Current Issues in Clinical Research: How Education, Certification, and Validation Will Improve the Quality of Research

September 25-26, 2003

Mayo Civic Center
Rochester, Minnesota

Presented by
Mayo Alliance For Clinical Trials and
Mayo Center For Patient Oriented Research –
Office For Study Coordinator Education
COURSE DESCRIPTION
This conference is designed for study coordinators, nurses, physicians, and other research personnel who are involved in the management and coordination of clinical research. The program will provide a comprehensive review of the responsibilities and processes of clinical research performance. The conference format balances topics of general interest, which are presented in large group sessions, with specific clinical research and management issues addressed in small breakout sessions.

COURSE LEARNING OBJECTIVES
At the end of this conference, participants should be able to:
• Interpret current issues involved in the informed consent process
• Recognize the importance of patient protection in the current research environment
• Evaluate new HIPAA requirements and how they relate to clinical research
• Illustrate the principles of Good Clinical Practice
• Identify current legal issues in clinical research
• Discuss adverse experience reporting requirements
• Demonstrate the mechanics of teamwork in clinical research
• Appreciate the FDA’s growing role in clinical research oversight
• Examine emerging future trends in research, including certification requirements for Investigators and Coordinators

Attendance at this Mayo course does not indicate nor guarantee competence or proficiency in the performance of any procedures that may be discussed or taught in this course.

INTENDED AUDIENCE
This course is designed for clinical research professionals including study coordinators, physicians, and nurses. It is intended for individuals who need a review of the mechanics of clinical research coordination.

CONTINUING EDUCATION CREDIT
Mayo Foundation is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to sponsor continuing medical education for physicians.

Mayo Foundation designates this educational activity for a maximum of 10.25 category 1 credits toward the AMA Physician’s Recognition Award. Each physician should claim only those credits he/she actually spent in the activity.

Mayo Continuing Nursing Education is accredited as a provider of continuing nursing education by the American Nurses Credentialing Center's Commission on Accreditation. Participants may earn up to 12.2 accredited nursing contact hours.

Society of Clinical Research Associates has approved this conference for 10.75 continuing education units. Program approval number 0309-003.

Association of Clinical Research Professionals accepts ANCC, ACCME, and SoCRA contact hours.

American Academy of Pharmaceutical Physicians accepts ACCME credit.

DATE AND LOCATION
The Current Issues in Clinical Research Conference will be held September 25-26, 2003. Course headquarters will be located in the foyer of Presentation Hall on the first floor of the Mayo Civic Center, 30 Civic Center Drive Southeast, Rochester, Minnesota. Meeting facilities are easily accessible by skyway, which connects Mayo Civic Center to shops, restaurants, and hotels.

REGISTRATION
To register, complete the attached registration form and return by mail or fax. The registration fee includes tuition, comprehensive course syllabus, continental breakfasts, break refreshments, and reception. Although it is not Mayo Alliance for Clinical Trials and Mayo Center for Patient Oriented Research Education policy to
limit the number of registrants for a course, conference room facilities may necessitate closing of enrollment; therefore, early registration is strongly advised. A letter of confirmation will be sent upon receipt of payment and completed registration form. Please present this letter when checking in at the meeting registration desk.

CANCELLATION POLICY
Your registration fee, less a $50 administrative fee, will be refunded when written notification is received by Mayo Alliance for Clinical Trials Education Office on or before September 5, 2003. No refunds will be made after September 5, 2003.

TRAVEL
Rochester, Minnesota, is a friendly city that greets thousands of visitors from around the world each year. The city is serviced by a modern international airport with multiple flights daily from Chicago and Minneapolis via American or Northwest Airlines. Access to and from the airport is provided by taxi cab and shuttle service. The airport is located approximately 10 driving miles from the Mayo Clinic complex.

To take advantage of possible special airfares for this meeting, contact Corporate Travel at 800-537-6379 or 651-287-4943, 612-866-3022 (fax) or marya@ctsinc.com (e-mail). Identify yourself as attending the Mayo Clinical Research Conference.

LODGING ACCOMMODATIONS
Blocks of guest rooms have been reserved with special course rates at each of the following downtown Rochester hotels. To ensure accommodations and the discounted rate, please make your reservations by September 3, 2003, and identify yourself as a participant of the Clinical Trials Conference.

Hilton Garden Inn
225 South Broadway
800-445-8667 or 507-285-1234
$89 single/double

Rochester Marriott Hotel
101 First Avenue SW
877-623-7775 or 507-280-6000
$129 single/double

Holiday Inn City Centre
220 Broadway
800-241-1597
$89 single/double

Radisson Plaza Hotel
150 South Broadway
800-333-3333 or 507-281-8000
$109 single/double

The hotels listed above are connected by skyway and pedestrian subway to conference facilities, downtown shops, and restaurants. You may also wish to visit the Rochester Convention and Visitors Bureau website (www.rochestercvb.org) for additional accommodation options.

PARKING
Parking is available in hotel, city, and Mayo Civic Center ramps. The cost for parking is not included in the registration fee. A map indicating the location of downtown parking facilities will be mailed with the registrant confirmation letter.

SOCIAL PROGRAMS
Public tours of Mayo Clinic are provided each day of the week beginning at 10:00 AM, except for holidays. The tours originate from Judd Auditorium, Subway Level of the Mayo Building, and last approximately 1 1/2 hours. The tour includes a 20-minute film on the history and operation of Mayo Clinic plus visits to points of interest in the Mayo, Plummer, and Hilton Buildings. Please make advance reservations by calling 507-538-1091.

Mall of America, the largest fully-enclosed retail and family entertainment complex in the United States, is an easy 90-minute drive or shuttle ride from Rochester, Minnesota. Along with 500 retail stores, restaurants, and nightclubs, the mall features Knott’s Camp Snoopy, the world’s largest indoor theme park, and UnderWater World, a walk through an aquarium featuring 15,000 fish. Rochester Direct shuttle service will pick up at all local hotels, and departs every 2 hours from 9:00 AM – 5:00 PM. The cost is $25 per person round trip. For reservations, call Rochester Direct at 800-280-9270.
### Thursday, September 25, 2003

<table>
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| 7:00 – 8:00 AM | Registration and Continental Breakfast  
Mayo Civic Center, Presentation Hall foyer |
| 8:00 – 8:15 AM | Welcome and Conference Overview  
Robert L. Frye, M.D.  
Stephen L. Kopecky, MD |
| 8:15 – 9:00 AM | **Keynote Address**  
Murray M. Lumpkin, MD |
| 9:00 – 10:00 AM | **Making Informed Consent Meaningful**  
Jeremy Sugarman, MD, MPH, MA |
| 10:00 – 10:30 AM | Refreshment Break |
| 10:30 – 11:30 AM | **Validation and Certification of Investigators**  
Hans deHaan, MB, BS, PhD, FRCS, FFPM |
| 11:30 AM – 1:00 PM | Lunch, Mayo Civic Center Ballroom |
| 1:00 – 1:50 PM | Breakout Session – see registration form |
| 2:00 – 2:50 PM | Breakout Session – see registration form |
| 3:00 – 3:30 PM | Refreshment Break |
| 3:30 – 4:30 PM | **Update on OHRP Initiatives**  
Bernard A. Schwetz, DVM, PhD |
| 5:00 – 6:30 PM | Reception, Mayo Civic Center Ballroom |

### Friday, September 26, 2003

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| 7:00 – 7:45 AM | Continental Breakfast  
Mayo Civic Center, Presentation Hall foyer |
| 7:45 – 8:35 AM | **Conflicts of Interest in Clinical Research – Issues for Investigators, Institutions, and Industry**  
Phil B. Fontanarosa, MD |
| 8:45 – 9:35 AM | Breakout Session – see registration form |
| 9:45 – 10:35 AM | Breakout Session – see registration form |
| 10:45 – 11:35 AM | Breakout Session – see registration form  
*(Box lunches available)* |
| 11:50 AM – 12:40 PM | **Promoting Clinical Trial Quality: An Update on Good Clinical Practice**  
David A. Lepay, MD, PhD |
| 12:40 – 1:00 PM | Closing Comments |
Faculty

**Course Directors**

Robert L. Frye, MD  
Consultant, Division of Cardiology*

Stephen L. Kopecky, MD, FACC  
Consultant, Division of Cardiovascular Diseases  
Medical Director,  
Mayo Alliance for Clinical Trials*

Jessie L. Salk  
Director of Operations,  
Mayo Collaborative Services, Inc.*

*Mayo Clinic, Rochester

**Guest Faculty**

Murray M. Lumpkin, MD  
Principal Associate Commissioner  
US Food and Drug Administration  
Rockville, Maryland

Hans A. deHaan, MB, BS, PhD, FRCS, FFPM  
President and Chairman of the Board  
American Academy of Pharmaceutical Physicians  
San Diego, California

Bernard A. Schwetz, DVM, PhD  
Director (Acting)  
Office for Human Research Protections  
US Department of Health and Human Services  
Rockville, Maryland

Jeremy Sugarman, MD, MPH, MA  
Director, Center for the Study of Medical Ethics and Humanities  
Professor of Medicine and Philosophy  
Duke University Medical Center  
Durham, North Carolina

Phil B. Fontanarosa, MD  
Executive Deputy Editor, JAMA  
Adjunct Professor of Medicine,  
Northwestern University  
Feinberg School of Medicine  
Chicago, Illinois

David A. Lepay, MD, PhD  
Senior Advisory for Clinical Science and Director, Good Clinical Practice Programs  
US Department of Health and Human Services  
Rockville, Maryland

Eugene P. DiMagno, MD  
Chair, Institutional Review Board  
Professor, Mayo Medical School

Ivana T. Croghan, PhD  
Associate Professor in Research  
Nicotine Research Program

Colmar DeVon Figueroa-Moseley, PhD  
Director, Office of Diversity in Clinical Research  
Center For Patient Oriented Research

Katherine J. Flippin, BSN, RN  
Nursing Education Specialist  
Education and Professional Development

Nanci Hawley  
Compliance Coordinator  
Office for Human Research Protection

Anne Holland, RN  
Site Recruitment and Feasibility Manager  
Mayo Alliance for Clinical Trials

Paula Hoyne, PhD  
Contracts Manager  
Mayo Clinical Trial Services

Robert M. Jacobson, MD  
Chair, Pediatric and Adolescent Medicine  
Associate Professor of Pediatric and Adolescent Medicine, Mayo Medical School

Karen L. Johnson  
Director of Regulatory Affairs  
Mayo Clinical Trial Services

Linda S. Knowlton, CCRP  
Clinical Trial Coordinator  
Mayo Alliance for Clinical Trials

John R. Mills, JD  
Legal Counsel, Legal Department

Crystal Molen  
HIPAA Project Coordinator  
Mayo Collaborative Services, Inc.

Susan K. Quella, BSN, RN, OCN  
Clinical Trial Coordinator  
Mayo Alliance for Clinical Trials

Mary Vehrenkamp  
Quality Assurance Coordinator  
Mayo Medical Laboratories

R. Scott Wright, MD, FACC, FAHA  
Consultant, Division of Cardiovascular Diseases  
Director of Site Recruitment,  
Mayo Alliance for Clinical Trials

**Faculty Disclosure**

As a provider accredited by ACCME, Mayo Foundation must ensure balance, independence, objectivity and scientific rigor in its educational activities. All faculty participating in a Mayo Foundation activity are required to disclose commitments to and/or relationships with pharmaceutical companies, biomedical device manufacturers or distributors, or others whose products or services may be considered to be related to the subject matter of the educational activity. Faculty will also disclose any off-label and/or investigational use of pharmaceuticals or instruments discussed in their presentation. Disclosure of these commitments and/or relationships will be published in course materials so those participants in the activity may formulate their own judgments regarding the presentation.
Registration Form

Current Issues in Clinical Research: How Education, Certification, and Validation Will Improve the Quality of Research

September 25-26, 2003
Presentation Hall
Mayo Civic Center
Rochester, Minnesota

Mail form and payment to: Telephone: 800-541-5815
Mayo Alliance for Clinical Trials 507-266-3074
Education Office Fax: 507-284-4542
150 Third Street SW Website: www.mayoclinicaltrialservices.org
Rochester, MN 55902 E-mail: mcnamara.nancy@mayo.edu

(Print name/title, as you would like printed on your name badge)

Name ____________________________________________________________________________

Title ____________________________________________________________________________

Company/Institution ____________________________________________________________________________

Institution address ____________________________________________________________________________

City: __________________________________ State/PV: __________ Zip/PC: __________

Country ____________________________________________________________________________

Telephone ( ) __________________ Fax ( ) __________________

E-mail ____________________________________________________________________________

☐ Please check if you have special accommodation needs and indicate specific need(s): __________________________

Registration Fee: $450.00

Payment Method
☐ Check Enclosed (US Currency) payable to Mayo Foundation
☐ Credit Card: ☐ Visa ☐ MasterCard

Card Number __________________ Expires Mo/Yr

Signature __________________ Date __________________

Breakout Sessions
Please indicate your preference of conference breakout sessions: (use 1-15, with 1 being the most preferred). You will be assigned to 5 breakout sessions.

☐ The A B C s of SOPs – Linda Knowlton
☐ How to Participate in an Audit (2 hour breakout session) – Karen Johnson & Mary Vehrenkamp
☐ Informed Consent – Susan Quella
☐ IRB Policy and Procedures, Common Deficiencies – Nanci Hawley
☐ The Impact of HIPAA on Clinical Trials – Crystal Molen
☐ The Challenge of Pediatric Research in the Twenty-First Century – Robert Jacobson
☐ How to Create a Respectful Work Environment – Katherine Flippin
☐ Legal Issues in Research – John Mills
☐ Adverse Experiences and Reporting – Eugene DiMagno
☐ A Device Trial versus a Drug Trial: What are the Differences? – Stephen Kopecky
☐ Data and Safety Monitoring Board/Event Adjudication – Karen Johnson & Shari Brunon
☐ Contracting and Budgeting – Paula Hayne & Jessie Salk
☐ Clinical Research Team: Roles and Responsibilities – Anne Holland & Ivana Croghan
☐ Clinical Practice versus Clinical Research – R. Scott Wright
Breakout Session Descriptions

The A B Cs of SOPs – Linda Knowlton
This interactive session will provide an overview of standard operating procedures (SOPs). During this session, policies, processes, procedures, and guidelines will be reviewed. The importance of writing good documents in a consistent manner for the readers who must use them will be discussed. By the end of this session you will Absolutely Be Compliant in writing your own SOPs.

How to Participate in an Audit (2-hour breakout session) – Karen Johnson & Mary Veirenkamp
This breakout session will cover the fundamentals of clinical trial audits including, a description of the different types of audits, how to prepare for an audit, the difference between an audit visit and a monitoring visit. Comparisons between an auditor and a monitor, how the FDA prepares for an audit, and how they are trained will be discussed. How participants should conduct themselves in an audit will be reviewed.

The purpose of this session is to highlight the importance, need, and challenges of including minorities in clinical research. This breakout will touch on ethnic demographics, concepts of race, health disparity issues, social and health barriers to minority health research, and the practical solutions in improving inclusion of minorities in research.

Informed Concent – Susan Quella
This session will convey that Informed Consent is a dynamic, interactive, ongoing process of critical importance. Discuss well and poorly written consent documents and review how to correct them. Understand your commitment to ensuring that every participant in a research study truly has the opportunity to make an informed decision.

IRB Policy and Procedures, Common Deficiencies – Nanci Hawley
A general overview of issues encountered through the course of research conducted within an institution. Concerns and outcomes of research related compliance issues and the outcomes for investigators. Common deficiencies occurring during the patient consenting process and patient procedures. General discussion on corrective measures both of a reactive and preventative nature.

The Impact of HIPAA on Clinical Trials – Crystal Molen
HIPAA impacts almost every single clinical trial conducted. This presentation will address the responsibilities HIPAA imposes on those involved in clinical research. The discussion will also explain fundamental concepts such as authorizations, privacy boards, and de-identification of data.

The Challenge of Pediatric Research in the Twenty-First Century – Robert Jacobson
This session gives an overview of the ethical limits, financial incentives, and practical problems that contemporary investigators face with regard to pediatric research as a prelude to a discussion among participants regarding the practical aspects of pediatric research that pose challenges for them.

How to Create a Respectful Work Environment – Katherine Flippin
The content of this breakout includes a definition of mutual respect. It also describes behaviors that could be considered disrespectful and gives the nuts and bolts of what it takes to create a respectful environment.

Legal Issues in Research – John Mills
This session will discuss current legal issues pertaining to clinical research. Some of the topics may include FDA’s current position on the need for an IND, recent OHRP guidance regarding inclusion of prisoners in research, waiver of informed consent for non-minimal risk research studies, and individual and institutional conflicts of interest.

Adverse Experiences and Reporting – Eugene DiMagno
This session will define and identify an adverse event and how to report the event. The responsibilities of the sponsor, monitor, and investigator, when an adverse event occurs, will be discussed. How participants should conduct themselves in an audit will be reviewed.

A Device Trial versus a Drug Trial:  What are the Differences? – Stephen Kopecky
This session will discuss the inherent differences in a drug trial vs. a device trial regarding the different scientific approach and regulatory environment each entails. Drugs and devices have different standards for safety and efficacy and FDA approval. This session will also review some of the basic differences in setting up and running a drug vs. a device trial and monitoring of patient events.

Data and Safety Monitoring Board/Event Ajudication – Karen Johnson & Shari Brumm
The content for this session will be basic. The presentation will be of interest to anyone interested in exploring the current trend toward the use of Data and Safety Monitoring Boards (DSMB) or Data Monitoring Committees (DMC). An introduction to the intent and functions of a DSMB will be provided. The membership, purpose, and contributions to both good clinical research and subject safety will be discussed. DSMBs will be compared to and contrasted with Clinical Event Committees. Information about writing a DSMB Charter and the cost of maintaining a Board will be included.

Contracting and Budgeting – Paula House & Jessie Salk
This breakout will discuss the basics of a Clinical Trial Agreement (CTA) and budgeting. At the end of this session, you will know the answers to such questions as: What is a contract? Why is a contract necessary? What are the key elements/issues of a CTA? Who should sign an agreement? What is included within the "four corners" of a contract?

Clinical Research Team: Roles and Responsibilities – Anne Holland & Ivana Crogan
This session will help the attendee define what constitutes a Clinical Research Team. The roles and responsibilities of each team member will be described: sponsor, investigator, IRB, clinical research coordinator, administrative support staff, and the data management center.

Clinical Practice versus Clinical Research – R. Scott Wright
This session will review how the clinical practice of medicine differs from the research practice. It will highlight the common mistakes all researchers tend to make, review recent FDA warning letters as practical examples, and discuss strategies to avoid the mistakes.