make its assessment programs accessible to persons with disabilities covered by the ADA. An applicant may request a change in certification procedures or process due to a disability, handicap, or other reasons. Appropriate and effective modifications and/or auxiliary aides will be provided to persons with such disability, handicap, or other reason unless doing so would impose an undue burden on the certification program or fundamentally alter the measurement of skills or knowledge that the programs are intended to test.

The certification committee will make every effort to accommodate applicants with special needs. If the applicant has special physical or testing needs due to a disability, special need, or other reason, the applicant should attach a written request for accommodation with the certification application and at least six weeks in advance of the examination date. The written documentation should include a diagnosis or description of the disability or special need, the current level of functioning, and the requested accommodation. This statement must be written and signed by a qualified medical professional (preferably a physician) and should be submitted on the letterhead of the medical professional or their institution or organization.

All special arrangements must be made and agreed upon in advance; such arrangements cannot be made at the time an examination is given. The certification committee will make the final determination as to the necessary accommodations for an individual with a verified disability.

For individuals with physical, visual or learning disabilities requiring an extended test time, there is no accommodation for untimed testing. Time and a half (6 hours) is appropriate accommodation for most disabilities. Double time (8 hours) may only be granted in special circumstances with the recommendation of qualified professionals.

At this time, the certification program does not have an auditory examination for the visually impaired.

For those testing at a Computer Based Testing Center:

All examination centers are equipped to provide access in accordance with the Americans with Disabilities Act (ADA) of 1990, and every reasonable accommodation will be made in meeting a candidate's needs. Applicants with disabilities or those who would otherwise have difficulty taking the examination should review the candidate information bulletin for instructions or call our ADA Services Team at 1-800-733-9267 ext 6750 for further information.

CCRP Certification Program
SOCRA Sponsored Exam Site Policies and Procedures

What to Bring to the Exam - SOCRA sponsored exam

To be admitted to the test center, you must bring:

- Your verification letter
- One form of identification that bears your photograph and signature. Acceptable forms of ID may include; a driver's license, military ID, employee ID, or passport. The name listed on the ID must match your name as it appears on the verification letter.
- Three or four sharpened, soft lead (No. 2) pencils and a good eraser. Pencils and/or erasers will not be provided. Mechanical pencils are not recommended.
- If you feel noise could disturb your ability to take the exam, you are permitted to bring and use ear plugs. NOT head phones. Please present the ear plugs to the facilitator when signing in so they and the case they may be in can be checked.

We suggest that you dress in layers to adapt to fluctuating room temperature.

What NOT to Bring to the Exam SOCRA sponsored

- No study material will be permitted in the testing room.
- No food or drink will be allowed in the testing room.
- The use of electronic devices is strictly prohibited, including the use of calculators, cell phones, smart phones, smart watches, pagers, photographic devices and/or other electronic or communication devices.
- Visitors are not permitted in the testing room for any reason.

Please note: If you have a medical need that necessitates food or drink, use of a medical device, or other special accommodation during the exam, contact the certification department to discuss as soon as your application has been approved.

Before Entering the Test Center for SOCRA sponsored exam

Visit a restroom before checking in at the test center.

Candidates will be admitted to the test center only if their name is on the exam roster, and they present a valid verification letter and an appropriate photo ID.

Candidates should be sure to arrive by the registration time as indicated on the verification letter.

Any electronic devices (cell phone, electronic devices) must be turned off and stored on the floor under the candidate's seat (in a backpack/purse) in the test center.

Once the Exam Begins at SOCRA sponsored exam sites

The exam will be monitored by the facilitator for test security and fairness. The facilitator is NOT permitted to answer ANY questions.

No breaks are scheduled. Candidates will not be permitted to leave the exam room without the exam facilitator's permission. Lost time will not made up. If the candidate must leave the room to use the restroom, he/she is not permitted to take anything out of the room, including purses, cell phones, or any other personal item. Outside communication is strictly prohibited including use of cell phones, pagers, and/or other communication devices.

Candidates will have four hours to complete the examination. There is no penalty for incorrect answers; therefore, it is advantageous to answer every question. The facilitator will inform the candidate when there are 30 minutes remaining. At the end of four hours, the facilitator will collect any remaining exam materials.

No testing aides are permitted. Calculators, personal digital assistants (PDAs), smart phones, books, reference material, note paper and/or other aides are not permitted. Scratch work may be done in the margins of the examination booklet. The examination booklets may be utilized for any note taking or calculations.

All communication is prohibited during the examination including talking and use of cell phones, pagers, and/or other communication devices.

The examination facilitator may dismiss a candidate from the test center at any time for any of the following reasons:

- Creating a disturbance
- Using or attempting to use an electronic device or unauthorized testing aide
- Using any outside communication
- Giving or receiving help on the examination
- Failing to follow testing procedures and/or instructions
- Attempting to remove examination materials or notes from the test center
- Impersonating another candidate

Upon Completion of the Exam at SOCRA sponsored exam

Candidates must sign and return all examination materials including the exam booklet and answer sheet, and instruction packet. Candidates may leave once they have turned in all materials and the exam facilitator confirms that the sign out column of the exam roster has been signed appropriately.

Examination Results

Satisfactory completion of the CCRP® examination indicates that the applicant has attained the minimum level of education and experience required of a certified clinical research professional.

Exam Scores

The examination pass/fail score, or "cut score", is determined by a panel of experts and is validated by review of a psychometric testing analysis. In order to achieve a passing score, candidates must correctly answer 72 out of 100 scored questions. There is no penalty for incorrect answers.

Score Reports for SOCRA sponsored exam sites

Scoring of the examination is completed electronically by an independent testing agency. Examinations are batch processed, and score reports will be e-mailed approximately six weeks after an exam date.
Exam results will not be given out by phone or fax. SOCRA considers test scores to be confidential and will not publish or release this information to anyone other than the candidate.

In order to ensure the security of the CCRP® examination questions, specific questions and/or answers will not be disclosed.

Successful applicants will receive a CCRP® certificate approximately four weeks after the score report has been received.

SOCRA publishes a directory of certified clinical research professionals (CCRP®s) on the website www.socra.org.

This directory is updated monthly; however, due to scoring and reporting schedules, candidates who tested within the past two months may not be included.

Information published includes the name of the individual, city, state, country, certifications, and CCRP® expiration date.

If you do not wish to be included in this directory, contact the SOCRA administrative office: office@socra.org or 215-822-8644.

Exam Review

Candidates who do not achieve a passing score will receive an exam review with their score report. This review outlines the exam content areas where the candidate requires additional review prior to retesting.

Appeals

All appeals related to examination results must be sent in writing to SOCRA Re: Certification Appeal by e-mail to office@socra.org, mailed to 530 West Butler Avenue, Suite 109 Chalfont, PA 18914 USA, or faxed to: (215) 822-8633

CCRP Certification Program
Computer Based Testing Site Policies and Procedures

- **Candidate Admission Letter:** You MUST present this letter to the testing center in order to be admitted. Also, the Candidate UserID and Passcode printed above are required for you to login and start your examination.
- **Arriving for Your Appointment:** Please arrive at the testing center A MINIMUM OF |ArriveMinutes| MINUTES BEFORE YOUR APPOINTMENT TIME. If you have any doubts about the location of the testing center, IQT strongly recommends that you go to MapQuest and print out a map to the location; 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: Drivers 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.
- **Authorized Materials:** Only reference materials on the IQT Authorized Materials List are allowed in the testing room. For some testing programs, calculators and other tools are also allowed, and will appear on the IQT Authorized Materials List. Candidates are asked to bring as few items as possible to the testing area. If you have questions about what you are permitted to bring into the examination room please email IQT at CBT@isoqualitytesting.com. You may also call at 1-866-773-1114 (USA) or 1-727-733-1110 (International callers). Only those materials that the EXAMINATION SPONSORING AGENCY notifies IQT as authorized will be permitted by the Proctor.
- **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: writing on anything other than the IQT Authorized Scratch Paper provided to you, 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.

CCRP Certification Program
Computer Based Home Proctoring Policies and Procedures

Confidentiality of Exam Content/Systems
The remote proctoring application, computer-based test delivery system, tutorial, exam content, and survey are the published, confidential, and proprietary materials or intellectual property of Prometric and/or your test sponsor. Communicating, publishing, reproducing, or transmitting any part of an exam, in any form or by any means (e.g. verbal, electronic, written, etc.) for any purpose is strictly prohibited. ANY reproduction or disclosure will result in immediate notification to your test sponsor and potential filing of administrative, civil and/or criminal charges against you and anyone directing or conspiring with you.

Environmental Requirements
Your office or home setting must meet the following requirements:
- Testing location must be indoors (walled), well lit, with a closed door and free from background noise and disruptions.
- No third party may be present in the room or enter the room for the duration of the exam. If this occurs, your exam will 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, will be present during your exam session.
- Two tissues are permitted at workstation, but must be inspected by the Proctor prior to start of exam.

Check-In Procedures/Breaks
- Original, valid (unexpired), government issued photo & signature bearing identification is required in order to take an exam. Validity and the number of acceptable IDs are predetermined by your test sponsor.
- You will be required to show your workstation and surrounding area.
- You will be required to raise your pants legs above your ankles, empty and turn all pockets inside-out and raise shirt sleeves above your wrists prior to every entry into the online test.
- If you are wearing eyeglasses you will be required to remove them for visual inspection to ensure they don't contain a recording device. Large jewelry items must be removed from your person prior to and throughout the duration of the exam.
- If you have long hair that covers your ears, you will be asked to pull your hair back to ensure nothing is attached to your ear that could provide an unfair advantage (such as a Bluetooth earpiece).
- Leaving the camera view while the exam is in progress is strictly prohibited.

Prohibited Items and Examinee Conduct in the Virtual Test Center
- Unauthorized personal items may not be accessible while testing. Such items include, but are not limited to: outerwear, hats, food, drinks, purses, bags or briefcases, notebooks, watches, cell phones, electronic devices, or wearable technology.
- Eating, drinking, smoking, and chewing gum are prohibited during the exam. Written notes, published materials and other testing aids are strictly prohibited.
- Light clothing items removed for comfort such as sweaters, suit jackets, scarves, etc., must be hung on the examinee's chair, not placed in laps or on the workstation desktop. Outerwear such as heavy coats, parkas, rain coats, etc., is not permitted in the immediate testing area.
- Changing location while testing, turning off lighting or audio, speaking to or receiving aid from other individuals is strictly prohibited.

Upon Completion of the Exam via Computer Basted Testing

Candidates will receive their score report via email within one week of testing. Candidates who pass the examination will receive a certificate specifying that the credential has been awarded. The certificate will be mailed within 3-4 weeks of the examination.

Examination Results

Satisfactory completion of the CCRP® examination indicates that the applicant has attained the minimum level of knowledge and experience required of a certified clinical research professional.

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. In order to achieve a passing score, candidates must correctly answer 72 out of 100 scored questions.

There is no penalty for incorrect answers.

Score Reports CBT Exams

Score reports will be emailed within one week of testing.

Successful applicants will receive a CCRP® certificate approximately four weeks after the score report has been received.

Exam results will not be disclosed by phone or fax. SOCRA considers test scores to be confidential and will not publish or release this information to anyone other than the candidate.

In order to ensure the security of the CCRP® examination questions, specific questions and/or answers will not be discussed. SOCRA publishes a directory of certified clinical research professionals (CCRPs) on the SOCRA website, www.socra.org.

This directory is updated monthly; however, due to scoring and reporting schedules, candidates who tested within the past two months may not yet be included.

Information published includes the name of the individual, city, state, country, certifications, and CCRP® designation expiration date.

If you do not wish to be included in this directory, contact the SOCRA administrative office: office@socra.org or 215-822-8644.

Exam Review

Candidates who do not achieve a passing score will receive an exam review with their score report. This review outlines the exam content areas where the candidate requires additional review prior to retesting.

Appeals

All appeals must be sent in writing to the certification committee Re: Certification Appeal by e-mailing: office@socra.org, or mailing: 530 West Butler Avenue, Suite 109 Chalfont, PA 18914 USA, or faxing: (215) 822-8633.

Maintenance of Certification

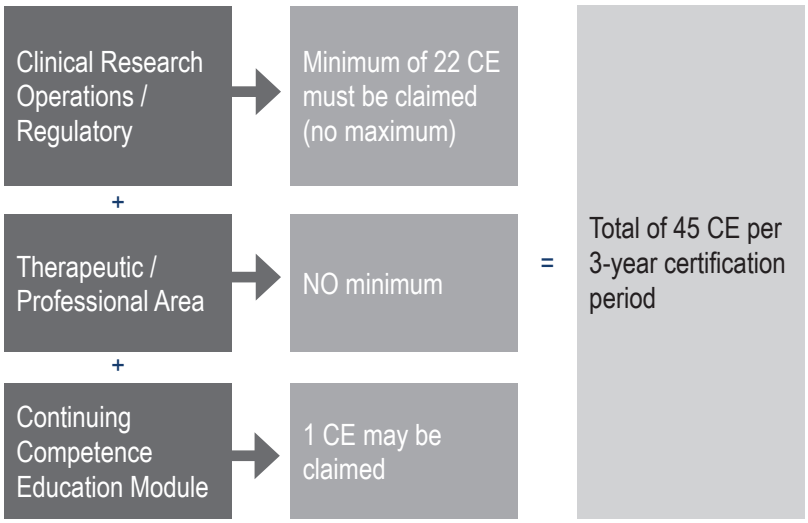
Term of Certification / Certification Period

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

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. **CE credit for work hours, and protocol specific SOPs may NOT be claimed.**



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.

Examples and Descriptions of Acceptable CE

Type of Activity	Description of Activity	Supporting Documentation Required (submit ONLY if audited)	Maximum CEU 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
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
Type of Activity	Description of Activity	Supporting Documentation Required (submit ONLY if audited)	Maximum CEU Allowed	
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

Examples and Descriptions of Acceptable CE, cont'd

Type of Activity	Description of Activity	Supporting Documentation Required (submit ONLY if audited)	Maximum CEU Allowed	
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) 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: recertification@SOCRA.org directed to the attention of the Certification Committee. More information can be found on the SOCRA website at www.SOCRA.org/html/recertif.htm .

Recertification / Renewal of Certification

In order to maintain active certification status, the CCRP® must apply for renewal of certification, to the Certification Committee, every three years. Those wishing to renew their CCRP® certification after three years 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 re-certification 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 a self-administered online regulatory learning module that will be included in the recertification packet sent to each member due for recertification, AND
- Submission of the recertification processing fee in U.S. Funds to the SOCRA administrative office.

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 of 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

All appeals must be sent in writing to SOCRA “Re: Certification Appeal” by e-mail:
certification@socra.org, mailed to 530 West Butler Avenue, Suite 109 Chalfont, PA 18914 USA,
or fax: (215) 822-8633.

Important Reminders

Paper and Pencil Format at SOCRA Sponsored Sites

- Register early. Applications received after the deadline will be considered for an alternate examination date designated by the applicant. Fill out the application completely and legibly. Applications that are incomplete or illegible will not be accepted.
- Enclose payment with the application. If an employer is paying the fee, please obtain the check from them to include with the application. This will prevent rejection of the application because of late payment. Applications and corroborating documentation must be completed in the English language.
- Requests for special accommodations must be made in writing to the Certification Committee. If a candidate has a disability 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.
- Once an application has been approved and payment has been processed, the candidate will receive a letter acknowledging acceptance along with access to the CCRP® Certification Program Reference Manual. Approximately two weeks prior to the examination, a verification letter will be sent that confirms approval to take the examination, the examination time, date and location. This letter must be presented to the facilitator for admission to the test site along with a picture ID card (driver's license, employee badge, etc.). (Driver's license is suggested)
- Arrive a minimum of 20 minutes prior to the exam start time for check in, as indicated on the verification letter, you may not be admitted to the test site after the door has been closed.

CBT Format at Testing Center

-
- 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.
- 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, at a test center of their choice
- 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 exam, candidate will forfeit the $115 CBT fee.
- The applicant MUST bring photo ID in order to be admitted to the examination site.
- Arrive a minimum of 30 minutes prior to the exam start time for check in as stated in the CCRP Candidate Approval Letter
- 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 the full $115 testing fee.

200804