

HARMONIZATION

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

JUNE 14, 2007	Session Descriptions	
<p>Barbara Garibaldi, D.V.M.</p> <p>Breakout session I 11:00 AM - 11:45 AM June 14, 2007</p>		<p>AAALAC International's Expectations for an IACUC</p> <p>Use of performance based standards to evaluate a program How to maintain a healthy and well balanced IACUC What constitutes a successful Animal Care and Use Program? Importance of IACUC Training Signs of a weak IACUC Most frequent IACUC deficiencies found by AAALAC Post-approval monitoring Oversight of laboratory/satellite areas</p>
<p>Deborah Barnard, MS, CIP</p> <p>Breakout session I 11:00 AM - 11:45 AM June 14, 2007</p>		<p>AAHARP ... Going for the Gold</p> <p>The audience will have an understanding of the purposes and goals of accreditation and the accrediting bodies that are in existence and what areas are covered during an accreditation visit</p>
<p>Regina Correa-Murphy</p> <p>Breakout session I 1:00 PM - 1:45 PM June 14, 2007</p>		<p>Participant Compensation: Morals, Money & Medical Research</p> <p>This presentation will look at the history and the ethics involved in compensation of human research participants, research investigators and institutions. Through a series of case studies the attendee will have the opportunity to critically evaluate the role of compensation in research and the ethical challenges faced by human research protection programs.</p>
<p>Claudia Mickelson, PhD</p> <p>Breakout session I 1:00 PM - 1:45 PM June 14, 2007</p>		<p>Training Your IBC for Today's Problems</p> <p>This session will focus on emerging technologies in biological research; identification of the health, safety and ethical issues raised by these techniques; and expanding the scope and purview of the IBC review process to ensure appropriate, and integrated oversight for these emerging areas of research.</p>
<p>Lynette Schenkel</p> <p>Breakout session III 1:50 PM - 2:35 PM June 14, 2007</p>		<p>Me, Myself and I: Compliance Training for the 3 I's; Team Building or Turf Wars?</p> <p>How much do your IRB personnel know about the people involved in, or the practices and responsibilities of your IACUC and/or your IBC? Do your PI's grouse about multiple compliance training requirements, or having to keep straight a morass (uh, that was a myriad!) of do's, don'ts and passwords? And who gets to write all those policies (as well as implement and maintain them), you? Join us for a lighthearted look at the 3 I's: overlapping (and maybe not so overlapping) policies, compliance issues, training and education, committee recruitments, protocol processing, PI interactions and more. Do you</p>

		<p>have questions or a success story to contribute? Come prepared to share.</p> <ol style="list-style-type: none"> 1. Explore different mechanisms to achieve 3 I's compliance through people, policies and procedures 2. Examine areas and ways where 3 I's compliance issues, training and other requirements may be jointly met
<p>Drs. Kelty and Price General session 3:00 PM - 4:15 PM</p> <p>June 14, 2007</p>		<p>General Issues in Research Integrity</p> <p>Drs. Kelty and Price will describe the elements of responsible science and define scientific misconduct. They will share their experiences of dealing with misconduct - Dr. Kelty as a former NIH Associate institute Director of and Dr. Price as former Associate Director of the DHHS Office of Research Integrity. A recent case will be presented and will be a focus of the presentation. The session will conclude with a discussion of the importance of education in responsible conduct of research.</p> <p>Learning Objectives: The learner will:</p> <ol style="list-style-type: none"> 1. Understand best practices for responsible conduct of research 2. Understand the definition of scientific misconduct 3. Learn how misconduct cases are handled. 4. Understand the importance of preventing misconduct and of education in research integrity.

JUNE 15, 2007	Session Descriptions
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<p>John Frangioni, MD, PhD General session 10:00 AM - 10:45 AM</p> <p>June 15, 2007</p>		<p>Translational Research ... from animal models to human models</p> <p>This session will describe the process of developing a new targeted diagnostic or therapeutic agent from idea, through chemical synthesis, small animal pre-clinical testing, large animal pre-clinical testing, and first-in-human testing. At the end of this session, the attendee should be able to:</p> <ol style="list-style-type: none"> 1) Identify the key development steps associated with bench-to-bedside translation of a new chemical compound. 2) Understand the general classes of small and large animal models of cancer available to researchers for pre-clinical testing. 3) Understand the micro-dosing and non-micro-dosing guidelines for first-in-human trials of a novel diagnostic or therapeutic agent under the FDA's new exploratory IND guidelines.

<p>Rhonda O'Keefe Carolyn Stahl</p> <p>Breakout session I 11:00 AM - 11:45 AM</p> <p>June 15, 2007</p>		<p>Realities of IBC Review</p> <p>In this session, we'll explore some of the practical realities of the IBC review process. We'll share ideas about how implementation of the review process can be divided among the Investigator, the Biosafety Professional, and the IBC to ensure a thorough review while making the best use of resources. Additional functions that the IBC can serve will also be discussed.</p>
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<p>Jerald Silverman, D.V.M. Breakout session I 11:00 AM - 11:45 AM</p> <p>Breakout session II 12:45 PM - 1:30 PM</p>		<p>Learning Objectives: Post Approval Compliance: Is it Much Ado about Something, or Nothing?</p> <ol style="list-style-type: none"> 1. To discuss if IACUC protocol noncompliance is a serious or minor problem. 2. To show how IACUCs currently react to noncompliance issues. 3. To suggest the reasons why noncompliance occurs, and how to address those reasons. <p>Learning Objectives: APHIS/AC Policy 15: Where Regulations Meet Reality</p>
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<p>June 15, 2007</p>		<ol style="list-style-type: none"> 1. To clarify what is meant by a USDA “policy.” 2. To pose and answer key questions concerning IACUC membership. 3. To provide an overview and commentary on how institutions are training IACUC members.
<p>John Katen Andrew Olmsted Breakout session II 12:45 PM - 1:30 PM June 15, 2007</p>		<p>Seamless Electronic Integration of the 3 I’s: Best Practices Discussion and Demonstration</p> <p>Join IRBNet for an interactive demonstration and discussion of electronic best practices, pitfalls, success stories, and important institutional considerations when successfully adopting a fully integrated, seamless compliance and oversight solution. Participants are encouraged to share their own experiences and ask questions.</p> <p>Using IRBNet’s Web-based Solution, topics covered will include:</p> <ul style="list-style-type: none"> ⇒ Study Design, Guidance and Researcher Compliance ⇒ Cross-Institutional Collaboration ⇒ Multi-Board Electronic Submission ⇒ Managing Committees and Board Reviews ⇒ Meeting Management, Agendas and Minutes ⇒ Letters and Correspondence ⇒ Post-Approval Management <p>IRBNet will also touch upon key institutional considerations for successful adoption of electronic systems, including:</p> <ul style="list-style-type: none"> ⇒ Financial implications and the business case to go electronic ⇒ Implementation risks and timeframes ⇒ Training and rollout ⇒ Post implementation support