

HARMONIZATION

BRINGING THE I'S TOGETHER:
Toward IACUC, IBC and IRB Harmonization
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Conference Agenda

The AWEN Group, Inc. &
 Massachusetts Society for Medical Research, Inc.

THURSDAY, JUNE 14, 2007

Track 1	IACUC - Berkshire A
Track 2	IBC - Auditorium
Track 3	IRB - Berkshire B

7:30 AM - 9:00 AM	Registration - Continental Breakfast			
8:30 AM - 8:45 AM Auditorium	WELCOME & INTRODUCTIONS Alan Dittrich, PhD, President, MSMR, Inc. Michele Cunneen, Principal, The AWEN Group, Inc.			
8:45 am - 9:45 am Keynote Address General Session Auditorium	Bench to Bedside: Opportunities for Advancing Ethical Review Dr Michael D E Goodyear, BMedSc MBBS FRACP FACPC Assistant Professor, Division of Medical Oncology, Department of Medicine Dalhousie University			
9:45 am - 10:30 am Plenary Speaker General Session Auditorium	Risk Assessments and Evaluations in Human Clinical Trials Ashok Batra, MD, Director Division of Clinical Evaluation & Pharmacology/ Toxicology CBER, FDA			
10:30 am - 11:00 am	BREAK - Exhibit Area			
11:00 am - 11:45 am BREAKOUT SESSION I	Exhibits Open 7:30 am - 4:00 pm	IACUC Function-The AAALAC Perspective Barbara Garibaldi, DVM Director Animal Research Facility Beth Israel Deaconess Medical Center AAALAC Council Member	State of the IBC Process vs. Function Allan Shipp, MHA Director of Outreach, NIH Office of Biotechnology Activities	AAHARP Accreditation Going for the Gold ... Deborah Barnard, MS, CIP Assistant Director Quality Assurance and Education Partners Human Research Committee Partners HealthCare System
11:45 pm - 1:00 pm		LUNCH - Dining Room		
1:00 pm - 1:45 pm BREAKOUT SESSION II		How to Design a IACUC Training Program Colleen Cody Sr. Manager IACUC/CompMed Millennium Pharmaceuticals	Training Your IBC for Today's Problems Claudia Mickelson, PhD Deputy Director, EHS Office MIT	Participant Compensation: Morals, Money & Medical Research Regina Correa-Murphy Administrative Officer Providence VA Medical Center
1:50 pm - 2:35 pm BREAKOUT SESSION III IACUC, IBC, IRB	Staying Ahead of the Curve ... Developing Best Practices for Laboratory Animal Compliance Department Ron Banks, DVM Director, Office of Animal Welfare Assurance Duke University Medical Center	Post Approval Compliance program for IBCs Ron Morales, Manager Biological Safety & Food Sanitation, Harvard University	Me, Myself and I: Compliance Training for the 3 I's; Team Building or Turf Wars? Lynette M. Schenkel, Director Office for Responsible Conduct of Research University of Oregon	

2:35 pm - 3:00 pm		BREAK - Exhibit Area
3:00 pm - 5:30 pm Charles River Room		MSMR Annual Board of Directors Meeting <i>Open to ALL MSMR Members</i>
3:00 pm - 4:15 pm General Session Auditorium		General Issues in Research Integrity ... <i>Miriam Kelty, PhD</i> <i>Alan Price, PhD</i>
4:15 pm - 4:30 pm		Closing Remarks
6:00 pm - 7:00 pm		MSMR Reception - Doubletree Suites Hotel Waltham
7:00 pm - 10:00 pm		MSMR Dinner & Awards

FRIDAY, JUNE 15, 2007

8:00 am - 9:00 am	Registration - Continental Breakfast		
9:00 am - 9:15 am Auditorium	WELCOME & INTRODUCTIONS Alan Dittrich, PhD, President, MSMR, Inc. Michele Cunneen, Principal, The AWEN Group, Inc.		
9:15 am - 10:00 am General Session Auditorium	DATA Sharing and Cyber Security Richard J. D'Augusta, R.Ph., M.P.A. President and CEO eMedicus Institutional Review Board		
10:00 am - 10:45 am General Session Auditorium	Translational Research ... <i>from animal models to human models</i> John Frangioni, MD, PhD, Division of Hematology/Oncology, Department of Medicine and Department of Radiology, Beth Israel Deaconess Medical Center, Harvard Medical School		
10:45 am - 11:00 am	BREAK		
11:00 am - 11:45 am BREAKOUT SESSION I	Post-Approval Compliance. Is it Much Ado about Something, or Nothing? Jerald Silverman, DVM Professor and Director Department of Animal Medicine UMASS Medical School	The Realities of IBC Review Carolyn Stahl, Senior Biosafety Officer MIT Rhonda O'Keefe, Senior EHS Officer, MIT	Integrating the three "I"s Dr. Melody Lin, Associate Director OHRP/IRB - IRBs & Protection of Human Subjects
11:45 am - 12:45 pm	LUNCH - Dining Room		
12:45 pm - 1:30 pm BREAKOUT SESSION II IACUC, IBC, IRB	Policy 15: When Regulations Meet Reality Jerald Silverman, DVM Professor and Director Department of Animal Medicine UMASS Medical School	Technical Options for Effective Automation and Post Approval Compliance Denise Niles Canales President & CEO API, Inc.	Effective IRB Review Process and Assessing Post Approval Compliance Dr. Melody Lin, Associate Director OHRP/IRB - IRBs & Protection of Human Subjects
1:30 pm - 2:00 pm General Session Auditorium	Wrap-up session with speakers		