

Beyond the Basics: Advanced Issues and Current Topics in IACUC Administration

**Hyatt Regency Bellevue
Bellevue, WA
April 1, 2019**

This **intermediate/advanced level** educational program is intended for participants that have a thorough understanding of the regulatory standards governing research, teaching, and testing activities that include vertebrate animals.

Is regulatory burden truly impeding advancements in biomedical research? Since 2005, federal agencies and numerous research organizations (Federal Demonstration Partnership) have been investigating this matter, and determined through meetings and surveys that investigators spend at least 42% of their time managing regulatory affairs rather than conducting research.

In 2009 and again in 2014 government-appointed committees considered the matter. As a result, the National Research Council and the National Science Board reviewed the impact of regulatory burden, and indeed confirmed that regulatory burden costs research organizations millions of dollars a year and hinders the ability of scientists to dedicate their time to advancements in biomedical research.

As a result of this effort, the 21st Century Cures Act, a bill intended to reduce regulatory burden, has been introduced and is progressing through Congress. This bill requires agencies to reduce administrative burden. The Cures bill passed the House and Senate in December 2016. Specific components of the bill are expected to impact animal research, teaching, and testing activities.

During this preconference program, participants will investigate specific and focused topics associated with reducing regulatory burden, through a variety of interactive and engaging activities. Attendees will participate in the review and discussion of program processes, and investigate potential opportunities for minimizing regulatory burden while ensuring animal welfare and ongoing compliance.

Learning Objectives: The attendee will develop program best practices that do not exceed the regulatory standards, but ensure animal welfare and ongoing program compliance.

Topics to be covered may include:

- 1) Matters relating to regulatory burden
- 2) Protocol template design
- 3) The amendment review process
- 4) IACUC oversight of approved animal activities

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AGENDA

7:30-8:30 AM	<i>On-Site Check-In (breakfast provided by PRIM&R)</i>
8:30-8:45 AM	Welcome and introduction
8:45-9:30 AM	Define regulatory burden
9:30-9:45 AM	<i>Break</i>
9:45 AM-12:00 PM	Developing a protocol template <ul style="list-style-type: none">• What information needs to be gathered for the IACUC to ensure animal welfare and ongoing program compliance?• Should PI assurance statements be used in the template?• Can it be expanded and also used to secure safety clearances rather than requiring a separate biosafety submission?• Can a single form be developed or are separate sections needed when activities include USDA covered species?
12:00-1:00 PM	<i>Lunch (on your own)</i>
1:00-2:00 PM	IACUC's review of modifications (significant and administrative) <ul style="list-style-type: none">• Develop a best practice to cover administrative amendments• Identify and develop a policy for Veterinary Verification and Consultation (VVC) changes• Best practices for covering amendments requiring committee review (Designated Reviewer (DR) and Full Committee Review (FCR))
2:00-3:00 PM	Monitoring approved animal use activities <ul style="list-style-type: none">• Through other IACUC functions• Using defined reporting requirements (e.g., annual reviews)• Using designated post-approval monitors
3:00-3:15 PM	<i>Break</i>
3:15-4:30 PM	Questions and Answers
4:30 PM	<i>Adjournment</i>

Please note this agenda is subject to change.