



## SOCIETY OF CLINICAL RESEARCH ASSOCIATES

### CERTIFICATION PROGRAM FOR CLINICAL RESEARCH PROFESSIONALS

The Society of Clinical Research Associates proudly announces the Certification Program for Clinical Research Professionals. This brochure contains information concerning this program, and certification application instructions. Applicants are those individuals with two or more years' experience in clinical research or those having completed specific degree work and/or having completed appropriate course work. Individuals meeting all of the eligibility and application requirements will be required to successfully complete a written examination.

#### STATEMENT OF PURPOSE

SoCRA established the Certification Program for Clinical Research Professionals in order to create an internationally accepted standard of knowledge, education, and experience by which clinical research professionals will be recognized by the health care research community. Those individuals so approved may use the title "Certified Clinical Research Professional" or "C.C.R.P."

#### ELIGIBILITY

The applicant must be a current member of SoCRA working with GCP guidelines under IRB/EC/REB approved (or specifically exempted) protocols.

The applicant must meet one of the following criteria:

1. Have two years of experience as a full-time Clinical Research Professional (or have 3500 hours part time) during the last five years, **OR**
2. Hold an Associate's Degree or Bachelor's Degree in *Clinical Research*, **AND** have 1 year of full-time experience (or 1750 hours part-time) during the last two years in an area of clinical research, **OR**
3. Hold a Certificate of Completion from an Undergraduate or Graduate *Clinical Research* curriculum of no less than 12 semester (credit) hours at an academically accredited institution of higher learning (community college, college or university) **AND** hold an Associate's Degree or a Bachelor's Degree in science, health science, pharmacy or a related field **PLUS** have 1 year of full-time experience (or 1750 hours part time) during the past two years in an area of clinical research.

#### DEFINITION OF A CLINICAL RESEARCH PROFESSIONAL

A Clinical Research Professional functions as a clinical investigator, sub-investigator, clinical researcher, research nurse, administrator, coordinator, consultant, or educator in clinical trial management. A Clinical Research Professional is involved in one or more aspects of clinical trials (GCP) research, including data collection, analysis, or monitoring; case management of protocol participants; recruitment and enrollment of human subjects; protection of subjects and subjects' rights through IRB relations; development of informed consents; preparation of adverse event experience reports; construction or monitoring of case report forms; maintenance of drug accountability records; grant and budget development; report preparation; education of other health-care professionals, patients or families regarding clinical trials, protocol development, program administration; and research program audit.

#### EXAMINATION CONTENT

The certification examination is made up of five major subject areas, which are listed on the examination outline. Each major area will be included in each examination, but specific questions will vary from one examination date to another. The percentage of questions from each area will change slightly from one examination to another, with each question equivalent in weight. The Certification Committee will revise this examination at least annually following a regularly scheduled review.

#### TERM OF CERTIFICATION

The CCRP (SoCRA) is awarded for three years to continuing members of SoCRA. Renewal after three years requires 45 hours of validated continuing education credit, completion of a re-certification quiz, a re-certification fee (which at this time is \$100), and consecutive years' membership in SoCRA.

**Falsification** or misrepresentation of application information will invalidate the applicant's certification.

# THE SoCRA CCRP CERTIFICATION EXAMINATION

## Examination Development

The certification examination has been developed by SoCRA's Certification Committee and designated members who have demonstrated expertise in the development, management, and administration of clinical trials. Test questions have been written by Clinical Research Professionals from diverse backgrounds and job descriptions. The examination is intended to evaluate the applicant's level of knowledge and skill in comparison to the demands on a Clinical Research Professional as they are found in clinical practice.

Unlike many certifying organizations in the health-care field, SoCRA's membership is made up of individuals with a wide variety of backgrounds and job descriptions. Much of the training required of a Clinical Research Professional is specific to the institution and discipline in which they are employed. It would be impossible to develop one examination that would measure a level of expertise for each specific area in the health-care field. Satisfactory completion of the SoCRA Certification Examination indicates that the applicant has attained the minimum level of education and experience required of a Clinical Research Professional.

The world of clinical research is a constantly changing work environment for the Clinical Research Professional. For that reason, the Certification Program and the certification examinations will be a continually evolving project, which will be directed by the needs of the membership.

## SoCRA Examination Outline

### **Conduct of Clinical Trials**

- Sponsors, CROs and research bases
- General CFR and ICH
- Study design, trial phases, blinding
- General study conduct for investigational drugs, devices, therapies and procedures
- Protocol development and amendments/ Investigator Brochure
- Record retention
- Adverse events, Serious adverse drug experiences (including reporting requirements)
- Monitoring, Quality Assurance and GCP (including source documentation)
- Grants and funding
- Forms completion (FDA form 1571, 1572, 3454, 3455, 3500, 3500A)
- Responsibilities and obligations
- Reporting requirements (annual reports, protocol changes, adverse events)
- Investigational drug accountability
- Investigational New Drug application (IND) and New Drug Applications (NDA)

### **Institutional Review Boards and Regulations**

- Membership
- Responsibilities and other regulations
- Records retention

### **Ethical Issues**

- FDA regulations and ICH guidelines
- Ethical codes and doctrines
- Elements of informed consent
- Disclosure of clinical information

### **Conduct of Clinical Trials• OHRP**

### ***Ability to follow directions***

- This portion of the exam will ask questions involving test schedules and dose modifications.

### **Abstracting Information From Medical Records**

- This portion of the examination is a practical examination, including; common mathematical calculations, reading clinical reports and clinical records, and reviewing eligibility criteria.

## **Applicants Having Special Needs**

Applicants having special needs should contact the SoCRA office to discuss testing requirements for persons with physical, sensory or learning disabilities.

## **Certification Preparation and Review Course**

This one-day course is offered three times annually. Please see our web site at [www.socra.org](http://www.socra.org) and click on "Courses," You may schedule a course at your facility if you can guarantee a minimum of 20 attendees. Call the office at 1-800-762-7292 for details.

## SoCRA Certification Examination Sample Questions

- Q1.** Informed consent documents must include the following:
- A statement that the study involves research.
  - A statement of the possible risks.
  - A discussion of possible alternative treatments.
  - All of the above.**
- Q2.** Responsibility for the participant's safety lies with:
- The sponsor
  - The investigator**
  - The IRB
- Q3.** Which of the following would generally indicate the breaking of a randomization code in a blinded study?
- The participant withdraws from the study before its conclusion.
  - Participants in only one of the investigating sites show any definite response to treatment.
  - A participant experiences a serious adverse experience, the etiology of which cannot be explained.**
  - None of the above.
- Q4.** The responsibility for ensuring that the investigator Understands a clinical trial lies with:
- The FDA
  - The IRB
  - The Sponsor**
  - None of the above

### Background Information

Clinical Research Professionals come from a wide variety of backgrounds with even more varied job descriptions. Some Clinical Research Professionals are MDs, while other are RNs, some may have a degree in health care technology, business administration, health information management, statistics, biology, teaching, or other areas. Every one of these backgrounds brings special areas of expertise to the clinical research field. Much of our training has come after our employment as a Clinical Research Professional. Every institution and discipline has unique requirements.

The examination must be based on those areas that are common to all Clinical Research Professionals. It must, out of necessity, be a basic examination. Questions are formulated to be straight -forward and easily understood.

Items on the examination outline that you deal with on a daily basis should not require extensive study on your part; it is anticipated that this is part of your working knowledge. Areas of the outline 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, 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 want to study the United States Federal Regulations concerning trials. (Most of these regulations cross national borders; however, this examination will relate specifically to United States federal regulations.)

SoCRA has a Study Guide to help you prepare for the examination. This guide consists of:

- 21 Code of Federal Regulations – Parts 11, 50, 56, 312, 812
- 45 Code of Federal Regulations- Part 46
- Sample regulatory forms from FDA
- The Nuremberg Code
- The Belmont Report
- Declaration of Helsinki
- Health Canada Information
- FDA Information Sheets for Clinical Investigators
- ICH GCP Guideline for Good Clinical Practice (E6)
- ICH Clinical Safety Data Management: Definitions and Standards for Expedited Reporting

The study guide will be included as part of your package upon registration for the examination. The study guide is also available for purchase at a cost of \$50.00 (U.S. Funds).

# SoCRA CCRP Certification Application

A completed Certification Application Portfolio must be forwarded to the SoCRA administrative office a minimum of six weeks prior to the test date. Upon approval, the applicant will receive a letter of acceptance and a copy of the SoCRA Certification Study Guide. Fees are refunded only if the application is unsuccessful. Please see [www.socra.org/html/certific.htm](http://www.socra.org/html/certific.htm) for more information on SoCRA CCRP certification. The CCRP credential is awarded in three year increments. Continuous membership in SoCRA is required to maintain the CCRP credential. Those wishing to renew their CCRP certification after three years must successfully complete a re-certification quiz and provide documentation of 45 hours of validated continuing education credit. The fee for re-certification is currently \$100. Please see [www.socra.org/html/recertif.htm](http://www.socra.org/html/recertif.htm) for more information.

**ELIGIBILITY CATEGORIES - Review the statements below.** In order to be considered for SoCRA certification, your experience must fall under one of the eligibility categories listed below. If you are unable to document your experience, SoCRA will not be able to consider your application. **Please select (check ✓): #1 or #2 or #3**

- 1.** Candidates having completed a **minimum of 2 years of full time employment** (or 3500 hours of part-time employment) during the past five years as a clinical research professional.
- 2.** Candidates holding a **degree in "Clinical Research"** from an Associate, Undergraduate or Graduate Degree Program **AND** having completed a **minimum of one year of full-time experience** (or 1750 hours part-time) during the past two years as a Clinical Research Professional. (Note: Requires Form 1011)
- 3.** Candidates holding an **Undergraduate or Graduate Certificate in "Clinical Research"** with a curriculum of no less than 12 semester (credit) hours or totaling a minimum of 144 credit hours from an academic institution of higher learning (community college, college or university) **AND** holding an **Associate's or Bachelor's Degree in a science, health science, pharmacy or related field** **AND** having completed a minimum of **one year of full-time experience** (or 1750 hours part-time) during the past two years as a Clinical Research Professional. (Note: Requires Form 1022)

**APPLICATION PORTFOLIO IMPORTANT:** In order to be considered for SoCRA certification, you must complete ALL fields below and provide ALL supporting documentation requested below. If you have questions regarding your eligibility, please contact the SoCRA office. Applications with discrepancies in employment documentation will not be approved.

Please Check  once completed

**Verification of Employment-** Include signed/dated letter(s) on institutional letterhead documenting the minimum work experience for your eligibility category. Include letters from EACH employer (supervisor or human resources) documenting EACH position. If required experience spans multiple positions and/or employers, multiple letters will be required.

Letters must include: - All position title(s) applying toward your eligibility  
- Corresponding dates of employment for each position title  
- Full-time or Part-time status for each position title (Include the number of hours/percentage of time worked in clinical research related duties for each position title)

**Job Description(s)** - Include the official job description issued by your employer/institution for EACH position title documented in your letter(s) of reference.

**Form 1011** - Only complete if applying under Eligibility Category #2. Find this form at [www.socra.org/html/certific.htm](http://www.socra.org/html/certific.htm)

**Form 1022** - Only complete if applying under Eligibility Category #3. Find this form at [www.socra.org/html/certific.htm](http://www.socra.org/html/certific.htm)

**Resume or Curriculum Vitae** - Attach a current version of your Resume or Curriculum Vitae (CV) documenting all relevant employment experience and educational accomplishments.

**Membership in SoCRA** - Indicate your SoCRA membership ID here \_\_\_\_\_, or write "applied for" if you've recently applied for membership, or attach a completed membership application (see [www.socra.org/html/membersh.htm](http://www.socra.org/html/membersh.htm)).

## TESTING INFORMATION

**Requested Date/Location/Time** \_\_\_\_\_ **Language**  English  French (if offered)  Japanese (if offered)

\*\*Applicants having special testing needs should contact the SoCRA office to discuss testing requirements for persons with physical, sensory, or learning disabilities. Please list your needs \_\_\_\_\_

## CANDIDATE INFORMATION

First Name \_\_\_\_\_ Last Name \_\_\_\_\_

Email Address \_\_\_\_\_ Phone Number \_\_\_\_\_

**\*\*I attest that the information provided is accurate and understand that falsification or misrepresentation of my application information will invalidate my certification status.\*\***

Candidate Signature \_\_\_\_\_ Date \_\_\_\_\_ (MM/DD/YY)

**PAYMENT** - SoCRA is a non-profit (membership organization) corporation, Federal Tax ID # 61-1208981

Application Fee: **\$195.00** (payable to SoCRA in U.S. Funds) **Check #** \_\_\_\_\_ or **VISA** \_\_\_ **M/C** \_\_\_ **AMEX** \_\_\_

Account # \_\_\_\_\_ Exp. Date \_\_\_ / \_\_\_

Cardholder Printed Name \_\_\_\_\_ Billing Zip Code \_\_\_\_\_

Cardholder Signature \_\_\_\_\_

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