Achieving ACRP Certification
What You Need To Know
WELCOME

Speaker:
Karan S. Fachet, MS, RN, NE-BC
What is Certification?

Certification is a **voluntary** process to recognize **individuals** for meeting **standards** set by a third party.

Certification **assures the public** that an individual demonstrates **specific knowledge** required of a practitioner at a certain level.
Certificate vs. Certification

Certificate
- Forever
- Teaches Something
- Training Program

Certification
- Hands On Experience
- Comprehensive Assessment Exam
- Code of Ethics
- Ongoing Education Every 2 years
Benefits of ACRP Certification

• Promoting Professionalism
• Validating Competence
• Committing to Quality Standards
• Setting Yourself Apart
Certification Programs

Over 18,500 certified since 1992

Over 10,000 certified since 1995

Over 1,000 certified since 2002

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New Credential ACRP-CP

Association for Clinical Research Professional – Certified Professional (ACRP-CP)

Why Now
• Evolution of roles of the clinical research professional
• Workforce innovation

Who is Eligible
• All professionals involved in clinical studies
• Regardless of roles, practice setting, or career stage
• Two (2) years experience
How Do I Get Certified?
Essential Duties

• Verify that the research site investigator(s) and study personnel are conducting the study according to the clinical protocol, GCP, and regulatory requirements to ensure protection and ethical treatment of human subjects.
• Ensure identification and reporting of safety issues, when applicable, from research site staff to the sponsor and the IRB/IEC.
• Perform monitoring activities per the monitoring plan.
• Review accuracy and completeness of site records.
• Ensure accountability of Investigational Product and related supplies are performed.
• Ensure complete reporting and proper documentation of monitoring activities.
• Conduct routine monitoring visits independently from the investigative site study staff.
• Ensure the site is identifying issues and implementing corrective and preventive actions to ensure inspection readiness.
Essential Duties

- Report and document safety issues
- Participate in the preparation or review of documents exchanged with 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
- Participate in the informed consent process
Certified Principal Investigator

Essential Duties

• Responsible for the safe and ethical conduct of a clinical trial
• Evaluates the study proposal and decides on participation
• Facilitates or verifies formal approvals according to regulatory requirements and ICH/GCP
• Ensures the all site initiation activities are performed to start and conduct the study
• Participates in the selection of trial subjects according to the recruitment strategy
• Performs or supervises the conduct of study-related procedures and monitors the safety of the trial subjects and investigational staff
• Collects accurate and verifiable data and other essential study documents
• Ensures compliance with regulatory requirements and ICH GCP, the protocol and the handling of the investigational product
• Communicates with subjects, sponsor’s personnel, and IRB
• Ensures adequate close-out of the study
Eligibility Requirements

Planning
Protocol design, feasibility assessment, business operations (budgeting, contracting, billing compliance), site selection activities, regulatory document (preparation, collection and/or submission), site management activities, clinical operations role (within site, academic medical centers or CROs)

Conducting
Conduct of clinical trials with participants

Overseeing – Management or Administration
Study site management (site, CRO, sponsor), monitoring activities (including in-house, central and remote), project management, quality control, quality assurance, data management, medical monitoring, safety monitoring (medical safety liaison, pharmacovigilance, IRB professional)
## Work Experience Requirement – based on education level

**CCRA, CCRC, ACRP-CP Applicants Only**

<table>
<thead>
<tr>
<th>Education</th>
<th>Required Work Experience</th>
<th>Required Documentation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bachelor’s Degree (or higher)</td>
<td>3,000 hours</td>
<td></td>
</tr>
<tr>
<td>Associates Degree or RN, LPN, LVN</td>
<td>4,500 hours</td>
<td>Detailed CV/Resume AND Job Description</td>
</tr>
<tr>
<td>High School Diploma or Medical Assistant, Lab Technician</td>
<td>6,000 hours</td>
<td></td>
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Work Experience Requirement – based on education level

CPI Applicants Only

Education
• Doctorate level degree (DDS, MD, or equivalent degree such as DO, MBBS, MBChB, PhD, PharmD, DNP
• Licensed Physician's Assistance or Nurse Practitioner (that has served in a PI role)

Required Documentation
• Detailed CV/Resume and Job Description
• Documentation from list below

Experience – for at least 2 of the most recent 5 years (since 2012)
• 1572 / PHS 398 / QIU (or equivalent) or
• IRB/IEC approval letter to conduct the study or
• Protocol approval letter for the study or
• Signed copy of an investigator agreement/protocol signature page or
• Other regulatory authority document verifying your role as a Principal Investigator on the clinical trial being submitted in support of eligibility
Application process takes approximately two weeks.
Computer-Based Testing

Receive Eligibility ID# via Email

Make Personal Testing Appointment via Website

600+ testing centers
80+ countries
6 days a week

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Exam and Preparation
Exam Format

125 Multiple Choice Questions – 100 Scored

Six Content Areas
- Recall – basic facts
- Application – using information

Three Types of Questions
- Analysis – scenario based

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What's On the Exam – CCRA, CCRC, CPI?

Detailed Content Outline (DCOs) Developed from Research Into Knowledge, Skills and Abilities Needed

<table>
<thead>
<tr>
<th>Content Areas</th>
<th>CCRA</th>
<th>CCRC</th>
<th>CPI</th>
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<tbody>
<tr>
<td>I. Scientific Concepts and Research Design</td>
<td>12%</td>
<td>8%</td>
<td>17%</td>
</tr>
<tr>
<td>II. Ethical and Participant Safety Considerations</td>
<td>20%</td>
<td>22%</td>
<td>25%</td>
</tr>
<tr>
<td>III. Product Development and Regulation</td>
<td>10%</td>
<td>14%</td>
<td>10%</td>
</tr>
<tr>
<td>IV. Clinical Trial Operations (GCPs)</td>
<td>25%</td>
<td>22%</td>
<td>15%</td>
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<tr>
<td>V. Study and Site Management</td>
<td>23%</td>
<td>22%</td>
<td>23%</td>
</tr>
<tr>
<td>VI. Data Management and Informatics</td>
<td>10%</td>
<td>12%</td>
<td>10%</td>
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ICH Guidelines


• E6(R2) – Guideline for Good Clinical Practice
• E2A – Definitions and Standards for Expedited Reporting
• E8 – General Considerations for Clinical Trials
• E9 – Statistical Principles for Clinical Trials
• E11(R1) – Clinical Investigation of Medicinal Products in the Pediatric Population

Declaration of Helsinki

https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/
Detailed Content Outline (DCOs) Developed from Research Into Knowledge, Skills and Abilities Needed

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ICH Guidelines

• More details to follow in the coming weeks
• Stay Tuned!

Declaration of Helsinki
https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/
Exam Preparation

1. Review the DCO
2. Compare DCO with Your Experience
3. Identify Gaps
4. Review ICH Guidelines
5. Review Texts or Takes Courses to Fill Gaps
Additional Exam Information

- Scored and reported on scale 200-800, 600 is passing.
- Score is provided before you leave the testing center.
- 73% of first-time test takers are successful.
- You can re-test during the next exam cycle.
Questions?

certification@acrpnnet.org