NEWSLETTER

PRESIDENT'S MESSAGE

The NY Metropolitan Chapter is bustling with change. Our current membership grew 10% since our March census! We continue to offer new opportunities to engage our members. At our 2015 symposium, we recorded the event and will be offering re-play options for those who could not attend. In the fall of 2016, we will be hosting our second live webinar evening event for those who cannot travel. Also, we are excited to announce our 8th Annual Fall Symposium Focusing on Audit and Monitoring. Please look for more details in our Education Committee update.

We recently drafted revisions to our chapter by-laws to change the president-elect and immediate past president terms. Stay tuned for more information updates and a member vote in the coming months.

On the board front, we are currently seeking new Members at Large and a Treasurer. Serving on the board is an excellent way to support the chapter. Please look for more details in our Nominating Committee update.

Wishing you a fun filled summer and we look forward to seeing you in the fall!

Best regards,
Erika

EDUCATION AND PROGRAMS COMMITTEE

Before you head into the summer, the NY Metropolitan Chapter's education committee would like to let you know what you can expect from us for the rest of 2016.

You asked; we listened. The webinar format works for many of you, and so we are giving you two opportunities this year to listen in to be eligible to receive contact hours.

For the first time our chapter is hosting a replay of an ACRP Global Annual Conference session on July 26th. This webinar session was one of the most popular presentations from this year's Global conference in Atlanta and will feature David Vulcano speaking on the topic of "Healthcare Changes and How They Affect the Clinical Research Industry". This topic is particularly timely in this election year.

Once the summer is over, you can look forward to two more chapter events this year. On September 22, we will host a live webinar on Diversity in Clinical Research. Then on November 4, we will host our 8th annual clinical research symposium at the Manhattan Club in Rosie O'Grady's on "All Things Monitoring". Stay tuned for more details about our upcoming events!
NOMINATIONS COMMITTEE

Due to a vacancy on our board, we will be holding a special election for a Treasurer.

Below is a description of the duties of the position.

**Treasurer**
Shall be the custodian of the chapter’s funds  
Supervises receipts and expenditures  
Renders an annual statement to the membership and ACRP  
Prepares and any reports required by law

Serving on the board is a great way to build your network, illustrate your leadership capabilities, and help our chapter fulfill its mission. Individuals must be chapter members in good standing and commit to actively participating in regularly scheduled meetings, held either in person or via teleconference.

MAY 11 EVENT PHOTOS

Speaker Lyn Goldsmith
UPCOMING CHAPTER EVENTS
ACRP Certification Exam Prep Classroom Course
Saturday, July 23, 2016
9:00 AM – 4:00 PM
Registration 8:30 – 9:00 AM
Trainer: Janet Ellen Holwell, CCRC, CCRA, TIACR
Clinical Research Consultant

Location
Weill Cornell Clinical and Translational Science Center
Weill Greenberg Center
2nd Floor, Rooms A/B
1305 York Avenue, New York, NY 10021

Course Description:
This new ACRP Certification Exam Preparation classroom course provides guidance on how to prepare for an ACRP Certification exam (e.g., CCRA®, CCRC®, and CPR®) to candidates eligible to take the exam. 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/handouts, interactive classroom exercises, discussions and question-and-answer sessions. No contact hours are offered.

Trainer Bio:
Janet E. Holwell, CCRC, CCRA, 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 five (5) relevant guidelines used to create the ACRP's Certification exams:
   a. ICH E2A—Safety Definitions
   b. ICH E6—Good Clinical Practice
   c. ICH E8—General Considerations for Clinical Trials
   d. ICH E9—Statistical Principles for Clinical Trials
   e. The Declaration of Helsinki
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
9:00—9:15  Welcome and Introduction
9:15—11:00  Module 1: Objectives, Agenda, Introduction to Certification
11:00—11:15  Refreshment Break
11:15—12:15  Module 2: Overview of the 5 relevant guidelines
12:15—1:00PM  Lunch provided
1:00—2:30  Module 2 Continued: Overview of the 5 relevant guidelines
2:30—2:45  Refreshment Break
2:45—3:45  Module 3: Practice Questions
3:45—4:00  Questions and Answers, Adjourn

Target Audience:
Eligible candidates for the CCRA®, CCRC®, and/or CPI© ACRP Certification Exam.

Fall Certification Exam Cycle: September 6 - October 1, 2016. Application deadline: August 15, 2016.

Questions About Certification Benefits, Requirements, and Preparation:
http://www.acrponline.org/MainMenu/Category/Certification.aspx

EVENT REGISTRATION closes Thursday, 21 July 2016, 11:59PM Eastern Time
Register NOW to ensure admission; PRE-REGISTRATION required

NY Metro Chapter ACRP member $250
ACRP member $275
Non-member $300

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.

V2 - 25 Apr 2016
Questions About ACRP Online Registration: chapters@acrpnet.org
Questions About This Classroom Course:
Janet Ellen Holwell, CCRC, CCRA, TIACR, Communications Chair, NY Metropolitan Chapter of ACRP,
jholwell@aol.com or call 718-263-4160.
Event Manager for Cancellations: Lisette Gonzalez, CCRA, Immediate Past-President, NY Metropolitan Chapter of ACRP, lgonzalez@phase2phaseconsulting.com or call 917-981-4295

Sponsorship Provided by

Weill Cornell Clinical and Translational Science Center
525 E 68th St
New York, NY

Please see http://www.acrpnet.org/GetInfoForUSChapters/NY/NewYorkMetropolitan.aspx
for more information about our Chapter and visit often to check on our 2016 events.

For those of you coming from out of town, click on the picture below for directions to Weill Cornell Greenberg Center where the Prep Course will be held

UPCOMING CHAPTER EVENTS
2016 Update: U.S. Healthcare Changes and How They Affect the Clinical Research Industry

Join us for a Replay of a Session from the 2016 ACRP Meeting and Expo
Tuesday, July 26, 2016
6:45-8:00 pm
Log in from the convenience of your home or office.

David Vulcano, LCSW, MBA, CIP, RAC
AVP & Responsible Executive, Clinical Research, HCA

Program Description:
Healthcare and clinical research reform in the United States is constantly moving forward. Monumental shifts created by new laws and administrative efforts will undoubtedly cause both direct and indirect impacts on the clinical research industry.

This session highlights the multiple activities that are expected to have an impact in an attempt to help the audience decipher what it may mean to their research operations and their subjects. This presentation will address the most recently enacted legislation/regulations as well as items in current play, which include overview of topics such as the 21st Century Cures Act, updates on Medicare payment rules, various laws on expanded access and state’s “Right To Try”, CHRP’s Notice of Proposed Rulemaking, new rules concerning research with dried newborn blood spots, IRS issues on patient suspends and much more.

Upon completion of this Webcast, attendees should be able to:
1. Review impact of healthcare and clinical research reform in the U.S. on research operations and study subjects.
2. Describe current and most recently enacted U.S. legislation/regulations.
3. Summarize both direct and indirect impacts on the clinical research industry.

Agenda:
6:45-7:00 Welcome and Chapter Meeting
7:00-8:00 Educational Program

Who Will Benefit from this Webcast: All Clinical Research Professionals.

Cost: Complimentary for Chapter Members/$25 Non-Members

Registration: Register at Eventbrite. Log in information will be sent one week prior to the event.

Contact hours: 1 contact hour and CME have been applied for through ACRP. Membership is not required for online registration of contact hours.

Contact Hour Cost: Complimentary for Chapter Members/$15 ACRP Members/$30 Non-Members

To receive contact hours: Purchase the contact hours on the NY Metro Chapter website and attend the program. Between 1 and 30 days after attending the webcast, log on to the ACRP website, then click on your ACRP Learning Portal Quicklink to complete the evaluation and receive the online certificate.
The New York Metropolitan Chapter of ACRP presents:

Diversity in Clinical Research

Speaker: Gary Puckrein, PhD
National Minority Quality Forum
Venue: WebEx

This event will focus on:
1. The importance of diversity in clinical research
2. The current status of diversity in clinical trials
3. How to increase diversity in your clinical trial population or research practice

Sept 2016
22
6:30—8 pm

Stay tuned to our Chapter website at Association of Clinical Research Professionals - Upcoming Chapter Events or send us an email at nymetroatcp@gmail.com.
FREE EDUCATIONAL OPPORTUNITIES

PRE-RECORDED WEBINARS

FDA's Role in Public Health: Drug Efficacy, Safety, Quality, and Beyond
Presented by the FDA

How to Prepare for an FDA Inspection
Presented by Forte Research Systems

Secrets to Negotiating Trial Budgets and Compensating Primary Investigators
Presented by Forte Research Systems

Accelerate Clinical Trials by Simplifying Data Quality
Presented by Business Review Webinars

How to Effectively Manage Internal Patient Recruitment Staff
Presented by Forte Research Systems

ARTICLES

Making the Most of Your Budget: Hidden Costs and Payment Terms
Presented by Forte Research Systems

Secrets to Negotiating Trial Budgets and Compensating PIs
Presented by Forte Research Systems

The New York Metropolitan Chapter of ACRP does not endorse nor profit from these advertisements or programs, but rather are providing a notification to its community for their own interest as part of its continuing initiative to promote education and opportunities in research.
to our new and returning chapter members!

We currently have 254 active members to date with 30 new and returning members joining us in the last quarter. We would like to give a warm welcome to:


For membership questions, email Jun Loquere at al2061@cumc.columbia.edu. You can also log on to www.acrpnet.org for ACRP and chapter membership applications.

WANT TO POST SOMETHING IN OUR NEWSLETTER OR JOB BOARD?

For information on placing advertisements in the quarterly newsletter or posting positions on the monthly Job Board, click HERE. You can also send your comments or suggestions to jholwell@aol.com.

SPONSORSHIP OPPORTUNITIES

The Marketing Committee is currently seeking sponsorship for our upcoming 2016 events. Corporations, recruiters, or institutions interested in sponsorship of any of our events should contact Gabi Gaspard at gabig382@yahoo.com. We have several levels of corporate sponsorship available.

The Marketing Committee is always looking for volunteers. Any members interested in becoming more involved in the chapter should also contact Gabi.
Try it free today