CLINICAL RESEARCH CERTIFICATION: IS IT FOR YOU?

What, Why, How and When?

Noreen L Connolly, MS, JD, CCRC Senior Health Project Coordinator Dept of Neurology/Epilepsy University of Rochester noreen_connolly@urmc.Rochester.edu

AGENDA

- ▶ What is certification?
- ▶ Why be certified?
- ▶ What do I need to be ACRP-certified?
- ▶ How do I become ACRP-certified?
- ▶ When do I have to renew my certification?
- ► ACRP Membership Benefits/Chapters
- **► ACRP Conferences**

What is Certification?

GOLD STANDARD OF PROFESSIONALISM [IN CLINICAL RESEARCH]

PURPOSE OF PROFESSIONAL CERTIFICATION?

>To protect the public

To guarantee that a person who holds the credential has met a minimum standard for professional and ethical standards

WHY Should I Get My Certification?

CLINICAL RESEARCH CERTIFICATION SHOWS THAT YOU:

► Have met standards that have been established and verified by a third-party organization

Are dedicated to maintaining quality and competency in your work

CERTIFICATION HELPS EMPLOYERS

- ▶ Evaluate potential new hires
- Analyze job performance
- ► Evaluate employees
- ► Select contractors
- ▶ Market services

5 REASONS TO GET CERTIFIED

- ▶ You'll be ahead of the competition
- ► You'll qualify for jobs with employers that set the highest standards
- ▶ You can expand your scope of practice
- ▶ You can increase your earning potential
- ► You'll build your reputation in your professional field

HOW DO I BECOME CERTIFIED?

Certifying organizations:

- **ACRP**
- ► SoCRA

Association of Clinical Research Professionals

ACRP

Since 1981 over 33,000 professionals and organizations around the world have been ACRP Certified

Mission is to promote excellence in clinical research.

Vision that clinical research is performed ethically, responsibly, and professionally everywhere in the world

ACRP: MULTIPLE CERTIFICATIONS

- ► Clinical Research Coordinator (CCRC)
- ► Clinical Research Associate (CCRA)
- ► Principal Investigator (CPI)
- ► ACRP Certified Professional (ACRP-CP)
- ► ACRP Medical Device Professional Subspecialty (ACRP-MDP)
- ► ACRP Project Manager Subspecialty (ACRP-PM)

CLINICAL RESEARCH COORDINATOR

The CCRC® credential is awarded to a CRC who has passed the standardized ACRP CCRC Certification exam

- ► ACRP offers exam twice a year: https://acrpnet.org/
 - Spring (around February to March) and Fall (around September to October)

WHAT'S NEXT?

- ▶ Verify eligibility before applying for the ACRP CCRC exam
- ► Apply to take Exam/Pay Fees
- ▶ Prepare for exam
- ► Maintain certification
- https://acrpnet.org/certifications/

AM I ELIGIBLE TO BECOME A CCRC®?

- ► In order to be deemed Eligible to take the CCRC® exam, applicants for the CCRC® credential must be able to provide evidence through a job description, detailed CV or other documentation that shows:
- ▶ 3,000-6,000 hours spent performing all of the CRC essential duties* for a required minimum number of hours.
- ► Hours performing the CRC essential duties can include hours documented up to the date of the exam and/or through previous employment. The required number of hours is dependent upon one's educational background.
- ► The <u>CRC Certification Handbook</u> has complete information on eligibility requirements.

^{*}Essential duties

CRC CERTIFICATION MUST DOCUMENT CUMULATIVE PERFORMANCE OF EACH OF THE FOLLOWING ESSENTIAL DUTIES DURING THE DATES OF EMPLOYMENT LISTED ON THE APPLICATION:

- Report and document safety issues (e.g. adverse events);
- ► Participate in the preparation or review of documents exchanged with the institutional review board (IRB);
- Participate in protocol review or study procedures planning;
- Participate in conducting subject visits;
- ► Collect accurate, verifiable data, source documents, and essential documents;
- Prepare for and participate in sponsor audits and/or regulatory inspections, if applicable;
- ▶ Participate in the informed consent process.

THREE ELIGIBILITY REQUIREMENT OPTIONS FOR THE CCRC® PROGRAM – MUST MEET AT LEAST ONE OPTION

Option 1: Bachelor's Degree (or higher)

- ► Minimum Hours Performing Essential Duties: 3,000 hours*
- Required Documentation of Performed Essential Duties:
 Detailed CV/resume and job description

* Substitution for Work Experience

OPTION 2 - CCRC EXAM ELIGIBILITY

Option 2: Associate's Degree or RN, LPN, LVN

- ► Minimum Hours Performing Essential Duties: 4,500 hours*
- Required Documentation of Performed Essential Duties: Detailed CV/resume and job description

^{*} Substitution for Work Experience

OPTION 3 - CCRC EXAM ELIGIBILITY

Option 3: High School Diploma or Medical Assistant, Lab Technician

- ► Minimum Hours Performing Essential Duties: 6,000 hours*
- Required Documentation of Performed Essential Duties: Detailed CV/resume and job description

* Substitution for Work Experience

NEXT: WHEN??

NEXT EXAM DATES: FEBRUARY 20 - APRIL 3, 2020

Early-Bird Application Dates & Fees

- ▶ Application Dates: November 1 December 31, 2019
- ► Application Fee: \$135 Member; \$135 Nonmember
- ► Exam Fee: \$300 Member; \$350 Nonmember
- ► Total: \$435 Member; \$485 Nonmember

SCHEDULING YOUR EXAM

NEXT EXAM DATES: FEBRUARY 20 - APRIL 3, 2020

Regular Application Dates & Fees

- ► Application Dates: January 1 February 29, 2020
- Application Fee: \$135 Member; \$200 Nonmember
- ► Exam Fee: \$325 Member; \$400 Nonmember
- ► Total: \$460 Member; \$600 Nonmember

HOW TO APPLY FOR THE CCRC EXAM

- ▶ Verify eligibility before applying for the exam -Before you apply, login to <u>acrpnet.org</u> to verify your ACRP Membership status and confirm the total payment due at time of application.
 - ► Apply/submit documentation of eligibility to ACRP online
 - ▶ Receive email confirmation 1-2 weeks
 - ▶ If "ineligible" may need more documentation
 - Eligibility Notice with ID number is sent
 - YOU must schedule the Exam online
 - ▶ Ineligible receive refund

HOW TO SCHEDULE EXAM

▶ Once you have been determined eligible you must schedule an appointment to take the exam within the exam date range. View testing locations at www.prometric.com/acrp or by phone.

1. Obtain Eligibility ID Number

- Receive your eligibility notice via email
- ► Go to <u>prometric.com/ACRP</u> or <u>call</u>

2. Make Your Appointment

Select location, date, and time

3. Keep Your Appointment Confirmation

Review and print your confirmation. Use it if you need to cancel or reschedule your appointment

CCRP CCRC EXAM –WHAT?

- ▶ Computer exam time allotted for learning the 'system'
- ▶ 125 multiple-choice questions
- ▶ Duration of exam: 3 hours maximum
- ► A minimum of 80% to pass
- ► Email notification
- ► Certificate in mail

WHAT IS ACRP EXAM - CONTENT

- ▶ The exam content is based on current practice in clinical research and was determined by an international job analysis.
- ► The exam is referenced to the International Conference on Harmonization (ICH) Guidelines. Other than the ICH Guidelines, no other regulatory framework is tested.
- ► The questions test knowledge at the recall, application, and analysis level, not just a recitation of facts. Some questions use hypothetical scenarios.

ACRP CCRC EXAM CONTENT

Core Knowledge Areas:

- Scientific Concepts and Research Design
- ► Ethical and Participant Safety Considerations
- Product Development and Regulation
- Clinical Trial Operations (GCPs)
- Study and Site Management
- Data Management and Informatics

MAINTENANCE OF ACRP CERTIFICATION

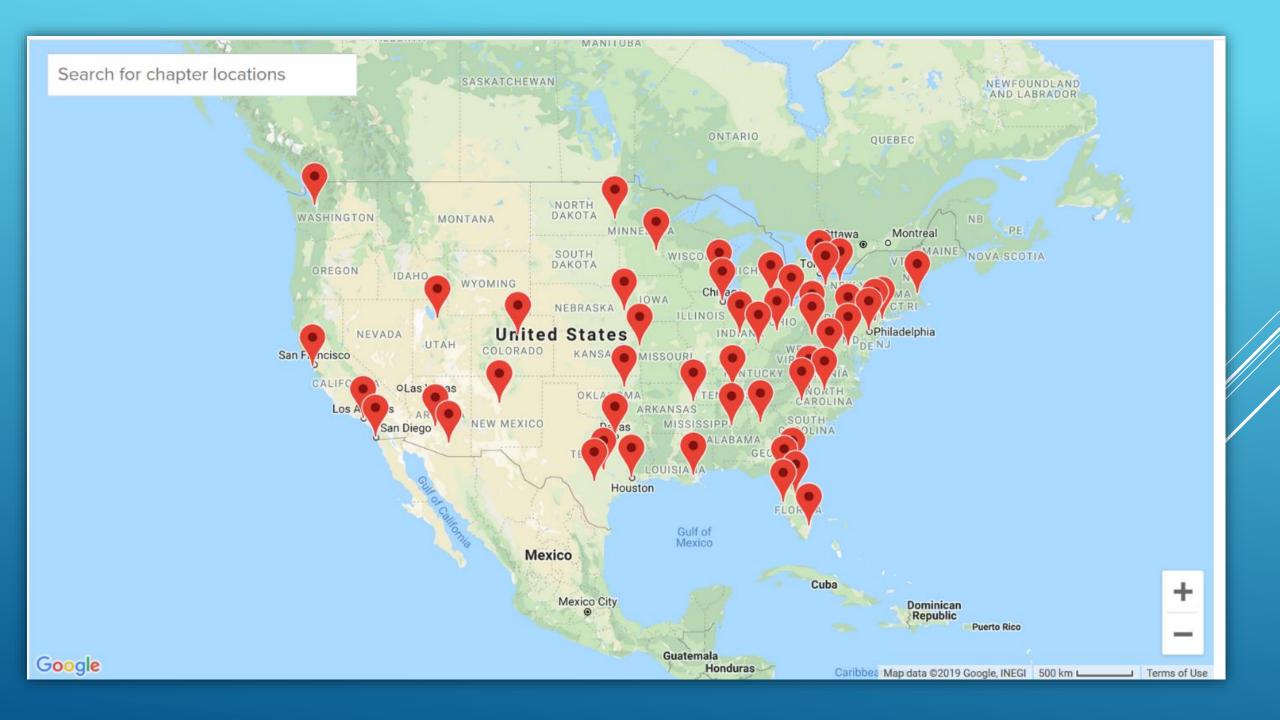
- Renew every 2 years
 - Report 24 contact hrs/CEUs every 2 years
 - **▶**OR
 - Re-take the current certification exam

HOW TO GET CONTACT HOURS

- ► ACRP Annual Conference April 2020 Seattle April 2021 – Toronto
- ▶ Networking!!
- ► Educational bonanza 2 years of Contact Hrs and access to all replays from conference free online

HOW TO GET CONTACT HOURS

- ► CME/AMA credits from attending CTSI or other Medical Seminars
- Certificate of Attendance, e.g., SCORE Annual Half-Day Program
- Grand Rounds/Department Medical Update Programs
- ► ACRP –On-line and Chapter Events
 - ▶ Free or highly-reduced courses/webinars on ACPR Nat'l website
 - Western New York (Chapter quarterly meetings with FREE webinar replay for 1-1.5 hrs credit AND dinner
 - ► Planning on more ZOOM meetings for 2020
 - Chapter membership just \$20 extra



TESTIMONIAL HELEN ELAM, MS, CCRA ACRP WNY CHAPTER SECRETARY

- ► CCRA and ACRP membership since 1996
- Opportunity to interact with other like-minded clinical research professionals
- ► Chance to learn different perspectives on current research topics and industry trends outside of work
- ▶ Socialize, have dinner and enjoy Clinical Research presentations
- ► Earn 8 ACRP CEUs each year of active duty as the chapter Secretary

WNY-ACRP Chapter invites you to our

ANNUAL HOLIDAY PARTY

Tuesday, December 10, 2019 5:30 -8:30 PM Dinner and Beverages Provided

Location: Five Star Bank Community Room (CityGate), 395 Westfall Rd., Rochester NY 14620.

Please R.S.V.P. by December 6, 2019 noreen_connolly@urmc.rochester.edu

To add some holiday fun, we invite you to join in a White Elephant Gift Swap (aka "Yankee Trader"). To take part please bring 1 gift-wrapped item, either something from home (think funny, kitschy or weird!) or a new item worth \$10 or less. You bring a gift and you'll go home with one!

Event Cost: \$0 for Chapter member /\$0 for guests, spending time together: priceless.