

NEWSLETTER

PRESIDENT’S MESSAGE

From the President, Christina Brennan, MD, MBA

Dear Fellow NY Metropolitan Chapter Members,

Clinical trials are an essential part of the device and drug development process. Data gathered from the enrollment in clinical trials is analyzed to see if the investigational device or drug is safe and effective for approval, to be made available to patients. We know that diseases affect people differently and this can impact how a patient responds to treatment.

Prostate cancer is twice as fatal for African Americans as Caucasians, yet only 4% of prostate cancer trial participants are African American. Cancer is the #1 cause of death in Asian Americans, yet only 2.8% of cancer clinical trial participants are Asian Americans. Despite efforts to enroll more women in studies, there continues to be an underrepresentation of female participants. According to the NIH, only one-third of cardiovascular clinical trial participants are female. Yet, cardiovascular disease is the number one killer of both men and women, and their presenting symptoms and response to treatments are different. Large gender gaps in research participation limit our findings on the difference between men’s and women’s health. Even when women are enrolled, the data is not analyzed and reported separately which can limit our understanding of findings.

Although progress has been made to reach these minorities for inclusivity, we have a long way to go. October was diversity awareness month, but we must continue this awareness every month. All patients, regardless of their gender or race, should have the opportunity to participate in clinical trials.

Hard to believe that 2017 is coming to an end. This will be the last newsletter for the year. I hope you had an opportunity to join us at one of our educational events this year. I look forward to seeing many of you at our annual holiday networking party, our marketing co-chairs have many fun things planned for the evening.

Happy Holidays!

Kind regards,

Christina

EDUCATION COMMITTEE UPDATE

As we approach the end of the year, the Education Committee would like to thank you for helping to make 2017 one of our best years yet! We can take some of the credit, but much of it goes to you for your help in designing our education agenda. Once again, we would like to ask for you to take a few minutes to respond to the email you received with our chapter’s end of year survey. This information helps us to understand more about our research community and enables us to cater our programs to suit what you would like to learn about. If you did not receive the survey, please reach out to us at nymetroacrp@gmail.com. We look forward to seeing you next year!

Halley Rogers
Chair, Education and Programs Committee

ELECTION RESULTS

We are pleased to announce the results of an uncontested election. The following are your newly elected board members:

- Halley Rogers, MPH, CCRC will serve as President-Elect in 2018 and assume the office of president from January 1, 2019 through December 31, 2020.
- Allison E. Randall, MPH, PMP, CCRC will serve as secretary from January 1, 2018 through December 31, 2019.
- Joyce Ann Moran, CCRC will serve as treasurer from January 1, 2018 through December 31, 2019.

Please join us in wishing them congratulations and good luck in their new positions.

Did you know? ACRP Certification is now possible for all clinical research professionals!

In the past only investigators, coordinators and clinical research associates were able to become certified through ACRP. That has now changed.

ACRP-CP® (ACRP Certified Professional) is a new credential formally recognizing professionals involved in all aspects of clinical studies/trials who have demonstrated the knowledge, skills, and abilities to perform ethical and responsible clinical research by passing the standardized ACRP Certified Professional Certification Exam.

This means that if you are an auditor, IRB member, study manager, project manager, administrator, etc. you may now apply for the exam and potentially become an ACRP Certified Professional (CP).

Our chapter is hosting an ACRP certification exam prep course on Saturday, December 9 at Mt. Sinai in Manhattan. This course is offered in advance of the spring and fall exams each year. To register, please click [here](#).

For more complete information about the prep course, please see the flyer in this newsletter.

For questions about the prep course, please call Janet Ellen Holwell at 718-263-4160 or e-mail jholwell@aol.com.



Join the New York Metropolitan Chapter of ACRP for our

14th Annual Holiday Networking Party

Enjoy an evening of tacos, cocktails, games and dance!

Thursday, December 7, 2017

6:00-9:00 pm

Pampano

209 East 49th Street (btwn 2nd and 3rd Ave)

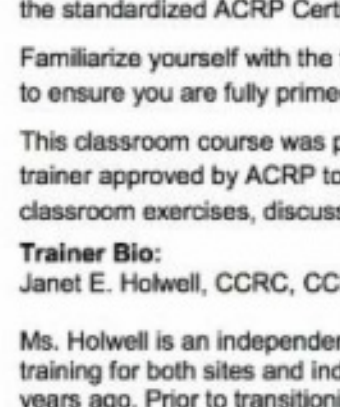
Directions:
Subway: Take the 6 train to the 51st stop and walk east along 49th St; the 4 or 5 trains to 42nd or the 7 to the Lexington Ave stop, exit onto Lexington Ave., walk north to E. 49th St and make a right to the restaurant. Metro-North: Take the train to Grand Central Terminal; exit onto Lexington Ave., walk north to E. 49th St. and make a right. FDR: Exit at the 42nd St. exit, make a right at Lexington Ave. and another right on 49th St.

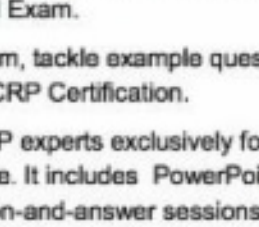
Registration:
Early Bird rates until Dec 1st: \$20 NYM Chapter/\$30 Non-NYM Chapter
After Dec 1st: \$30 NYM Chapter/\$40 Non-NYM Chapter
At the door: \$40 NYM Chapter/\$50 Non-NYM Chapter
No refunds after December 1st.
Space is limited. Register Online Now at Eventbrite.

Vendors and Sponsors:







ACRP Certification Exam Prep Classroom Course
Saturday, December 09, 2017
9:00 AM – 4:00 PM
Registration 8:30 – 9:00 AM

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

Location
Mount Sinai Medical Center
Leon and Norma Hess Center for Science & Medicine
1478 Madison Avenue, 2nd Floor Seminar Room B
(Between 101st and 102nd Streets)
New York, NY 10029

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

The exam has 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 E8, E8, E9 and now E11 Clinical Trials in Pediatric Population. ACRP-CP® (Association of Clinical Research Professionals – Certified Professional) is a new credential formally recognizing professionals involved in all aspects of clinical studies/trials who have demonstrated the knowledge, skills, and abilities to perform ethical and responsible clinical research by passing the standardized ACRP Certified Professional 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/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 CROs, 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:	
8:30AM	<i>Registration Sign-in</i>
9:00–9:15	Welcome and Introduction
9:15–11:00	Module 1: Objectives, Agenda, Introduction to Certification
11:00–11:15	<i>Refreshment Break</i>
11:15–12:15	Module 2: Overview of the 6 relevant guidelines
12:15–1:00PM	<i>Lunch provided</i>
1:00–2:30	Module 2 Continued: Overview of the 6 relevant guidelines
2:30–2:45	<i>Refreshment Break</i>
2:45–3:45	Module 3: Practice Questions
3:45–4:00	Questions and Answers, Adjourn

Target Audience:
Eligible candidates for the CCRA®, CCRC®, CPI® and/or new ACRP-CP® ACRP Certification Exam.
Fall Certification Exam Cycle: February 2nd - March 20, 2018. Application deadline: February 2, 2018.
Early Bird Exam Registration: October 16, 2017 - December 1, 2017. Regular Registration: Starts December 2, 2017.
<https://www.acrpnert.org/professional-development/certifications/>

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

EVENT REGISTRATION closes <u>Thursday, 07 December 2017, 11:59PM</u> Eastern Time	
Register NOW to ensure admission; PRE-REGISTRATION required	
www.acrpnert.org/nymetro	
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.	

Questions About ACRP Online Registration: chapters@acrpnert.org

Questions About This Classroom Course:
Janet Ellen Holwell, CCRC, CCRA, FACRP, 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



Program for the Protection of Human Subjects
Investigational Review Board
Mount Sinai Medical Center
New York, NY 10029

Please see www.acrpnert.org/nymetro for more information about our Chapter and visit often to check on our upcoming 2017 events.

For those of you coming from out of town, click on the picture below for directions to Mount Sinai Medical Center, Leon and Norma Hess Center for Science and Medicine, 2nd Floor, Seminar Room B where the Prep Course will be held.





NYU DENTISTRY

MS Program in Clinical Research

- 1-year Master’s of Science degree
- Courses in Clinical Trials, Ethics, Epidemiology, and more

Now accepting applications for Fall 2017 enrollment! To learn more and apply, click here.



FREE EDUCATIONAL OPPORTUNITIES

UPCOMING WEBINARS

[2017 in Review - How Legal and Regulatory Changes Impact Your Research](#)
December 5 and 7, 2017 at 1:00 pm EST
Presented by Kinetiq

[Considerations in First-In-Human Clinical Trials: Planning for Success](#)
December 5, 2017 at 12:00 pm EST
Presented by Business Review Webinars

[Maximizing the Value of Your EDC Investments](#)
December 6, 2017 at 10:00 am EST
Presented by Business Review Webinars

ON DEMAND WEBINARS

[How to Improve Your Clinical Trial Patient Recruitment: A Panel Discussion](#)
Presented by Forte Research Systems

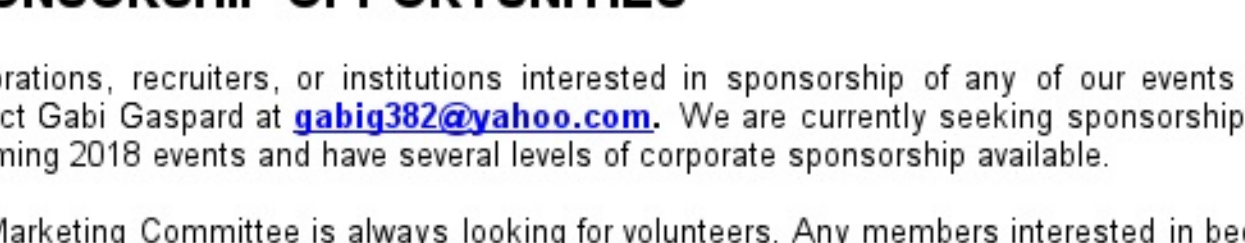
[Avoiding Delays to the Clinic](#)
Presented by Forte Research Systems

[Solving the Problem of Clinical Research Enrollment](#)
Presented by Business Review Webinars

ARTICLES

[Tips to Ensure Data Quality When Implementing or Optimizing a CTMS](#)
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 266 active members to date with 13 new and returning members joining us in the last quarter. We would like to give a warm welcome to:

Jerusa Altama; Mary Ann Fable; Shahid Mahmood; Maureen Purcell; Sarah Ramoutar-Persaud; Devin Columbus; Alina Veretennikova; Louise Purcell; Shana Manuel; Mary Yohannan; Ion Marinescu; Lauren Odynocki; John Sealock

For membership questions, email Jun Loquere at al2061@cumc.columbia.edu. You can also log on to www.acrpnert.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

Corporations, recruiters, or institutions interested in sponsorship of any of our events should contact Gabi Gaspard at gabi382@yahoo.com. We are currently seeking sponsorship for our upcoming 2018 events and 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.

UPCOMING EVENTS

14th Annual Holiday Networking Party
December 7, 2017
6:00 - 9:00 PM

ACRP Certification Exam Prep Classroom Course
December 9, 2017
9:00 AM - 4:00 PM

2017 Officers

President
Christina Brennan, MD, MBA

Immediate Past President
Erika Stevens, MA

Past Presidents Advisory Committee Chair
Erika Stevens, MA

Secretary
Joyce Ann Moran, CCRC

Treasurer
Sumathi Sundarababu, PhD

Parliamentarian
George Gasparis

Bylaws Committee Chair
George Gasparis

Communications Committee Chair
Janet Ellen Holwell, CCRC, CCRA, FACRP, TIACR

Education & Programs Committee Chair
Halley Rogers, MPH, CCRC

Marketing Committee Chair
Gabi Gaspard, MPH, CCRC

Membership & Retention Committee Chair
Jun Avelino Loquere RN, MD, CCRC, CCRP

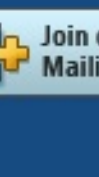
Nominations Committee Chair
Carlotta Rodriguez, MS, CIP, CHRC

Member at Large
Alison Randall, MPH, CCRC
Gina Guattiere
Raynelle Mensah

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