November 20-21, 2006

National Conference on Alternative IRB Models: Optimizing Human Subject Protection

Wardman Park Marriott
Washington, DC

OHRP

Co-Sponsored by: AAU, COGR, COSSA, DOD, NACUA, and PRIM&R

National Conference on Alternative IRB Models: Optimizing Human Subject Protection

Table of Contents:

Meeting Information

The conference is sponsored by the Office of Human Research Protections (OHRP), the National Institutes of Health (NIH), the Association of American Medical Colleges (AAMC), the American Society of Clinical Oncology (ASCO), and the Department of Veterans Affairs (VA); it is co-sponsored by the Association of American Universities (AAU), the Council on Government Relations (COGR), the Consortium of Social Science Associations (COSSA), the Department of Defense (DOD), the National Association of College and University Attorneys (NACUA), and Public Responsibility in Medicine and Research (PRIM&R). It is intended to enhance the protection of human subjects of research by exploring the use of innovative IRB models as alternatives to local IRBs under appropriate circumstances.

The goals are:

- To optimize and facilitate institutions' access to appropriate ethical and scientific expertise for reviewing increasingly sophisticated projects, and
- To optimize institutions' resources to review such projects.

The changing nature of research involving human subjects, particularly as it relates to investigations involving multi-institutional trials, has created the need to be more innovative in selecting IRB models. The use of alternative IRB models to enhance the safety of research subjects and the efficiency of the research process is important for all types of research, including biomedical, social, behavioral science, and health services research. The results of a November 2005 workshop on alternatives to local IRBs, sponsored by OHRP, NIH, AAMC, and ASCO, will be presented as the background for this national conference. The workshop participants found that the greatest challenges for selecting an IRB model include liability, definition of shared authorities and responsibilities, costs and timeliness of various models, quality of review, and consideration of local context. Conference attendees will discuss the extent to which these challenges are barriers to the use of alternative models of IRB review and suggest ways to minimize their impact to allow maximum flexibility in the selection of IRB models.

Who Should Attend this Conference?

Everyone is welcome to attend, but it is particularly important that attendees include those individuals who are involved in decisions about whether or not their institutions should use an alternative to their local IRBs. This conference will have the greatest impact if attendees include institutional officials, institutional counsel, investigators, sponsors, subjects and their advocates, representatives of trial management organizations, research deans, IRB chairs and members, IRB administrators, and government regulators. Participants will be asked to identify their choice of panel they wish to attend during the concurrent breakout discussions. Every effort will be made to accommodate individual preferences, but some alternative assignments may be necessary in order to balance discussion groups.

Meeting-At-A-Glance

Sunday, November 19, 2006

6:00 – 8:00 pm	Registration

Monday, November 20, 2006

8:00 – 8:30 am	Registration and Continental Breakfast
8:30 – 8:40 am	Welcome and Opening Remarks
8:40 – 10:00 am	**Plenary Session** **Conference Introduction**
10:00 am – Noon	**Concurrent Workshops, 1-4**
Noon – 1:30 pm	Lunch on own
1:30 – 2:30 pm	Concurrent Workshops, 1-4 continued
2:30 – 3:00 pm	Break
3:00 – 5:00 pm	**Plenary Session** **Panel Reports**
5:00 pm	Dinner on own

Tuesday, November 21, 2006

8:00 – 8: 30 am	Continental Breakfast
8:30 – 8:45 am	**Plenary Session** **Charge**
8:45 – 10:15 am	**Stakeholder Discussion Groups A-E**
10:15 – 10:30 am	Break
10:30 – Noon	**Plenary Session** **Turning Recommendations into Actions**
Noon – 12:30 pm	Summary and Next Steps

Agenda

Sunday, November 19, 2006

6:00 – 8:00 pm Registration

Monday, November 20, 2006

8:00 am Registration

8:00 – 8:30 am Continental Breakfast

8:30 – 8:40 am Welcome and Opening Remarks: Dr. Bernard Schwetz

8:40 – 10:00 am **Opening Session**

Conference Introduction

Moderator:

Robert J. Levine, MA, PhD
Professor, Internal Medicine, Director, Law, Policy and Ethics Core Investigator, International Research Core
Yale University Center for Interdisciplinary Research on Aids

Speakers:

Bernard Schwetz, PhD, DVM
Director
Office For Human Research Protections

Lowell E Schnipper, MD
Theodore and Evelyn Berenson Professor of Medicine
Harvard Medical School
Chief, Hematology/Oncology Division, Beth Israel Deaconess Medical Center

Richard W. Bianco
Assistant Vice President for Regulatory Affairs, Academic Health Center
Assistant Professor Of Surgery
Department of Experimental Surgical Services
University of Minnesota

The moderator will introduce the meeting by explaining its background, scope and format, objectives, and possible follow-up activities. Speakers will summarize the 2005 Workshop on Alternatives to Local IRBs and present issues associated with alternative IRB models.

Monday, November 20, (cont'd)

10:00 am – Noon **Concurrent Panel Presentations and Discussion**

Participants will be organized into four concurrent panels where they will hear presentations by panelists, followed by open discussion on the following issues. Building on the work of the November 2005 workshop, each panel will identify the issues, barriers, and challenges they see in their respective areas.

Panel 1: Liability

Moderator:

Judith E. Leonard, JD
Vice President for Legal Affairs, General Counsel
University of Arizona

Speakers:

Alexander E. Dreier, JD
Partner
Hogan and Hartson

Diane Lopez, JD
University Attorney
Harvard University

Ara Tahmassian, PhD
Associate Vice Chancellor, Office of Research
University of California, San Francisco

David Wynes, PhD
Senior Associate Vice President for Research
The University of Iowa

What implications would the use of alternative forms of IRB review have for regulatory or civil liability? Under what circumstances would the various forms of alternative review be most appropriate from this perspective?

Monday, November 20, (cont'd)

Panel 2: Shared Authority and Responsibilities

Moderator:
Angela Bowen, MD
President
Western IRB

Speakers:

Marjorie Speers, PhD
Executive Director
Association for the Accreditation for Human Research Protection Programs

Angela C. Wishon, JD
Assist Vice Chancellor, Regulatory Compliance
University of Colorado at Denver and Health Sciences Center

Don E. Workman, PhD, CIP
Executive Director, Office for the Protection of Research Subjects
Northwestern University

How can shared authority and responsibilities best be managed to ensure appropriate control and accountability? Under what circumstances would the various forms of alternative review be most appropriate from this perspective?

Panel 3: Quality of Review, including Capacity to Consider Local Context

Moderator:

Daniel K. Nelson, MS
Director, Office of Human Research Ethics
University of North Carolina, Chapel Hill

Speakers:

Suzanne R. Pattee, JD
Vice President of Public Policy and Patient Affairs
Cystic Fibrosis Foundation

Stephen Sallen, MD
Chief of Staff
Dana-Farber Cancer Institute

Monday, November 20, (cont'd)

Peter Vasilenko, PhD
Director, Human Research Protection Program
Michigan State University

Stuart Horowitz, PhD, MBA
Director
Miami Children's Hospital Research Institute

What implications would the use of alternative forms of IRB review have for quality of review, including the capacity to fully address issues related to the local context? What are the critical concerns to be addressed? Under what circumstances would the various forms of alternative review be most appropriate from this perspective?

Panel 4: Costs, Timing, and Loss of Revenues

Moderator:

Martin Charns, DBA, MBA
Professor of Health Services
Director, Program on Health Policy and Management
Boston University School of Public Health

Speakers:

Felix Khin-Maung-Gyi, PharmD, MBA, CIP
Founder and CEO
Chesapeake Research Review, Inc

Moira A. Keane, MA, CIP
Director, Research Subjects Protection Program-RSPP
University of Minnesota

Jean-Louis Saillot, MD
Vice President
Head, Global Pharmacovigilance
Schering Plough

Todd H. Wagner, PhD
Health Economist
Health Economics Resource Center (HERC)

Monday, November 20, (cont'd)

What are the significant issues surrounding the costs of alternative forms of IRB review? How would the use of alternative forms of IRB review affect the timely completion of milestones in research oversight? Would the use of alternative forms of IRB review have a negative affect on funding for human subjects protection at the institutional level? Under what circumstances would the various forms of alternative review be most appropriate from this perspective?

12:00 – 1:30 pm Lunch

1:30 – 2:30 pm **Concurrent Panel Discussion (continued)**

Participants will return to their respective panels to formulate specific recommendations and suggestions based on the panelists' presentations and the ensuing general discussion.

2:30 – 3:00 pm Break

3:00 – 5:00 pm **Plenary Session: Panel Reports**

Participants will come together to share and respond to reports from the four panels. The moderator will seek consensus on the key recommendations to be addressed on Day 2.

5:00 pm Dinner on own

Tuesday, November 21, 2006

8:00 – 8:30 am Continental Breakfast

8:30 – 8:45 am **Charge**

Moderator:

Dr. Alan Fleishman
National Institute of Child Health and Human Development

The moderator will review key recommendations that emerged from Day 1 and explain the charge to Stakeholder Discussion Groups.

8:45 – 10:15 am **Stakeholder Discussion Groups (5)**

Participants will be organized into Stakeholder Discussion Groups based on their perspectives (e.g., IRB Chairs, Members, and Administrators; Institutional and Signatory Officials and Research Officials; Research Subjects and Advocates; Investigators; and Institutional Legal Counsel). Participants whose responsibilities do not match one of the Stakeholder Groups will be encouraged to join the group of their choice. Each group will evaluate the Panels' recommendations from its unique perspective, accomplishing the following:

- A critique of the recommendations, including proposed revisions:
- Specific actions required to implement these recommendations, in priority order;
- Who should be responsible for each action;
- Barriers and challenges that affect the implementation of these recommendations; and
- Means of addressing barriers and challenges.

10:15 – 10:30 am Break

10:30 am – Noon **Plenary Session**
Turning Recommendations into Actions
With assistance from the moderators of the Stakeholder Discussion Groups, the moderator will guide attendees through a process of finalizing recommendations in priority order and clarifying actions required to implement them successfully.

12:00 – 12:30 pm	**Summary and Next Steps** The moderator and Dr. Schwetz will review conference outcomes and lead a discussion of next steps required to further the aim of optimizing the protection of human subjects through the use of alternative forms of IRB review.
12:30 pm	Conference Adjourns

Meeting Facts

Location

Wardman Park Marriott
2660 Woodley Road, NW
Washington, DC 20008
Phone: 202-328-2000
Fax: 202-234-0015
http://marriott.com/property/propertypage/wasdt

Reservations and Room Rates

The room rate, which is subject to a tax of 14.5% is:

$159.00 Single/Double Occupancy

To make your hotel reservations, complete the enclosed Hotel Reservation Form and either mail it directly to the hotel or fax it to the hotel at 202-234-0015. You may also make reservations by calling 800-228-9290. Be sure to identify yourself with the AAMC in order to receive the group rate. To confirm your reservation, a deposit equal to one night's room charge must accompany your reservation request. A check or major credit card will be accepted. **Reservations must be made prior to October 23, 2006.** Rooms held for this meeting will be released on this date. Any reservation requests received after October 23, 2006 will be accepted only on a space available basis at the group rate. Please note that the room block may fill before October 23, 2006**,** so we encourage you to make your reservations early.

Cancellation of any guaranteed room reservation must be received by the hotel at least 72hours prior to arrival to recover your deposit. Check-in time is 3:00 pm and check-out time is 12:00 Noon.

Air Transportation

United Airlines is offering special discounted rates for this meeting:

- 2% discount off the lowest applicable discount fare.
- 5% discount off unrestricted mid-week coach fares. Seven-day advance purchase is required.
- 10% discount off first-class fare.
- You can earn an additional 5% discount if you purchase your tickets at least 30 days in advance of your travel.

To receive the discount, you (or your travel agent) must call 1-800-521-4041 and refer to the **AAMC Meeting ID Code: 550TH** when making your reservation. Taking advantage of this discount program not only reduces your own travel costs, it also assists the AAMC in earning free airline tickets that help reduce speaker and staff travel costs for the meeting. Mileage Plus members receive full credit for all miles flown to this meeting.

Ground Transportation

Taxi
Ronald Reagan National Airport (DCA) is approximately 25 minutes from the Marriot Wardman ParkHotel, and taxi fare costs approximately $25.00 each way. Washington's Dulles International Airport (IAD) is approximately 60 minutes from the Marriott Wardman Park, and one way taxi fare will cost around $55.00. Washington, DC experiences heavily congested rush hour traffic; travel times during peak hours can be greatly extended.

Metro System
Metro is Washington, DC's mass transit rail system. Metro offers convenient stops at Ronald Regan National Airport, as well as a stop that is steps from the hotel's entrance at Woodley Park – Zoo Station. Travel between the Reagan National Airport stop (blue line) to the Woodley Park -Zoo Station (red line) requires a transfer at the Metro Center Station and takes approximately 25 minutes. Once you exit at Woodley Park – Zoo Station please walk approx. one block Southeast on Connecticut Ave. The approximate one way metro fare is $2.00; the fare depends on whether you are traveling during peak rush hour times.

Rental Car

Hertz is offering the following special rates for this meeting:

		DAILY	**WEEKEND**	**WEEKLY**
	CAR CLASS	**PER DAY**	**PER DAY**	**5-7 DAYS**
A	ECONOMY 2 DR	$46.99	$20.99	$189.99
B	COMPACT 4DR	$51.99	$23.99	$204.99
C	MIDSIZE 2/4DR	$55.99	$25.99	$219.99
D	STANDARD 2/4DR	$57.99	$30.99	$234.99
F	FULLSIZE 4DR	$60.99	$32.99	$249.99
G	PREMIUM	$65.99	$37.99	$259.99
I	TOWNCAR	$79.99	$61.99	$346.99
L	4WD/AWD SUV	$79.99	$61.99	$346.99
R	MINIVAN	$82.99	$63.99	$354.99
U	CONVERTIBLE	$79.99	$61.99	$346.99

The rates, effective one week before and one week after the meeting dates, include unlimited mileage. Rates do not include tax or optional coverages. Rentals are subject to age, driver's license and credit requirements. Weekend rentals are available for pickup between 12 Noon Thursday and 12 Noon Sunday and must be returned no later than 11:59 pm Monday. To reserve a car, call toll free **800-654-2240** and give the reservation agent the **AAMC Discount CV# 02WZ0004** .Reservations are subject to car availability, so please make your reservations in advance.

Climate and Dress

Late November in Washington, DC generally brings brisk Fall weather with temperatures as high as the 50's during the day and 40's in the evening. As always the temperature of the meeting rooms may be somewhat warmer or cooler than you might expect. You are encouraged to wear layered outer clothing.

Local Attractions

From its celebrated symbols of patriotism and freedom to its undiscovered neighborhoods, the sights and sounds of the nation's capital inspire millions of visitors every year. Packed with famous sights, free attractions, and an endless calendar of special events, Washington, DC offers year-round inspiring experiences.

Beyond Washington DC's most familiar vistas, the capital city unwinds into a lively urban center. Casual cafes and upscale bistros line the trendy streets of Georgetown, while the downtown district sizzles with a host of new restaurants. Spontaneous Jazz notes tumble out the windows of U Street's nightclubs, while world-class performers take the stage at the highly acclaimed Kennedy Center.

Wardman Park Marriott is located directly across Connecticut Ave from The National Zoo and is minutes away from the National Cathedral and Downtown DC. The area also boasts dozens of fine dining options within walking distance of the hotel.

Registration Fees and Procedures

Registration Online:
All registration must be completed online. Please visit www.aamc.org/meetings. Online registration will close on **November 15, 2006.**

Registration Fee: Complimentary

Cancellation Policies

As this is a no fee meeting there is no penalty for cancellation. We do ask that you extend the courtesy of letting us know if you will not be able to attend by emailing Chanel Eatmon at ceatmon@aamc.org.

A Note for those with Special Needs

The Association of American Medical Colleges wishes to ensure that no individual with a disability or a special need is excluded, denied services, segregated or otherwise treated differently from other individuals because of the absence of auxiliary aids and services.

If you are in need of auxiliary aids or services, or if you have any dietary concerns or restrictions, please contact Chanel Eatmon at 202-828-0892, or via e-mail at ceatmon@aamc.org.

Questions

For questions concerning registration procedures, please contact our Meetings Registrar Chanel Eatmon at 202-828-0892, or via e-mail at ceatmon@aamc.org. For questions concerning the logistics of the meeting, please contact Meghann Shinners at 202-828-0047, or via e-mail at mshinners@aamc.org. For content and session questions, please contact Susan Ehringhaus at 202-828-0543, or via e-mail at sehringhaus@aamc.org.

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