Instructor-Led Prep Course/Study Group for ACRP Certification
Saturday, June 22nd, 2019
9:00 AM – 4:30 PM
Registration 8:30 – 9:00 AM

Facilitator: Janet Ellen Holwell, CCRC, CCRA, FACP, TIACR
Clinical Research Consultant

Location
Hospital for Special Surgery
Richard L. Menschel Education Center
2nd Floor Conference Room A and B
535 East 70th Street
New York, NY 10021

Course Description:

This combination Prep Course/Study Group for ACRP Certification provides guidance, for candidates eligible to take the exam, on how to prepare for an ACRP Certification (e.g., CCRA®, CCRC®, ACRP-CP®, CPI®). N.B.: This course will not cover the medical device or project management subspecialty designations.

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 and investigator. The exam covers the 6 relevant guidelines: Declaration of Helsinki, ICH E2A, ICH E6, E8, E9 and E11.

The course will help you 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. The Detailed Content Outlines (DCOs) will be used to customize your personal needs. Please bring a copy of the DCO with you.

This course includes presentation/hand-outs, interactive classroom exercises, discussions and question-and-answer sessions. No contact hours are offered.

Trainer Bio:

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

Ms. Holwell is an independent consultant specializing in maximizing excellence in GCP quality, compliance and training for both sites and industry. She works contractually with sponsors, CROs, academic medical centers, site investigators and their personnel to provide training in the clinical research process, specializing in ICH-GCP compliance. She has over 35 years’ experience in clinical operations working with cross-functional, global and diverse teams. Innovative ideas to continuously improve upon projects and training modules and maintain the highest quality product. She provides customized training and mentoring. She is dual-certified by the Association of Clinical Research Professionals (CCRA/CCRC) as well as a Fellow of ACRP. She achieved status as an Accredited Qualified Clinical Research Trainer (TIACR) through the International Academy of Clinical Research (IAOCR) UK.

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(R2)—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:

8.30AM  
Registration Sign-in and Light Breakfast

9:00–9.15  
Welcome and Introduction

9:15–10:00
Module 1: Format of Exam– What to Expect

10:00–11:00
Module 2: Overview of the 6 Relevant Guidelines

11:00–11:15
Refreshment Break

11:15–12:00PM
Module 3: Personal Analysis of DCO

12:00–12:45
Lunch provided

12:45–2:30
Module 4: Kick-Start of Study Group/Sample Questions

2:30–2:45
Refreshment Break

2:45–4:15
Module 4: Kick-Start of Study Group/Sample Questions

4:15–4:30
Wrap Up Questions and Answers, Adjourn

Target Audience:

Eligible candidates for the CCRA®, CCRC®, ACRP-CP®, and CPI® ACRP Certification Exam.

Fall Certification Exam Cycle: September 10 – October 10, 2019.
www.acrpnet.org/certification

Questions About Certification Benefits, Requirements, and Preparation: www.acrpnet.org/certification

| EVENT REGISTRATION closes Thursday, June 20, 2019, 11:59PM Eastern Time |
| Register NOW to ensure admission; PRE-REGISTRATION required |
| www.acrpnet.org/nymetro |

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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.

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For Prep Course Registration Contact: Lisette Gonzalez, CCRA, NY Metropolitan Chapter of ACRP, lgonzalez@phase2phaseconsulting.com or call 917-881-4295.

Questions About This Webinar/Facilitator Course: Janet Ellen Holwell, CCRC, CCRA, FACP, TIACR, Communications Chair, NY Metropolitan Chapter of ACRP, jholwell@aol.com or call 718-263-4160.

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

Sponsorship Provided by

Research Division, Hospital for Special Surgery
525 E 70th St
New York, NY 10021

Please see www.acrnet.org/nymetro for more information about our Chapter and visit often to check on our upcoming 2019 events.

For those of you coming from out of town, click on the picture below for directions to the Hospital for Special Surgery, Richard L. Menschel Education Center, 2nd Floor Conference Room A and B
535 East 70th Street
New York, NY 10021 where the Prep Course/Study Group will be held.