To Certify or Not to Certify
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We have no financial relationships to disclose.

Clinical Research Professional
• Definition:
  One who is involved in one or more aspects of clinical trials research.
  i.e.: Data collection, data analysis, case management of protocol, subject recruitment,
  human subject protection, informed consent development, adverse event reporting,
  construction and monitoring of CRF’s, drug/device accountability, protocol
devvelopment, budget development, site monitoring/auditing, education of health-care
professionals, report preparation, IRB relations, etc.

Clinical Research Professional
• Role Description:
  ■Can be described as: administrator, coordinator, educator, and/or researcher in the management
  of clinical trials.
  ■Hold a wide range of roles and responsibilities.

Who is a Clinical Research Professional?
• George Washington University survey study:
  ■CRP is likely from a healthcare background.
  ■Work as part of a team.
  ■Driven by the opportunity to advance scientific discovery.
  ■To improve peoples lives.

Historical Model of Research
• A self-contained business unit for managing clinical studies. (i.e. it was the sponsor, the investigator in one site)
• Far less complex studies
• Far fewer regulatory requirements.
**Present Role**

- Increasingly complex trials.
- Ever increasing regulatory requirements.
- Multi-site.
- Ever expanding globalization.
- Academic or private institutions.
- Corporate – pharmacy, device and biotechnology.
- CRO – Contract Research Organizations.

**CRP Backgrounds**

- Come from varying backgrounds:
  - Nursing
  - Pharmacy
  - Medical Technology
  - Business administration
  - Health records maintenance
  - Statistics
  - Biology
  - Teaching
  - Other areas

**Training and Education Requirements**

- No education requirements.
  - No undergraduate degree programs.
  - Few Certificate programs.
  - Few graduate programs.
- No training requirements.
  - Most training comes from "on the job" or "baptism by fire" training.

**Anoka Ramsey Clinical Research Professional Certificate Program.**

- The Clinical Research Professional Certificate program is designed for students with a degree in nursing, pharmacology, or biological sciences who desire to move into clinical research positions in biomedical or other health-related companies.
- Admission requirement:
  - Baccalaureate degree in pharmacology, biology or a related field or have completed RN (AS, AD, BSN) degree.

**Program Goals:**

By completing this certificate, students will achieve the following learning goals:

1) explain the steps in the research process;
2) describe the process for data collection and documentation;
3) demonstrate an understanding of applicable regulations for conducting clinical trials in the US and other countries; and
4) describe the elements of Good Manufacturing Practices (cGMP) and Good Clinical Practices (cGCP); and,
5) understand and demonstrate components of clinical research protocol.

**Is there a need to be certified?**

- Clinical research professional holds a pivotal role in the execution of studies.
- Can significantly affect the trial outcome.
- Can significantly affect the data that is captured.
- Can affect the patient safety and well-being.
## Value of Certification

1. **Credibility.** - Impartial 3rd party endorsement of knowledge and experience. Sets you apart from other professionals.
2. **Enhances skills and knowledge.** - Certification requires training, studying and keeping up-to-date with changes. Requires re-certification.
3. **Validation.** - Provides evidence of experience and qualifications to the FDA and other regulatory bodies during inspections.
4. **Accomplishment.** - Validates your skill set by meeting internationally recognized standards.
5. **Demonstrates your engagement.** - Shows your commitment to your career and to higher standards.
6. **Increases on-the-job responsibilities.** An indicator of your willingness to invest in your own development.
7. **Improves career opportunities and Advancement.** Identifies you as one who has demonstrated proficiency of accepted research principals, techniques and applications of best practices.
8. **Earnings potential.** - Many experience salary and wage increases and are in high demand and recruited aggressively.

## Why Certification

- **ACRP website states:**
  "Certification can serve several purposes from providing evidence of experience and qualification of a research team to the FDA or other regulatory bodies during inspections to validating competency when considering a new employee."

## Retrospective Study

"...formal training and Certification of investigators and clinical research coordinators in GCP has the potential to increase protocol adherence and improve clinical trial quality."


## Certification Eligibility
ACRP Certification Exam Eligibility

- ACRP certifies on the basis of job function.
- Different exam for CRC and CRA

ACRP CCRC Exam Eligibility

- Clinical Research Coordinator (CRC) works at a clinical site under direction of PI.
- Academic qualification and practical work experience:
  - Option 1:
    - Associate/Bachelor's degree or RN
    - Work Experience performing the essential duties of a CRC: 3,000 hours
  - Option 2:
    - Other (e.g., LPN, LVN, Medical Assistant, Lab Technician, H.S. diploma)
    - Work Experience performing the essential duties of a CRC: 4,500 hours

ACRP CCRA Exam Eligibility

- To be eligible to take the CRC exam, the following duties are considered essential:
  - Participating in conducting subject visits
  - Collecting data directly from subjects
  - Completing Case Report Forms (CRFs)
  - Maintaining source documents

ACRP CCRA Exam Eligibility

- Clinical Research Associate (CRA) supervises, monitors, and supports the administration and progress of a clinical trial on behalf of a sponsor, whether from a field monitoring or in-house monitoring perspective.
  - Option 1:
    - Master's or Bachelor's degree or RN
    - Work Experience performing the essential duties of a CRA: 3,000 hours
  - Option 2:
    - Associate's degree
    - Work Experience performing the essential duties of a CRA: 4,500 hours
  - Option 3:
    - Other (e.g., LPN, LVN, Medical Assistant, H.S. diploma)
    - Work Experience performing the essential duties of a CRA: 6,000 hours

Substitution of Clinical Research Education

- If an applicant has completed an education program in clinical research from an accredited institution this may be used to substitute for 1,500 hours of the work experience
  - Content that substantially maps to the essential duties of a CRC or CRA
  - Consisting of at least 216 contact hours
- In all cases, a minimum of 1,500 hours of work experience performing the essential duties is required.
### ACRP Exam Content
- All exams have specific core requirements of Good Clinical Practices as identified by the International Conference on Harmonization guidelines:
  - ICH Clinical Safety Data Management: Definitions and Standards for Expedited Reporting (E2A)
  - ICH General Considerations for Clinical Trials (E8)
  - Declaration of Helsinki

### CCRC Exam Content
- Protocol Evaluation
- Site Preparation and Initiation
- Investigational Product Accountability
- Laboratory and Diagnostic Issues
- Safety/Adverse Events
- Subject Recruitment/Informed Consent
- Case Report Forms
- Source Documentation

www.acrpn.org/PDF/CRC_Guide.pdf

### CCRA Exam Content
- Protocol Development
- Design of Case Report Forms
- Site Initiation
- Study Monitoring
- Data Management
- Study Close-out

www.acrpn.org/PDF/CRA_Guide.pdf

### Certification Exam Eligibility
**SoCRA**
- Determined by academic qualification and practical work experience.
- SoCRA Membership.
- Category 1: 2 yrs full time employment during the past five years.
- Category 2: Hold a degree in "Clinical Research" and completed 1yr full time work during past 2 yrs.
- Category 3: Certificate in "Clinical Research" and A.A. or B.A degree in science, health science, pharmacy or related field plus 1yr full time work.

### SoCRA Exam Content
- Exam is intended to create an internationally accepted level of knowledge, education, and experience.
- Exam was developed to test the knowledge of a standard core of competencies to reflect the basic knowledge as required by research professionals.

### Basic Core Competencies
- 5% - Foundations and principals of clinical research ethics.
- 20% - Laws, regulations and standard operating procedures.
- 15% - Responsibilities of sponsors, monitors and PI according to the principals of the ICH, GCP and FDA regulations.
- 15% - Regulations for Informed consent, IRB's, and financial disclosure.
- 15% - Principals of study design, study closure and record retention.
- 5% - Application of safety reporting requirements.
- 25% - Ability to utilize critical thinking skills in practical applications.
Good Clinical Practices

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

Exam Outline

- Conduct of Clinical Trials
  - Sponsors and research bases
  - Funding
  - Study design, trial phases, blinding
  - Protocol development
  - Protocol amendments
  - Investigational drugs, devices, therapies, and procedures
  - Record retention
  - Adverse events
  - Monitoring and quality assurance
  - Informed consent
  - Grants and funding
  - Forms completion and monitoring
  - Audits and site visits

Exam Outline

- Institutional Review Boards and Regulations
  - IRB membership
  - Reporting requirements (annual reports, protocol changes, and adverse events)
  - Clinical Drug Requests
  - Federal Drug Administration statement of Investigator (FDA 1571/1572)
  - Investigational drug accountability
  - Investigational New Drug, New Drug Application

Exam Outline

- Ethical Issues
  - Element of Informed Consent
  - Clinical Fraud
  - Disclosure of Clinical Information
  - FDA & ICH Guidelines on Research

Exam Outline

- Ability to Follow Directions
  - This portion of the examination will ask questions involving test schedules and dose modifications. There will also be questions directly related to your ability to follow directions.

Exam Outline

- Abstracting Information from Medical Records
  - This portion of the examination is a practical examination, including common mathematical calculations, reading clinical reports, and reading medical records.
Value of Certification

“…Formal training and certification of investigators and clinical research coordinators in GCP has the potential to increase protocol adherence and improve clinical trial quality.”


Feedback from the industry is clear. Certification is invaluable.

SoCRA

- Clinical Science Courses – Exam Prep course
  - 5 day course - 2 modules
    - Module I - a 3 day course
      - Regulatory/Procedural Module
        - Member $750  non-Member $825
    - Module II - a 2 day course
      - Medical/Scientific Module
        - Member $600  non-Member $675

Certification Qualification

Exam Certification Information:
- Association of Clinical Research Professionals
  - ACRP  Website: acrpnet.org
    - Exam fees: Member CRA = $648, CRC = $612
  - Society of Clinical Research Associates
    - SoCRA  Website: socra.org
    - Exam Fees: Member = $195

ACRP

- Fundamentals of Clinical Research
  - 2 day course
  - Provides core knowledge and skills that a clinical research professional needs in order to better execute their functions.
    - Member $930
    - non-Member $1110

Continuing Education

- Both SoCRA and ACRP require current membership.
- Both organizations require continuing education credits to maintain certification status.
  - ACRP – 24 CEUs every 2 years
  - SoCRA – 45 CEUs every 3 years and completion of re-certification quiz
- At least half of CEUs must be in clinical research topics
Continuing Education
- Both SoCRA and ACRP offer continuing education programs ranging from webinars to 2-3 day seminars.
- Both SoCRA and ACRP have annual conventions.
- Both organizations also offer CEUs via webinars, journal articles, and local chapters.

Local Chapters

Global Chapters

Local ACRP Chapter Event Tonight
- Recent Monitoring Guidance from the FDA
  - This work session will review THREE recent releases from the FDA about Monitoring.
    - "Compliance Program Guidance Manual" for BIMO inspectors
    - "CHAPTER 48 – Bioresearch Monitoring" (CPGM 7348.810 for sponsors, CROs and monitors and CPGM 7348.811 for clinical investigators and sponsor-investigators) for foods, biologics, drugs and devices which was implemented on March 11, 2011
    - "Guidance for Industry: Oversight of Clinical Investigations – A Risk-Based Approach to Monitoring" which was released August, 2011 to enhance human subject protection and the quality of clinical trial data.
  - 2.0 Contact Hours have been approved by ACRP

Questions?