

The mission of the Office for Human Subject Protection (OHSP) is to establish the University of Rochester Medical Center as a leader in protecting the rights, welfare, and safety of human subjects participating in research. To that end, the OHSP has introduced a number of training and educational opportunities including compulsory training programs in research ethics and human subjects safety, a monthly seminar series for research personnel, training courses in the proper conduct of clinical trials and Good Clinical Practices, University wide department training sessions, and assistance with obtaining certification for Clinical Research Coordinators.

Course Director:

Erin E. Krohl, B.S., M.S., M.P.H.

Erin E. Krohl serves as the President of **EHK**Krohl Consulting, Inc. , a company founded in January of 1996, providing advice, expertise, and training to the pharmaceutical, medical device, biologics, biotechnology and affiliated industries, with regards to compliance to FDA GMP, GLP, and GCP requirements/expectations. **EHK**Krohl Consulting, Inc. has practical experience in establishing and implementing corrective action plans, performing mock-FDA audits, working with fraud/scientific misconduct situations, aiding firms with all other compliance-oriented GXP activities.

Ms. Krohl received a B.S. in Biochemistry from Louisiana State University, a M.S. in Pharmacology from Louisiana State University Medical Center, and a M.P.H. from the University of Alabama at Birmingham. Ms. Krohl spent six years as a FDA Field Investigator, conducting GMP, GLP and GCP inspections of foreign and domestic medical device, veterinary and human drug manufacturers, as well as conducting pre-approval inspections.

Course Outline

(workshop hours 1:00 pm - 5:00 pm)

INTRODUCTION TO THE FDA

Overview of Clinical Research
The Regulatory Process
Laws vs. Regulations vs. Guidelines
Product Development Standards
“Good Clinical Practices “(GCPs)

TRIAL SITE ROLES/RESPONSIBILITIES

Principal Investigator
Study Coordinator
Study Monitor

THE FORM FDA 1572

Recent FDA citations

FINANCIAL DISCLOSURE

ELECTRONIC RECORDS/ELECTRONIC SIGNATURES

ICH GUIDELINES FOR GCP

THE FDA BIORESEARCH MONITORING PROGRAM

CLINICAL INVESTIGATOR INSPECTION PROGRAM

DETAILS OF THE FDA GCP SITE AUDIT

Authority and Administration
Protocol
Institutional Review Board
Human Subjects’ records – Informed Consent
Source Documents
Case Report Forms
Other Study Records
Financial Disclosure
ElectronicRecords/Electronic Signatures
Test Article Control
Records Custody and Retention
Reports to Sponsor
Monitoring
Device Studies

UNDERSTANDING THE FDA INSPECTION

Who is the FDA Inspector?
What Makes the FDA Suspicious?
FDA Inspection Outcome Possibilities
Typical Study Conduct Observations
Example of Recent FDA Warning Letter Observations

FDA AUDIT STRATEGY

Practical Hands-On Workshop

The goal of the 1/2 day workshop is to provide training in a workshop setting to prepare research coordinators and Investigators for an FDA Good Clinical Practice Audit.

Each participant will receive a copy of the PowerPoint presentation and handouts for future reference.

WORKSHOP OBJECTIVES

- 1) Present the background aspects affecting the requirements of clinical research on human subjects per the FDA perspective
- 2) Identify the FDA requirements for Principal Investigators for conducting human clinical research and describe recent examples of non-compliance issues
- 3) Identify other FDA regulations that may be required for clinical trial conduct
- 4) Present the various activities conducted by the FDA auditor and how to prepare for a site audit
- 5) Discuss the FDA inspection process, describe possible outcomes and observations, and discuss audit strategy tips

Who Should Attend:

- Clinical Research Coordinators, Research Nurses, RNs, LPNs, and investigators who want to learn how to prepare for a FDA GCP audit.

To register see back page.
For additional information call:
(585) 273-4127 fax (585) 273-1174
www.urmc.rochester.edu/ohsp

Registration Information

***25.00 Workshop fee**

Fee includes copy of PowerPoint Presentation, handout materials, and a refreshment break.

Payment by check, payable to the University of Rochester, or by U.R. 312 Requisition. Forward registration information and payment to:

**University of Rochester
Office for Human Subject Protection
601 Elmwood Ave., Box 628
Rochester, New York 14642**

* This workshop is supported by a grant from the University of Rochester Office for Human Subject Protection and the Pulmonary Hypertension Research Program under the direction of Dr. James White.

The Society of Clinical Research Associates accepts documentation of candidate participation in continuing education programs for re-certification if the program is applicable to clinical research regulations, operations or management, or to the candidate's clinical research therapeutic area. This program offers 3.75 CE credit.

This activity has been submitted to the New York State Nurses Association for approval to award contact hours. The New York State Nurses association is accredited as an approver of continuing nursing education by the American Nurses Credentialing Center's commission on accreditation.

Name	_____
Title	_____
Organization/ Department	_____
Address/ Box Number	_____
Work Phone	_____
Fax	_____
Email Address	_____

**University of Rochester
Office for Human Subject Protection
601 Elmwood Avenue, Box 628
Rochester, New York 14642**

*Please pass this on to individuals
who may benefit from attending
this 1/2 -day workshop. Thanks*

*Preparing for the FDA GCP Site
Audit
Workshop Series*

UNIVERSITY OF ROCHESTER

**Office for Human Subject
Protection
&
The Pulmonary Hypertension
Research Program**



presents

Preparing for the FDA Good Clinical Practices (GCP) Site Audit

1/2 -Day Workshop

October 26, 2009

Location

**University of Rochester Medical Center
Rochester, N.Y.**

Class of '62 Auditorium(G-9425)