



ACRP Northeastern Ohio Chapter Presents:

“Ensuring Quality Monitoring by Utilizing Auditing Techniques”

Speaker: Jeannine Ramsey, RN, BSN, CCRA
Clinical Auditor
IMARC Research, Incorporated

Thursday, December 8, 2011
5:00 – 6:30 p.m.

Bolwell Conference Room A in the Bolwell Building
University Hospitals Case Medical Center
11100 Euclid Avenue
Cleveland Ohio 44106

Brief Description:

This presentation will review the various mistakes commonly made during while monitoring a study. We will identify the top five issues cited during FDA audits and the root cause of this. Through the review of case studies, we will describe how the techniques of auditing can be applied to your monitoring process to avoid these common mistakes.

Program/Presentation Objectives:

- 1) Identify the top five issues regarding investigators and sponsors that have been cited in FDA Warning Letters in the past decade.
- 2) Describe how inadequate monitoring processes may have contributed to these findings.
- 3) Apply auditing techniques to monitoring processes in order to mitigate risk at the site and sponsor level.

Agenda:

5:00 – 5:30 pm Networking and light meal

5:30 – 6:15 pm Presentation

6:15 – 6:30 pm Questions and answers

Mission: To provide global leadership to promote integrity and excellence for the clinical research profession.



Target Audience:

Research Professionals

Continuing Education Contact hours:

This Event Has Been Approved For 1.0 Contact Hour thru ACRP.

Contact hours can **ONLY** be purchased on the Northeastern Ohio website and are available until **DECEMBER 15TH**. If you are not sure you can attend the event don't sign up for the CEU until after you have attended, as obtaining a refund may be a lengthy process.

For ACRP Members: If you would like to receive Continuing Education Credits you will need to sign up instructions below

- Go to www.acrpnet.org and login
- Click on Northeastern Ohio ACRP on the right side of the screen
- See Education event
- Click on purchase CEU's
- Pay \$10 with Visa/MasterCard
- 10-30 Days after the event you can access your evaluation. It will appear in your "My Tests, Evaluations and Certificates" section of the ACRP website.
- Your CEU's certificate will be available to print once you complete the evaluation. The evaluation will be available on your ACRP records from **DECEMBER 18TH-January 18th**

For Non-Members: If you would like to receive Continuing Education Credits, a fee of \$25 applies. Follow the above directions, but you will be paying \$25. If you have never logged into ACRP before, you will need to select the "new visitor registration link" on the sign in page. After you have created an "account" you may purchase the CEUs at the nonmember rate. As a reminder, to join or renew your **Northeastern Ohio** Chapter membership, ACRP Global membership must also be maintained.

To join or renew your membership in ACRP Global, Please go to the ACRP website: <http://www.acrpnet.org>; click on "Join ACRP" in the upper right hand corner of the home page and follow the instructions.

To join or renew your membership in our local Northeastern Chapter, go to the ACRP's home page, click on "Chapters/Forums," then on the "Northeastern Ohio



Chapter.” At the very bottom of that page, click on “Join This Chapter,” then follow the instructions given. We invite your active participation in our local

chapter. Your participation will help our chapter develop into a group that meets the needs of our members. It will also enable us to continue to offer excellent educational programming.

If you are interested in presenting or have a suggestion for a program or speaker OR if you are interested in participating on one of our Chapter’s committees OR have information or ideas for the Northeastern Ohio Newsletter, please contact any Board member. We want to know how we can best meet your interests and needs and also utilize the skills, ideas, and energies of each of our members.

Thank you for your membership in the Northeastern Ohio Chapter of ACRP. We look forward to seeing you December 8, 2011.

President: Sonya Mihalus sonya.mihalus@uhhospitals.org

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For more information about the Northeastern Ohio Chapter, please see our Chapter web page at: <http://www.acrpnet.org/GetInfoFor/USChapters/northeasternohio.aspx>

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If you would like your name to be removed from the Local Chapter mailing list, please contact: toniamrn@yahoo.com

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