

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 30 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."

Day 1 - April 2, 2009
Evaluating a Protocol and Starting a Study
1 day Workshop
(workshop hours 8:30 am - 5:00 pm)

Day 1 - April 2, 2009

Evaluation A Protocol

- Protocol content
- Standard protocol requirements
- Checklist activity

Define Key Areas To Implement The Study

- Clinical versus scientific elements of the protocol
- Subject protection
- Subject population

Identify Key Obstacles To Conducting A Study & Suggesting Solutions To Obstacles

- Financial obstacles
- Population limitations
- Sponsor related obstacles

Identifying Activities To Begin A Clinical Study

- Review of protocol
- Budget
- Study population
- Working with other departments
- Establishing the documentation
- Organizational aids

Define Key Concepts In Managing Personnel

- Roles and responsibilities
- Communication

Evaluating progress of Study And Implement Changes

- What can go wrong
- Strategies for changes

Day 2 - April 3, 2009
Managing a Clinical Study: Beyond Study Start-up
1 day Workshop
(workshop hours 8:30 am - 5:00 pm)

Day 2 - April 3, 2009

Assessing protocol and Needs

- Using a protocol determine personnel and needs to conduct study
- Assessing study file
- Evaluate IRB and Informed Consent Needs

Subject Interactions

- Screening
- Consenting Subjects

Scheduling Subjects

- Exercise: using case studies plan and schedule multiple subject visits using protocol requirements

Subject Visits

- Role Play: Interview subject to determine compliance and Adverse Events
- Using information gathered in this session, complete a CRF, which will be collected and graded as part of exam process

Managing Personnel

- Problem that can occur
- Strategies for resolution to problems

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

Registration Information

\$200.00 for each 1-day workshop
\$375.00 if you sign-up for both
workshops*

Fee includes workshop materials and refreshment breaks.

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
Box 628

***Signing up for both workshops qualifies for partial (80%) U of R tuition reimbursement**

Please indicate your preference:

Evaluating a Protocol and Study Start-up
(Day 1 only)

Managing a Clinical Study –Beyond Study
Start-up (Day 2 only)

I wish to attend both workshops

This continuing nursing education activity has been approved by the New York State Nurses Association, an accredited approver 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
these workshops. Thank you.*

*Advanced Clinical Research
Coordinator Training Workshops*

UNIVERSITY OF
ROCHESTER
OFFICE FOR HUMAN SUBJECT PROTECTION
www.rochester.edu/ohsp



presents

*Two Advanced Clinical Research
Coordinator Training Workshops:*

Evaluating a Protocol and Starting a
Study
1-day Workshop
April 2, 2009
and
Managing a Clinical Study – Beyond
Study Start-up
1-Day Workshop
April 3, 2009

Location

University of Rochester Medical Center
Rochester, N.Y.