Global CompliancePanel

Netzealous
Knowledge, a Way Forward…

2-day In-person Seminar:

Human Subjects Research Seminar: Current Regulations under FDA and HIPAA

Atlanta, GA

November 3rd & 4th, 2016

9:00 AM to 6:00 PM

Price

Price: **$1,295.00**

(Seminar for One Delegate)

Register now and save $200. (Early Bird)

Register for 5 attendees (With stay)

Price: **$3,885.00** You Save: $2,590.0 (40%)*

~~$6,475.00~~

ENROLL

***Please note the registration will be closed 2 days (48 Hours) prior to the date of the seminar.*

Sarah Fowler-Dixon

Education Specialist and instructor , Washington University

Sarah Fowler-Dixon, PhD, CIP is Education Specialist and instructor with Washington University School of Medicine. She has developed a comprehensive education program for human subject research which has served as a model for other institutions. She crafted budgets, policies, procedures, reporting, and training for the new program. She has initiated the planning, development, authorship and implementation of many human subjects research policies, practices, guidelines, submission and reviewer forms often working with state and federal authorities.

Overview :

This two day seminar will provide the foundation for the application, concepts and theories of clinical research. Within the two days, attendees will learn about the historical evolution of research, current regulations and guidelines including the Common Rule, FDA regulations and HIPAA. We will discuss site and study staff responsibilities in the conduct and reporting of research, types of studies and the regulatory requirements that apply to different study designs. We will discuss a variety of research including genetic, drug, device, and studies that use off-site or community partners. Current examples will be used and the audience will be invited to share their experiences and information.

Agenda:

Day One

Lecture 1: The Evolution of Human Experimentation Regulation and Overview of Clinical Research and Ethics in Human Research

Lecture 2: Current Federal Regulations and Agencies involved in Human Research

Lecture 3: Selection and Recruitment of Research Subjects

Lecture 4: Informed Consent in Clinical Trials

Lecture 5: Confidentiality of Clinical Trial Information

Lecture 6: The Investigator

Lecture 7: Research Protocols

Day Two

Lecture 1: Multisite, Community and Collaborative Studies

Lecture 2: The Institutional Review Board

Lecture 3: Patient Safety in Clinical Trials Research

Lecture 4: Research Under the Food, Drug & Cosmetic Act

Lecture 5: International Research

Lecture 6: Compliance and Human Research

Lecture 7: Accreditation and Risk Management in Clinical Trials

Areas Covered in the Session:

- Department of Health and Human Services regulations, 45 CFR 46
- Office for Human Research Protections Guidance
- The FDA regulations, 21 CFR 50, 56, 312, 314, 812, 814
- HIPAA and HI-Tech
- ICH E6 Good Clinical Practices
- Coercion vs. undue influence
- Recruitment of Research Subjects
- Vulnerable populations
- Non-English speaking populations
- Inclusion of Women and Minorities

Who Will Benefit:

- Principal Investigators / Sub-investigators.
- Clinical Research Scientists (PKs, Biostatisticians,)
- Safety Nurses
- Clinical Research Associates (CRAs) and Coordinators (CRCs)
- Recruiting staff
- QA / QC auditors and staff
- Human Research Protection professionals
- Clinical Research Data managers
- Human Research Protection professionals

Group Participation

10%	2 Attendees to get offer
20%	3 to 6 Attendees to get offer
25%	7 to 10 Attendees to get offer
30%	10+ Attendees to get offer

Payment Option

1. Credit Card: Use the Link to make Payment by Visa/Master/American Express card click on the register now link
2. Check: Kindly make the check payable to NetZealous DBA GlobalCompliancePanel and mailed to 161 Mission Falls Lane, Suite 216, Fremont, CA 94539, USA
3. PO: Please drop an email to support@globalcompliancepanel.com or call the our toll free +1-800-447-9407 for the invoice and you may fax the PO to 302 288 6884
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What You will get

1. Learning Objectives
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Contact Information: Event Coordinator

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Kindly get in touch with us for any help or information.

Look forward to meeting you at the seminar

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