

Office for Human Subject Protection (OHSP)
www.rochester.edu/ohsp

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:
Deborah L. Rosenbaum, CCRA, CCRC

Deborah Rosenbaum, lead consultant for Sarrison Clinical Research, LLC, has over 23 years experience in research. Ms. Rosenbaum is certified by ACRP as a CRA and CRC. She is accredited Clinical Research Trainer (CCRT) by ACRP, and a certified Training Generalist by Langevin Learning Services. Her experience includes conducting preclinical research, clinical research scientist for industry (Burroughs Wellcome and Hoffmann LaRoche), and clinical research coordinator (Bowman Gray School of Medicine).

Ms. Rosenbaum develops and presents customized training programs for industry sponsors and research institutions.

Additionally, Ms. Rosenbaum has completed three books on clinical research entitled, "The Practical Clinical Trial Series."

Course Outline

(workshop hours 8:30 am - 5:00 pm)

DAY ONE:

OVERVIEW OF CLINICAL RESEARCH

General aspects of drug development
Preclinical drug development concepts
Clinical study designs
Protocol development
New Drug Application (NDA) to the FDA

THE FEDERAL REGULATIONS

History of regulatory development
Obligations of investigators
IRB requirements
Required elements of informed consent, additional elements

THE INFORMED CONSENT PROCESS

Regulatory aspects
Writing the informed consent document
Presenting informed consent
Proper informed consent
INFORMED CONSENT WORKSHOP

STUDY LOGISTICS

Definition of roles
Site selection
Study planning
Study start-up
Study coordination strategies and tools

EXERCISE: STUDY FILES

DAY TWO:

SUBJECT RECRUITMENT AND RETENTION

Subject recruitment plan
Subject enrollment
Making participation attractive
Subject retention and compliance

SITE VISIT OVERVIEW

Study initiation
Periodic monitoring
Study termination

DATA MANAGEMENT

DATA MANAGEMENT WORKSHOP

DAY THREE:

ADVERSE EVENTS

Assessing adverse event information
FDA definition of serious adverse events
FDA reporting requirements for serious adverse events

SERIOUS ADVERSE EVENTS WORKSHOP

INVESTIGATIONAL AGENT MANAGEMENT

Packaging and shipping of investigational agents and supplies
Drug accountability

INSPECTIONS BY THE FDA

Types of FDA inspections
Preparation for an FDA inspection
Outcomes and consequences of the inspection

INSPECTION WORKSHOP

Practical Hands-On Workshop

Experience on:

- Obtaining informed consent
- Maintaining study files
- Data management
- Managing adverse events
- Preparing for an FDA inspection

Each participant will receive a Course Manual for future reference.

You Will Learn:

- 1) The federal regulations and guidance that are a part of Good Clinical Practice required to conduct clinical studies.
- 2) How to conduct a study - from preparation to final report.
- 3) Standards for conducting high quality clinical research at your site.

Who Should Attend:

- New clinical research coordinators who want to learn how to conduct clinical studies properly.
- Experienced coordinators who are interested in updating their knowledge regarding GCPs and eager to learn the most up-to-date methods for the conduct of clinical research to the highest standard.

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

Registration Information

\$900.00* 3-day workshop fee

Fee includes workshop manual, all workshop materials, and 1 lunch.

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**

* Since the course is supported by a grant from the University of Rochester Office for Human Subject Protection, University of Rochester employees can attend the course for \$600.00.

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/Degree	_____
Title	_____
Department/ Organization	_____
Box Number/ Address	_____
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 3-day workshop. Thank you.*

**UNIVERSITY OF
ROCHESTER**
OFFICE FOR HUMAN SUBJECT PROTECTION
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presents

Conducting Clinical Trials

3-Day Workshop

December 1 - 3, 2009

Location

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

*Conducting Clinical Trials
Workshop Series*