



Recent News Headlines:

Government Orders Columbia University to Tell Patients "True Nature" of Drug Study

Ten years ago, more than 200 open-heart surgery patients were part of a two-year medical study at Columbia University that government regulators now say was carried out with ethical and regulatory mistakes and may have caused harm to some patients. The study was testing a commonly used intravenous surgical fluid that previous studies had shown could cause hemorrhaging at high doses. At least two patients in the study died shortly after receiving the fluid, and more than two dozen others required transfusions, according to documents submitted to the federal government by the hospital. In the past decade, Columbia has conducted three separate internal reviews of the study. The reviews raised serious questions about the drug trial's design, management, and oversight, but they concluded that there was no evidence that the fluid caused deaths or other medical problems for the patients and that there was no need to provide the patients with additional information about the study. Now, federal regulators have decided not to accept that conclusion. They have taken the rare action of demanding that Columbia track down the patients and their families, and acknowledge that they never were informed about the "true nature" of the drug study, the risks they faced, or the consequences of their participation. Source: [Flesh and Stone/Huffington Post Investigative Fund](#) 10/8/09

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National ACRP is imposing the following policy changes:

- ◆ Additional fees for contact hours (amount based on number of contact hours). This fee will be paid directly to national by the attendee. This Chapter will maintain seminars at 1-2 contact hours to keep charges at a minimum.
- ◆ Registration and payment for local Chapter seminars will now be conducted through the National website link to the Greater Pittsburgh Chapter.

Officers for 2008-2010

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The Greater Pittsburgh Chapter of ACRP is pleased to present
2009 Annual Dinner Meeting



November 12, 2009

University of Pittsburgh University Club

123 University Place



Electronic Data Management in Research
Speaker: Elizabeth Ronk Nelson, MPH
President and Senior Consultant, Regulatory Risk Management, LLC

5:00 PM	Registration/Networking
5:30 PM	Dinner
6:00 PM	Speaker presentation and questions
7:30 PM	Wrap-up and door prizes

Ms. Nelson will review the basic requirements from 21 CFR Part 11, FDA's guidance on electronic record-keeping. She will give real-life examples of system failures and how to control and prevent them.

Program Objectives:

- ◆ Apply 21 CFR Part 11 Electronic Records and Signatures regulations
- ◆ Assess basic Part 11 compliance issues with electronic medical record systems
- ◆ Put systems in place to manage electronic data

Target Audience: Clinical Research Coordinators, Clinical Research Associates, Investigators, IRB Staff, Regulatory Document Associates and anyone working within clinical research.

**** Please Note New Policies ****

Registration is not yet open. When open, it will be conducted through the National ACRP website - www.acrpnet.org

Greater Pittsburgh members—\$20

Non-members—\$30

Please register by November 5, 2009

1.5 Contact Hours have been applied for through ACRP.

There is an additional charge of \$10 for members to obtain the contact hours.

2009 Seminars

The Research Rally on the River was a great program. David Wehrle discussed conflicts of interest and their relevance in human subject research.

The Fall seminar unfortunately had to be cancelled. We hope to offer this event again next fall.

We hope to have a networking session at the University Club in the beginning of December. Please feel free to bring your colleagues. There will be no charge for this event. Details soon.

We would like to hear your ideas for future presentations and seminars. Please contact a board member with your suggestions.

Our chapter is in need of additional people to assist with various chapter activities. Please contact a committee member for details.

Unsure about the federal research regulations?

Here are the web addresses for the Department of Health and Human Services and the FDA.

<http://www.hhs.gov/ohrp/faq.html>

<http://www.fda.gov>



Please join a committee to help make the upcoming year a success!

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