



**ACRP Certification Exam Prep Classroom Course**  
**Saturday, June 23, 2018**  
**9:00 AM – 4:00 PM**  
**Registration 8:30 – 9:00 AM**

**Trainer: Janet Ellen Holwell, CCRC, CCRA, FACRP, TIACR**  
**Clinical Research Consultant**

### **Location**

**Columbia University - Irving Institute for Clinical and Translational Research**  
**[622 West 168th Street, Presbyterian Hospital \(PH\) 10 - 405 A](#)**  
**New York, NY 10032**

### **Course Description:**

The ACRP Certification Exam Preparation classroom course provides guidance on how to prepare for an ACRP Certification exam (e.g., CCRA<sup>®</sup>, CCRC<sup>®</sup>, ACRP-CP<sup>®</sup> and CPI<sup>®</sup>) to candidates eligible to take the exam.

The exam changed in 2017. The certification programs are now aligned with the Clinical Trial Competency Framework developed by the Joint Task Force for Clinical Trial Competency. Knowledge areas reflect current practice as a monitor, study coordinator or investigator. The exam has been expanded from 5 relevant guidelines to 6 relevant guidelines: Declaration of Helsinki, ICH E2A, ICH E6, E8, E9 and now E11 Clinical Trials in Pediatric Population.

Familiarize yourself with the format of the exam, tackle example questions, and conduct a personal gap analysis to ensure you are fully primed to earn your ACRP Certification.

This classroom course was prepared by ACRP experts exclusively for Chapters to offer locally, and is taught by a trainer approved by ACRP to teach this course. It includes PowerPoint presentations/hand-out, interactive classroom exercises, discussions and question-and-answer sessions. No contact hours are offered.

### **Trainer Bio:**

Janet E. Holwell, CCRC, CCRA, FACRP, TIACR

Ms. Holwell is an independent consultant specializing in maximizing excellence in GCP quality, compliance and training for both sites and industry. She began her career as a clinical research coordinator in academia over 30 years ago. Prior to transitioning to industry, she managed the clinical pharmacology unit in dermatology at NY Presbyterian Medical Center - Columbia University, overseeing all operations. She was an instructor in good clinical practice (GCP) and helped develop the first GCP program in an academic institution while at Columbia. She was an invited Lecturer for Columbia University School of Nursing's post-graduate Course for Clinical Research Coordinators. Prior to her position in quality management as a Clinical Quality Lead with Pfizer, she held positions as a clinical research associate, site selection specialist, study manager with oversight of vendor CRAs, trainer and independent consultant. She has been an active member of the Association of Clinical Research Professionals (ACRP) since 1992, having served on the board of trustees, North American Council and various forums, including track chair for the site managers' forum and co-chair of the CRA forum. She is a founding member, past president and presently an active board member of the New York Metropolitan Chapter of ACRP.

## Course Learning Objectives:

1. Be able to list and use the benefits of certification to drive their exam preparation efforts
2. Be familiar with the question-style and layout of ACRP's Certification exams, including how to approach their multiple-choice format
3. Be able to identify and describe at least three (3) strategies for preparing for ACRP's Certification exams
4. Be able to use and reference the six (6) relevant guidelines used to create the ACRP's Certification exams:
  - a. The Declaration of Helsinki
  - b. ICH E2A—Safety Definitions
  - c. ICH E6—Good Clinical Practice
  - d. ICH E8—General Considerations for Clinical Trials
  - e. ICH E9—Statistical Principles for Clinical Trials
  - f. ICH E11—Clinical Trials in the Pediatric Population
5. Be able to assess their individual level of readiness by practicing exam questions based on the [Detailed Content Outline \(DCO\)](#) under training conditions (NOT exam conditions)

## Agenda:

<b>8.30AM</b>	<i>Registration Sign-in</i>
<b>9:00–9.15</b>	<b>Welcome and Introduction</b>
<b>9:15–11:00</b>	<b>Module 1: Objectives, Agenda, Introduction to Certification</b>
<b>11:00–11:15</b>	<i>Refreshment Break</i>
<b>11:15–12:15</b>	<b>Module 2: Overview of the 6 relevant guidelines</b>
<b>12:15–1:00PM</b>	<i>Lunch provided</i>
<b>1:00–2:30</b>	<b>Module 2 Continued: Overview of the 6 relevant guidelines</b>
<b>2:30–2:45</b>	<i>Refreshment Break</i>
<b>2:45–3:45</b>	<b>Module 3: Practice Questions</b>
<b>3:45–4:00</b>	<b>Questions and Answers, Adjourn</b>

## Target Audience:

Eligible candidates for the CCRA<sup>®</sup>, CCRC<sup>®</sup>, ACRP- CP<sup>®</sup> and/or CPI<sup>®</sup> ACRP Certification Exam.

**Fall Certification Exam Cycle: September 10 - October 8, 2018. Application deadline: August 17, 2018.**

**Early Bird Exam Registration: May 1, 2018 - June 15, 2018. Regular Registration: Starts June 16, 2018.**

<https://www.acrpnet.org/professional-development/certifications/>

Questions About Certification Benefits, Requirements, and Preparation: [www.acrpnet.org/certification](http://www.acrpnet.org/certification)

**EVENT REGISTRATION closes Thursday, 21 June 2018, 11:59PM Eastern Time**

Register NOW to ensure admission; **PRE-REGISTRATION** required

[www.acrpnet.org/nymetro](http://www.acrpnet.org/nymetro)

	<b>Early Bird Pricing Before June 4 2018</b>	<b>Pricing After June 4, 2018</b>
<b>NY Metro Chapter ACRP member</b>	<b>\$250</b>	<b>\$275</b>
<b>ACRP member</b>	<b>\$275</b>	<b>\$300</b>
<b>Non-member</b>	<b>\$300</b>	<b>\$325</b>

Event registration information: Membership not required for online registration. Bring your email confirmation to the event. Please notify Event Manager of cancellation. No refunds or transfers. No contact hours offered.

**Questions About ACRP Online Registration:** [chapters@acrpnet.org](mailto:chapters@acrpnet.org)

**Questions About This Classroom Course:**

Janet Ellen Holwell, CCRC, CCRA, FACRP, TIACR, Communications Chair, NY Metropolitan Chapter of ACRP, [jholwell@aol.com](mailto:jholwell@aol.com) or call 718-263-4160.

**Event Manager for Cancellations:** Lisette Gonzalez, CCRA, NY Metropolitan Chapter of ACRP, [lgonzalez@phase2phaseconsulting.com](mailto:lgonzalez@phase2phaseconsulting.com) or call 917-881-4295

**Sponsorship Provided by**



**Ismael Castaneda, Research Manager  
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Columbia University - Irving Institute for Clinical and Translational Research  
622 W. 168<sup>th</sup> Street  
New York, NY 10032**

Please see [www.acrpnet.org/nymetro](http://www.acrpnet.org/nymetro) for more information about our Chapter and visit often to check on our upcoming 2018 events.

**For those of you coming from out of town, click on the picture below for directions to the Columbia University, Presbyterian Hospital (PH) 10 - 405A, where the Certification Prep Course will be held.**

