PRESIDENT'S MESSAGE
Lisette Gonzalez, CCRA

Welcome to our final newsletter for 2014 and my last message to you as President of the New York Metropolitan Chapter. It has been a privilege to serve as president twice since the chapter was started and I hand over the role of President to Erika Stevens. I would like to thank the Board and all of the volunteers who willingly give their personal time to be able bring you the types of programs and events that you may not be able to otherwise attend due to distance and/or cost. As I look back to our beginnings at the end of 2003 to where we are today and where I believe will be in the future, it makes me very proud to be part of this chapter and thankful for all of the amazing clinical research professionals that I have come to know.

The Board would like to thank everyone who supported the chapter and attended our events this past year and we look forward to seeing you at all of our events next year.

Our last event of the year will be our ever popular 11th Annual Holiday Networking Party, which will take place on Thursday, December 4th. We will be holding it at a new venue for us - Tír Na Nóg, an Irish Bar & Grill, located on West 39th Street between 8th and 9th Avenues. Please see the flyer below. It is a beautiful space with stonework and wood panels that have been brought over from old homes and churches in Ireland. Once again the Rockefeller Christmas tree will have been lit the previous evening and the kiosks and skating rink are open in Bryant Park at 42nd Street and 6th Avenue. The early bird registration expires on November 26th at 11:55 PM so be sure to visit the Upcoming Events page of on our website for a copy of the flyer and to register for the event.

We will be holding our 4th Certification Classroom Prep Course on Saturday, December 13th. The ACRP certification exams will take place from February 26 to March 21, 2014. The cost will be the same as for the previous prep courses: $250 New York Metropolitan Chapter ACRP member, $275 ACRP member and $300 Non-Member. Check our Upcoming Events page or Global ACRP’s Certification and Professional Development pages for registration information.

We would like to thank our chapter members who cast their votes for the 2017-2018 President position. This position begins as President-Elect during 2015-2016. The winner is announced below.

Education Co-Chairs, Halley Rogers and Gabrielle Gaspard, are hard at work summarizing the results of the responses received for the end of year survey sent to all chapter members and attendees of our 2014 educational events. Your suggestions for future topics to be presented will be reviewed and help shape our 2015 educational presentations. The 2014 education program was developed based on last year's survey responses. You told us what you wanted presented and we listened.
Are you planning to attend the 2015 ACRP Global Conference in Salt Lake City? If you are, don’t forget to register before the end of December to save up to $500 on the registration price. The Keynote Speaker will be Rebecca Skloot, author of *The Immortal Life of Henrietta Lacks*. Ms. Skloot will be signing copies of the book at the conference (your own copy or one that you purchase at the meeting).

One last reminder, ACRP is offering a number of eLearning courses at a 50% savings through December 31st.

We are looking forward to seeing you at Tír Na Nóg on December 4th. Please enjoy your upcoming holidays and have a wonderful New Year. See you in 2015!

Best regards,
Lisette

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**BOARD ELECTION RESULTS ARE IN!**

We would like to announce that Christina Brennan, M.D., Director of Clinical Research for the Cardiovascular Division at North Shore Long Island Jewish Health System, been elected President for the term of 2017-2018. She will serve as President-Elect from 2015-2016. Join us in congratulating Christina and welcoming her to the Board.

Thank you to all of our chapter members who voted.

*New York Metropolitan Chapter of ACRP*
New York Metropolitan Chapter of ACRP Cordially Invites You to Attend Our

11th ANNUAL HOLIDAY PARTY

December 4, 2014
6:00 p.m. to 9:00 p.m.

TÍR NA NÓG - IRISH BAR & GRILL
315 West 39th Street (bet. 8th and 9th Avenues)
New York, NY

• Join us for a memorable night of conversation, networking and fun
• Enjoy good company, hot buffet, wine & beer and a special holiday cocktail
• Win fabulous door prizes

Early bird ends November 26th: $20 NYM Chapter/ $30 Non-NYM Chapter
After November 26th: $30 NYM Chapter/ $40 Non-NYM Chapter
At the Door: $40 NYM Chapter/ $50 Non-NYM Chapter
No Refunds After November 26th

Space is limited! Register Online Now at:
http://NYMetroACRP2014HolidayParty.eventbrite.com
ACRP Certification Exam Prep Classroom Course
Saturday, December 13, 2014
9:00 AM – 4:00 PM
Registration 8:30 – 9:00 AM
Trainer: Janet Ellen Holwell, CCRC, CCRA
Clinical Research Consultant

Location
NYU Langone Medical Center
Coles - 1st Floor – Room 105
550 First Ave
New York, NY 10016

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

Trainer Bio:
Janet E. Holwell, CCRC, CCRA:
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, territory development 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:

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<tr>
<th>Time</th>
<th>Activity</th>
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<tbody>
<tr>
<td>8:30AM</td>
<td>Registration Sign-in</td>
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<tr>
<td>9:00-9:15</td>
<td>Welcome and Introduction</td>
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<tr>
<td>9:15-11:00</td>
<td>Module 1: Objectives, Agenda, Introduction to Certification</td>
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<tr>
<td>11:00-11:15</td>
<td>Refreshment Break</td>
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<tr>
<td>11:15-12:15</td>
<td>Module 2: Overview of the 5 relevant guidelines</td>
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<tr>
<td>12:15-1:00PM</td>
<td>Lunch provided</td>
</tr>
<tr>
<td>1:00-2:30</td>
<td>Module 2 Continued: Overview of the 5 relevant guidelines</td>
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<tr>
<td>2:30-2:45</td>
<td>Refreshment Break</td>
</tr>
<tr>
<td>2:45-3:45</td>
<td>Module 3: Practice Questions</td>
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<tr>
<td>3:45-4:30</td>
<td>Questions and Answers, Adjourn</td>
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Target Audience:

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


Early Bird Exam Registration now open. [Link](http://www.acrponet.org/applicationandrates)

Questions About Certification Benefits, Requirements, and Preparation:
[Link](http://www.acrponet.org/MainMenuCategory/Certification.aspx)

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**EVENT REGISTRATION closes Thursday, 11 December 2014, 11:59PM Eastern Time.**

Register NOW to ensure admission; PRE-REGISTRATION required
[Link](http://www.acrponet.org/GetInfoFor/USChapters/NYNewYorkMetropolitan/UpcomingChapterEvents.aspx)

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</tr>
<tr>
<td>Non-member</td>
<td>$300</td>
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</tbody>
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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.
Give Us Your Ideas. We want to hear from you...

You spoke, and we listened. The education program agenda for 2014 was developed based on topic suggestions from our chapter members. We encourage you to continue to make recommendations for event topics or venues by completing an evaluation form at one of our chapter events, responding to our year end chapter survey, or by sending an email to nymetroacrp@gmail.com.

Our chapter’s mission is to serve the needs of its members, so we appreciate and welcome your ideas and feedback!
FREE EDUCATIONAL OPPORTUNITIES

PRE-RECORDED WEBINARS

Improve the Inclusion & Exclusion Criteria for Your Next Clinical Trial
Presented by Rho

Translating Quality by Design Principles into Practice
Presented by Clinical Trials Transformation Initiative (CTTI)

Understanding Real World Evidence: A Registry Study Perspective
Presented by MedPace

Preparation for Effective Management of Research Misconduct Allegations
Presented by Huron Consulting Group

Where is the Sunshine Act going? An update and forecast.
Presented by Forte Research Systems

IN THE NEWS

HHS and NIH take steps to enhance transparency of clinical trial results

Proposed rules will vastly expand trove of clinical trial data reported in U.S. database

Half of patients do not take meds as prescribed, yet no effective interventions in place

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 262 active members to date with 35 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@columbia.edu. You can also log on to www.acrnet.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 nessaroche@gmail.com.

SPONSORSHIP OPPORTUNITIES

The Marketing Committee is currently seeking sponsorship for our upcoming 2014 events. Corporations, recruiters, or institutions interested in sponsorship of any of our events should contact Janet Ellen Holwell at jholwell@aol.com or (718) 263-4160. 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 Janet.