Greater Charlotte ACRP
And
UNCC Center for Professional & Applied Ethics
Presents
"Back to Basics…And Beyond"

Friday October 30, 2015

7:30 am – 3:30 pm

David H. Murdock Research Institute
150 N Research Campus Drive
Kannapolis, NC 28081

7:30 - 8:00 a.m.	Registration and Continental Breakfast
8:00 - 8:15 a.m.	Welcome and Introductions
8:15 - 9:15 a.m.	**Laurin Mancour**, **CCRA,** Account Executive, Trial Results Program, CISCRP "Communicating Trial Results: Data Sharing that Engages Patients as Partners"
9:15 -9:30 a.m.	**Break**
9:30 -10:30 a.m.	**Lisa Haney, BS CCRC**, Data and Safety Monitoring Committee Manager, University of Colorado Cancer Center "Beyond Audit Survival: The Busy Clinical Research Professional's Guide to Audit Preparation"
10:30 a.m.-11:30	**Diane Uzarski, DNP, MPH, RN,** Associate Director – Biobanking Program Duke Translational Research Institute, "Precision Medicine and PCORNet: Harnessing the Power of Clinical Data and Biospecimens to Change Clinical Practice"
11:30 – 12:15 p.m.	**Lunch Buffet**
12:15 – 1:15 p.m.	**Mary K.D. D'Rozario, MSCR, MBA, CCRP, RAC, CCRA**, President CRP Social Media "Social Media Strategies for Clinical Research Professionals"
1:15 – 2:15 p.m.	**Sandra (Sam) Sather, MS, BSN, CCRA, CCRC, "**Clinical Data, EHR, Informed Consent and Privacy. What Are the Rules and How to Ensure Compliance?
2:15-2:30 p.m.	**Break**
2:30-3:30 p.m.	**Robert Romanchuk, BSHS, CIP, CCRC, CHRC, CCRCP,** Vice Chair, Schulman Associates IRB, "Expanded Access to Investigational Drugs and Devices: *Navigating the Maze"*
3:30 - 4:15 p.m.	Tour of Kannapolis Research Campus

Registration for attendance available through Constant Contact:
http://events.constantcontact.com/register/event?llr=h6xnl5rab&oeidk=a07ebo8sd3a0e0c90cc

***Contact hours available for purchase separately at ACRP site pending ACRP approval**
http://www.acrpnet.org/GetInfoFor/USChapters/GreaterCharlotte.aspx

Fees:

GCACRP member	Program $100	Contact Hours $0	6.0 Contact Hours
ACRP Member	Program $100	Contact Hours $35	through ACRP,
General Public (non-ACRP)	Program $145	Contact Hours $50	pending approval

UNCC Faculty & Students: No charge for attendance but registration is required at: http://acrpnet.org/
Contact hours may be purchased during registration.

Parking Information:

Entrance to the parking deck is on Laureate Way adjacent to the building. (No tokens or tickets are required).

Brief Description
This all-day event will provide updates on topics of interest to those involved in clinical research. We'll cover the basics - from regulatory to privacy, and reach into newer topics: biobanking, social media, expanded access and disclosure of trial results to subjects.

Objectives
Upon completion of the program, attendees will be able to:
1. Describe simple and scalable processes for communicating trial results and information in a patient-friendly format to study participants.
2. Provide data on the impact of sharing trial results with patients from patients' and sites' perspective.
3. Distinguish between monitoring and auditing activities.
4. Formulate a plan for conducting clinical research that is always "audit ready".
5. Develop approaches for dealing with potential audit findings that occur during research conduct.
6. Describe the Precision Medicine initiative and its short and long term goals.
7. Understand the critical role that biospecimens and harnessing clinical data play in genomics and translational research.
8. Gain understanding of the national PCORNet initiative; its structure, goals, and new observational studies aimed to change clinical practice.
9. Understand shift to social businesses.
10. Understand how to develop social media skills.
11. Understand social media for advertising (patient recruitment).
12. Identify the latest expectations for enabling records access in a HIPAA-compliant manner.
13. Describe how sites and sponsors are being impacted by privacy rules.
14. Recall the historical and ethical underpinnings of request for access to investigational products.
15. Analyze the differences between regulations governing access to investigational devices vs drugs.
16. Evaluate recent "Right to Try" laws in the context of expanded access.

Target Audience
This course is intended for clinical research professionals, including clinical research associates (CRAs), clinical research coordinators (CRCs), research nurses, principal investigators (PIs), clinical study managers, project managers and project directors, and clinical research administrators, working in academia or for pharmaceutical, biotech, or device firms, or for research sites or contract research organizations (CROs). Students and others interested in learning more about translational medicine are welcome.

To receive contact hours: Contact hours will be available for purchase for up to 14 days following the event. Complete the online evaluation found on the ACRP homepage www.acrpnet.org under "My Tests, Evaluations, and Certificates"on the right-hand side of the page under "Your Quicklinks" (must be logged in to view). Evaluations expire after 30 days.

Refund Policy: Cancellations must be made in writing to GCACRP. If a registrant must cancel for the workshop, the fees, less a $15 nonrefundable processing fee may be refunded, provided that the request for cancellation is received at least 15 calendar days prior to the course. Requests for cancellations received after that time will not be refunded. Exceptions will be decided on a case by case basis. The refund will be sent to the party who initially paid for the course.

Cancellation Policy: The Greater Charlotte Association of Clinical Research Professionals reserves the right to cancel any class or event at any time due to speaker conflicts / cancellations, registration of fewer than 6 persons, or other unexpected event. The Greater Charlotte Chapter of ACRP will refund any registration fees associated with cancellations, but has no funds set aside to reimburse for related expenses (such as absence from work, travel or hotel expenses). Please call or email to check on availability.