

Monday, April 1: Preconference Programs

7:30 AM-5:30 PM On-Site Check-In Open

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7:30 AM-8:30 AM Breakfast Breakfast will be provided by PRIM&R (attendees are on their own for lunch)

8:30 AM-4:30 PM	
Beyond the Basics: Advanced Issues and Current Topics in IACUC Administration	Сы
Essentials of IACUC Administration: Achieving Success as an IACUC Administrator	CPIA
IACUC Fundamentals	Сри
8:30 AM-12:00 PM	
Decreasing Regulatory Burden: Is <u>THAT</u> Required?	CPIA
1:00-4:30 PM	
Effective Communication Strategies for Animal Care and Use Programs	
4:30-5:30 PM	

Preconference Programs Networking Reception This reception is for preconference program attendees. Light refreshments will be served.

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 Advanced: Assumes mastery of central ethical concepts and principles, the regulations, and the processes of applying them to the day-to-day work of protocol review or research oversight activities. Provides in-depth knowledge of an area and robust set of skills for addressing difficult problems and navigating "grey areas," improving IACUCs, shaping institutional cultures, or advancing careers. Attendees are expected to have sufficient experience and understanding to contribute to the discussion of and solution to difficult problems.

Icon Key lucing, I/I

CPIA Sessions span two time periods CPIA recertification credit Call for Session Proposals



7:00 AM-8:00 AM

Attendee Breakfast

Breakfast will be provided by PRIM&R

7:00-8:00 AM

Breakfast to Welcome to First-Time Attendees

Attending the IACUC Conference for the first time can be exciting and overwhelming, which is why PRIM&R invites **first-time attendees** to participate in this special breakfast session. This session is a great opportunity for first-time attendees to ask questions of the PRIM&R staff about the conference and PRIM&R in general, and to learn about strategies and resources that can help them make the most of their conference experience. **Pre-registration required.**

8:00-8:15 AM

Welcome and Presentation of PRIM&R's Distinguished Service Award to B. Taylor Bennett, DVM, PhD, DACLAM, DACAW, Senior Scientific Advisor, National Association for Biomedical Research

8:15-8:35 AM

Welcome from PRIM&R's Executive Director, Elisa A. Hurley, PhD

8:35-9:35 AM

Henry Spira Memorial Lecture and Discussion with David Grimm, PhD, Journalist; Online News Editor, *Science*, Professor, Science Writing, Johns Hopkins University: Challenges of Writing about Animal Research

9:35-10:00 AM

Beverage Break With the Supporters and Exhibitors

Join us for coffee in the exhibit hall. PRIM&R would like to thank Cayuse for helping support this break.

10:00-11:15 AM

f: Real Time IACUC—This Meeting is In Session!

Moderator: Janet Stemwedel

Panelists: IACUC Administrator: Rebecca Henry (c) (Back-ups: Joan Phillips from the Oregon National Primate Research Center; Vince Politano (Oregon State), Lindsay Pascal (Seattle Children's))

IACUC Chair: Jane Sullivan (Bckup: George Sanders)

Attending Vet: Gordon Roble (FHCRC) (c) (Back-ups: Cindy Pekow; Steve Niemi; Kim Stocking (UW) or Jennifer Wilk (Legacy, Oregon)) – kate forwarded to new address 1/23; give until 1/25

Scientist: John Gebe, PhD (Backup: Michael Rosenfeld from the University of Washington - scientist who also chaired the IACUC at one point - not a current member but a lot of experience; Robert Faucett from UW - not a member of the IACUC but has had a n interesting experience with the IACUC and offers a great perspective; Jane Elliott (UW);: Steve Libby (UW); or check to see who the science members are for other companies)

Non-affiliated member/non-scientist: Elisa A. Hurley (c), Scott Haskell, Kristen LeMieux (UW)

Axel Wolff NIH/OLAW

Helen Diggs AAALAC representative

Carol Clarke USDA

Decline: Katherine Lewis (uc), Jerry Poling, Mike Christe, Eli Lilly (uc)

Be sure not to miss this real-time discussion by our mock IACUC panel of a variety of issues that might arise in a real IACUC meeting. Agenda items will be made available to conference attendees prior to the "meeting" and attendees will have the opportunity to participate in deliberations. Representatives from AAALAC International, OLAW, and USDA will provide their perspective on the issues discussed by the mock IACUC. Have an idea for an issue the mock IACUC should discuss? Submit it <u>here</u> by February 1!

11:15-11:30 AM Break

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Icon Key

CPIA CPIA recertification credit

Call for Session Proposals



8.

CPIA

Tuesday, April 2: IACUC19 Breakout Sessions Series A, 11:30 AM-12:45 PM

A1: Special Considerations for IACUC Review (Animal Well-Being and the 3Rs Track) Sonia Miranda (Novartis) Eric Hutchinson

Decline: Lisa Halliday, David Smith, Jeff Fortman, TBD (back-up: one of the authors of this document would be able to speak to how cumulative suffering scores can be used to determine if an animal is an appropriate candidate for re-use:

http://journals.sagepub.com/doi/full/10.1177/0023677217744587# i32);

The reuse of animals in laboratory experiments requires a number of considerations for both IACUCs and scientists, including that animal colonies can be reused for multiple studies, and various study types require ethical and scientific considerations as it relates to this reuse (i.e., where do we draw the line in terms of ethical reuse, what scientific considerations need to be given to non-protein, naïve nonhuman primates, etc.). During this session, speakers and attendees will:

- Discuss the ethical and scientific integrity considerations involved in the reuse of animals
- Share strategies for animal welfare, those necessary for animals during use and reuse
- Review strategies for optimal reuse

A2: A Time to Connect—Agency Highlights from the Oversight Bodies—Part I (Communication and Networking Track) Eileen Morgan, Brent Morse, Mike NeafsyLarry Shelton, Gary Borkowski

Decline: VA

NIH OLAW, USDA APHIS, AAALAC International, DOD, and the VA provide guidance and interpretation on the various regulations, policies, and guidance documents associated with each oversight body. During this session, attendees will receive critical updates from each agency representative. In advance of the session, attendees may <u>submit questions</u> to be addressed publicly during either this session, or Part II (B2: A Time to Connect—Q&A with the Oversight Bodies – Part II), as time allows (some questions may be edited or combined as appropriate, and not all will be able to be addressed). This session will provide an opportunity for attendees to:

- Receive agency specific updates from each oversight body
- Participate in a short dialogue about issues relevant to stakeholders, as time allows

Note: While there will be time for Q&A, most of this session will be devoted to agency updates. If you have specific questions for these representatives, please also attend Part II (B2: A Time to Connect—Q&A with the Oversight Bodies – Part II).

A3: A Resurgent Interest in Marmoset Models (Hot Topics and Emerging Trends Track)

Saverio "Buddy" Capuano, Wisconsin National Primate Research Center (session moderator); Suzette Tardiff,

Backup: Jessica Izzi, Johns Hopkins University Corinna Ross, Texas A&M University - San Antonio; Jean Patterson, Texas Biomedical Research Institute; Monika Burns, MIT; Casey Fitz

Decline: Anna Goodroe

Given recent advances in genetic engineering (e.g., CRISPR), there is an increased interest in the use of marmosets as a potentially novel primate model for research on human neurodegenerative diseases, zoonotic infections, etc. However, this species remains challenging to work with in the laboratory setting given its relative fragility in captivity. This session will highlight cutting edge research with marmosets, as well as address gaps in our knowledge of marmoset biology, husbandry, and medicine. This session will also underscore how institutions (and their IACUC's) consider how to add novel species (such as marmosets) to their programs to avoid bad outcomes due to unfamiliarity and inadequate resources. Scenarios for expert guidance and oversight from peers beyond conventional regulations and accreditation standards will be raised for discussion. Attendees are encouraged to review in advance the recent ILAR Roundtable Workshop, "Care, Use and Welfare of Marmosets as Animal Models for Gene Editing-based Biomedical Research." *During this session, speakers and attendees will:*

• Learn about marmosets as a research model and the differences in their care and use compared with other nonhuman primates.

• Explore options for expert guidance and oversight beyond conventional regulations and accreditation standards for novel animal models or procedures.

• Discuss approaches IACUCS can take when faced with novel studies (either new animal models or new procedures) to engage the PI to ensure animal welfare, scientific integrity, and compliance.

A4: IACUC Administration for New IACUC Administrators/Coordinators (IACUC Administration/Management and Process Track)

Stacy Pritt, Trina Smith

This session is for individuals relatively new to the responsibilities of providing administrative support to the IACUC. During the session, speakers will provide a review of responsibilities typically assigned to IACUC administrators/coordinators. The session will also explore ways to run a meeting and options for conducting post-approval monitoring. Attendees should be familiar with IACUC administrative duties. This session is geared toward individuals who have less than two years' experience in their role. During this session, speakers and attendees will:

- Discuss the various ways IACUC administrative staff can support the protocol review process
- Go over how to run an IACUC meeting and make decisions among a diverse group of people
- Provide various options for conducting post-approval monitoring
- Review IACUC member training requirements

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Sessions span two time periods

CPIA recertification credit

Call for Session Proposals









Tuesday, April 2: IACUC19 Breakout Sessions Series A. 11:30 AM-12:45 PM

A5: IACUC Basics for the Use of Wildlife in Research and Education (Oversight of Non-Typical Animals and Situations Track)

Patrice Klein,Bob Sikes

Decline: Hillary Burgess (COASST representative, Executive Director; coasst@uw.edu; Back-up: Julia Parrish), John Blake, Dan Mulcahy, Regina

This session will introduce basic information that IACUCs need to consider during the review of a wildlife study. Topics to be discussed include: evaluating species, animal numbers, pharmaceuticals, occupational health and safety, personnel training, and euthanasia. Additionally, the challenges of reviewing wildlife teaching protocols and studies by volunteer animal researchers/citizen science will be presented. Citizen science is becoming a growing research tool, and this session will explore what the IACUC's role is in evaluating studies using these methods (e.g., whether the volunteers involved are trained and supervised by experienced researchers, biologists, or ecologists; utilizing apps/social media to share data with experts; and potential issues for animal welfare and data application). During this session, speakers and attendees will:

- Review numbers and species of animals, including opportunistic and non-target species
- Discuss the differences in the use of pharmaceuticals, occupational health, and euthanasia in wildlife studies
- Consider educational and training activities involving wildlife research in field settings
- Define "citizen science" and the increasing role of volunteers in research activities
- Explore the challenges for IACUCs in evaluating training and qualifications of students and volunteers handling live animals for research data collection, and the pros and cons for collecting and utilizing data from research involving citizen science applications/methodology

A6: Program Review and Facility Inspections (Program Management Track)

Monica DeFeo; Tracy Heenan; Carolyn McKinnie Venita Thornton (resource person)

Conducting program reviews and facility inspections are an important aspect of IACUC responsibility. This session will explore the basics, as well as introduce new and innovative ideas related to program reviews and facility inspections. During this session, speakers and attendees will:

- Review the basic precepts of program review and facility inspections
- Identify the challenges of program review and facility inspections and share successful practices from experienced institutions
- Explore innovative approaches and ideas for performing and following up on program review and facility inspections

A7: Significant Changes and Veterinary Verification and Consultation (Protocol Review Track)

<mark>Jane Na</mark> <mark>Elaine Kim</mark> – Cc Jori on the planning memo so she can send the slides

Decline: Gwen Waddingham,

The Significant Changes Guidance has been established for a few years and was intended to allow institutions to more rapidly respond to the changing needs of investigators, while still ensuring there is appropriate review, including those that fall under traditional veterinary

purview, such as anesthetics and analgesics. Attendees should review the <u>two OLAW webinars on this topic</u> before attending this session. Through case-based discussions, speakers and attendees will:

- Review examples of how to implement the Guidance appropriately by developing institutional policies and guidance documents
- Provide real life institutional examples
- Share examples of strategies that can be used to change protocols, either through VVC or administrative review, while also meeting the documentation standards of the Guidance
- Discuss how to create standard operating procedures for common experimental procedures, including the pros and cons of having pre-approved procedures

A8: Regulatory Nirvana: An Engaged Research Team Committed to Compliance and Beyond (*Qualifications and Training Track*)

F. Claire Hankenson, Helen O'Meara, Jessi Kittel

Backup: Mike Ream and Jessi Kittel

Decline: William Singleton, Lauren Danridge, Dawn O'Connor, UMich, Bill Greer

When technical proficiency in the care and use of research animals is met, we move closer to the coveted goals of assuring compliance, qualifying personnel, meeting regulatory mandates, and improving both animal welfare and research quality. This cannot be easily accomplished without a training program that is comprehensive and consistently executed with excellence. Federal regulations and recommendations clearly define the need for training, but that can be perceived as a burden. However, by adding "soft" skills to engage the research team, the trainer and the IACUC can enhance their capability to meet their goals and, when exceeded, achieve a higher "state" of compliance nirvana. Attendees should have an understanding of the regulatory mandates for training before attending this advanced session. Active learning scenarios will be used. During this session, speakers and attendees will:

- Describe proven mechanisms to assess a researcher's technical competence
- Discuss ways in which staffing, metrics, time, resources, and documentation influence the development of an assessment program to improve compliance
- Emphasize the institution's role in assuring regulatory compliance and technical competence and provide examples to fulfill it (e.g., culture, the institutional official, support, the 3Rs, etc.)
- Identify and develop strategies for helping stakeholders in the research community better understand their role in improving animal care and welfare through compliance and proficiency obtained through training

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CPIA recertification credit

Call for Session Proposals









Tuesday, April 2: IACUC19 Breakout Sessions Series A, 11:30 AM-12:45 PM

A9: The Green Mile: Considerations for Humane Euthanasia (Hot Topics and Emerging Trends Track) Deb Hickman, Kate Pritchett-Corning (back-up: Natalie Bratcher), Tracy Thompson – send the planning memo, she's part of the shutdown

Euthanasia of animals used in research activities remains a challenge and requires a number of ethical considerations for researchers, animal care staff, veterinary staff, and IACUC members. This session intends to continue the conversation regarding appropriate and humane methods of euthanasia, including upcoming revisions to the AVMA Guidelines for use of CO2, challenges faced when wild animals in research activities require euthanasia in the field, the IACUC's role in evaluating proposed methods, and considerations for holding conditions prior to euthanasia, ensuring the entire process is as humane as possible. This session will also discuss the relation of euthanasia and compassion fatigue by examining ways to mitigate and address the impacts of euthanasia on research and animal care and use care staff. During this session, speakers and attendees will:

- Discuss the revisions to the AVMA Guidelines for CO2 euthanasia criteria, as well as how animal welfare may be impacted or improved
- Evaluate methods of euthanasia commonly used in wildlife research
- Examine ways to address and mitigate compassion fatigue and the impact of euthanasia on research and animal care and use care staff

Note: This session will also take place on Wednesday April 3 from 11:15 AM-12:30 PM (Session D3).

A10: Follow-Up Discussion with David Grimm, PhD (Hot Topics and Emerging Trends Track)

Jim Newman, David Grimm

In an effort to promote productive dialogue with Dr. Grimm, we will have a follow-up session after his lecture, where attendees will be able to continue to discuss the issues he has presented.

A11: Everything You Wanted to Know About the CPIA® Credential Michelle Aparacio, Tanise L. Jackson, Richelle Scales, Connor Bryant (c)

Decline: Caryn Hashimoto

During this breakfast session, members of the CPIA Council, a recently certified individual, a recently recertified individual, and attendees will discuss obtaining the CPIA credential and the recertification process. This session is geared toward individuals who are responsible for IACUC administrative functions and who will be eligible to take the certification exam in the next one to two years. Pre-registration is required. During this breakfast session, speakers and attendees will:

- Discuss the CPIA program and its value
- Go over exam preparation techniques and what to expect on exam day
- Share first-hand advice from a recently certified individual
- Review the path to recertification

12:45-2:00 PM

Attendee Open Lunch Period

During this time, attendees will eat lunch on their own. Learn more about dining options in the hotel and area here.

2:00-2:15 PM Remarks from PRIM&R's Chair of the Board of Directors, Heather Pierce, JD, MPH

2:15-3:15 PM

Keynote Address by Lesley A. Sharp, PhD: The Everyday Ethics of Human-Animal Encounters in Laboratory Science

3:15-3:30 PM

Beverage Break With the Supporters and Exhibitors

Tuesday, April 2: IACUC19

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B1: Understanding, Monitoring, and Maintaining the Psychological Health of Nonhuman Primates: Animal Welfare Before, **During, and After Transportation** (Animal Well-Being and the 3Rs Track)

Gary Tucker, VP of Orient Bioresources in Texas (<u>gtucker@O</u> <u>nter.com</u> leading NHP import practices and industry perspective);<mark>,</mark> Carolyn Allen Carolyn MckKinnie (resource person) Carol Clarke (resource person)

Back-up: backup for Bill:Kirk Leech (kleech@eara.eu)Eric Hutchinson - back-up to Joe if he responds by 1/25, Rita Bellanca, Washington Primate Center Dave Elmore, retired DVM? But has extensive knowledge of NHP transport, CRL, primate center? Dr. David Reim (david.reim@crl.com) at CRL's Nevada preclinical facility who has extensive experience in NHP transport and conditioning. Karen Guerra (Karen.guerra@crl.com) who heads our import, quarantine and conditioning facility in Houston.

Decline: Matt Bailey (leading NABR campaign for DOT to open up air transportation for lab animals, policy perspective); University of Illinois at Chicago in their primate colony would move animals between studies: Lisa Halliday and Jeff Fortman would be the best people to check with to see if they would be willing to speak, Joe Simmons, DVM (MD Anderson, academic perspective, led discussion in NHP transport as part of ILAR Round table on Transportation of Laboratory Animals); Taylor Bennett Bill White

Have you ever considered where research animals come from and what they experience before they arrive at research facilities? This session will cover how we can work together to better understand, monitor, and maintain or improve the psychological health of research animals prior to, during, and after transportation. Attendees should be from programs that have or potentially will house large, AWA covered species including nonhuman primates. They should also have some awareness of the challenges, both practical and welfare related, for ordering and transporting purpose-bred animals. During this session, speakers and attendees will:

- Consider animal welfare implications and potential unknowns related to transportation and the challenges to welfare
- . Discuss where to draw the line when it comes to where the responsibility to the animals begins
- Present ways we can implement 3Rs/refinements to improve welfare once they arrive at research facilities .

B2: A Time to Connect—Q&A with the Oversight Bodies—Part II (Communication and Networking Track) Eileen Morgan, Brent Morse, <mark>Mike Neafsey Larry Shelton, Helen Diggs, Gary Borkowski</mark>

Decline: VA

NIH OLAW, USDA APHIS, AAALAC International, DOD, and the VA provide guidance and interpretation on the various regulations, policies, and guidance documents associated with each oversight body. During this session, attendees will have an opportunity to ask questions of the agency representatives. In advance of the session, attendees may submit questions to be addressed publicly, and these questions will be addressed during either this session, or Part I (A2: A Time to Connect—Agency Highlights from the Oversight Bodies—Part I) (some questions may be edited or combined as appropriate, and not all will be able to be addressed). This session will provide an opportunity for attendees to:

Participate in an open discussion about issues relevant to stakeholders

B3:Biobanking: What Can We Learn from Human Subjects and Animal Protection Ethics Best Practices? (Hot Topics and Emerging Trends Track)

Stephen Schmechel (uc), <mark>TBD,</mark> TBD

Decline: Julie Turbide (CSP author), Felicia Tiseo Karl Hellstrom Ingegerd Hellstrom

Back-up: MA Candidate Quality Assurance Research Ethics Specialist, West Central Montreal Health--proposed idea for this and Databanking session in CSP In research, there are more and more studies that are cross-modal (i.e., including both an animal and a human subject). These studies must undergo more than one ethical process to obtain approval. During this session, speakers will share examples of both achievements and mistakes regarding the approval process, and have meaningful discussion about the future of biobanking and regulatory oversight. During this session, speakers and attendees will:

- Discuss best practices for data collection and banking from human subjects protections
- . Integrate information and apply to cross-modal biobanking
- Demonstrate how to navigate and combine two different systems (i.e., Institutional Review Boards on the human subjects side vs. IACUCs on the animal side)

B4: Meeting the Challenges of IACUC Administration: Case Studies in Handling Complex Protocol Issues/Situations—Part I (IACUC Administration/Management and Process Track)

Stacy Pritt, Rosa Harmon

Backup: Alan Ekstrand

Decline: Anna Hampton

Many IACUC administrators, members, and staff struggle with protocol questions and what the IACUC should consider in reviewing protocols. In the first part of this two-part session, speakers and attendees will work through case studies on protocol review issues and discuss possible ways to handle these complex situations. Attendees should have a sound working knowledge of the IACUC and the regulations that provide guidance before attending this session. Important to the session are well-versed IACUC administrators who can share their experiences with protocol challenges. During Part I of this session, speakers and attendees will:

- Discuss and analyze simulated, problematic scenarios o IACUC protocol reviews
- Discuss potential solutions to problems with protocols while maintaining compliance

Note Part II of this session will take place on Tuesday April 2 from 4:45-6:00 PM (Session C4).

explaining, and illustrating basic concepts, principles, regulations, policies, or best practices. Advanced: Assumes mastery of central ethical concepts and principles, the regulations, and the

processes of applying them to the day-to-day work of protocol review or research oversight

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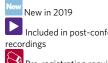
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Included in post-conference Pre-registration required





CPL

Advanced



Breakout Session Series B, 3:30-4:45 PM

B5: The Role of the Attending Veterinarian (AV) in the Review and Oversight of Wildlife Research (Oversight of Non-Typical Animals and Situations Track)

Tracy Thompson John Bryan, Patrice Klein (c)

AVs at research facilities are expected to be familiar with the species on which activities are conducted. Wildlife research poses numerous challenges for AVs due to the variety of species, an uncontrolled research environment, procedures which are not common in laboratory settings, and different anesthesia/analgesia/euthanasia techniques. This session will help address these challenges and identify ways to engage the AV in consultation, review, and assessment of wildlife research activities. During this session, speakers and attendees will:

- Identify the veterinary role in consultation, review, and oversight of wildlife research
- Examine the challenges for AVs in meeting the regulatory and IACUC requirements for wildlife research and in minimizing pain and distress in field procedures
- Propose methods for AVs to become more engaged and knowledgeable about the species and procedures involved in wildlife research at their institution

B6: Compassion Fatigue: Beyond Sharing Your Pain (Program Management Track)

eston van Hooser, <mark>Lesley Sharp</mark>

(Back-up: Andreanna Pavan)

This session will provide discussion on the use of surveys for taking the pulse of the workforce with respect to compassion fatigue and the effectiveness of group or personalized countermeasures to move the needle. During this session, speakers and attendees will:

- Discuss how to gain an accurate snapshot of compassion fatigue across an institution's animal care and use staff
- Demonstrate what proven group or personal interventions from similarly emotionally taxing workplaces are available for laboratory animal care providers and users
- Explain how to employ staff surveys to track effectiveness of interventions

B7: The Compliance Unit Standard Procedure (CUSP)—An Option to Address Administrative Burden at the Institutional Level (Protocol Review Track)

Schoenleben (submitted CSP), Madeline Budda, Jaret Langsto

Under the auspices of the Federal Demonstration Project, the CUSP Project offers an option to address administrative burden at the institutional level. The goal of the project is to create a repository where institutions can share standard substances and procedures used in animal care protocols with the broader animal welfare compliance community. During this session, speakers and attendees will:

- Provide an overview of the CUSP Project and the responsibilities of participants using the system
- ٠ Demonstrate how participants can utilize the system through the use of a model
- Share the current status of the Project and future timelines

B8: New Investigator at the Institution? How Do You Get Them on the Right Track from the Get-Go? (Qualifications and Training Track)

Chieko Azuma (needs strong co-presenter), Mandy Kozlowski, Hana Bao (c)

Backup: Kelly Cole: Cole, Kelly (NIH/NHLBI) [E] coleke2@nhlbi.nih.gov Kirk Cunningham (actually the chair, but he is very involved): Cunningham, Kirk (NIH/NIAID) [C] KCUNNING@niaid.nih.gov Hana Bao: Bao, Hana (NIH/VRC) [C] hana.bao@nih.gov Decline: Evan Shukan from OACU/NIH, Kelly Cole

Each institution may have different processes and procedures for onboarding new investigators. Successful relationships with new researchers not only better facilitates the research process, but can create a platform for open communication regarding training and compliance matters. Speakers will discuss onboarding processes to facilitate establishment of animal research program evaluating overall needs and avoiding unnecessary delay as some of the research programs may need to be reviewed by other compliance committees. During this session, speakers and attendees will:

- Share strategies for designing a new investigator onboarding process •
- ٠ Review methodologies used to assist investigators in better developing animal protocols
- Identify training needs and institutional resources through animal protocol application

B9: Institutional Biosafety Committee (IBC) Administration and the Intersection With IACUC Administration (IACUC Administration/Management and Process Track)

Michelle Aparicio, Natalie Mays, Jennifer Perkins

Many IACUC administrators are charged with additional responsibilities, such as providing support for the IBC. Session speakers will review the basic responsibilities of the IBC, and share their personal experiences with managing both IBCs and IACUCs. During this session, speakers and attendees will:

- Review the responsibilities of the IBC
- Share strategies for providing administrative support for institutional adherence to the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules
- Identify points of overlap between IBCs and IACUCs, and opportunities for reducing burden on staff and researchers

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B10: Teaching Protocols and Classroom Activities (Protocol Review Track)

Bob Sikes, Ben Clarke- when sending planning memo, emphasize the need to make sure that they spend more time covering smaller animal teaching labs as last year there was large Ag focus and so the participants wanted to hear more about what to do with rodents, frogs, etc. Back-up:

Decline: Jon Reuter, Claire Hankenson

Teaching protocols provide a different kind of challenge in protocol review for IACUCs. These include how IACUCs consider the goals of the research, as well as how to identify students and ensure they are receiving the appropriate training related to the goals of the classroom, but also with regard to animal welfare reporting, occupational health concerns, the use of animals, and how to document these issues. During this session, speakers and attendees will:

- Discuss how protocol review differs from research protocols with regard to evaluating learning objectives
- Provide strategies to identify students enrolled in these courses and review how to ensure students are knowledgeable about the • species-specific dangers, project-specific dangers, risks, and animal welfare/regulatory considerations, as well as how these can be documented
- Discuss concerns specific to teaching protocols, including pedagogical value of repeated activities

Breakout Session Series C, 5:00-6:15 PM

C1: Animal Play—It's Not Just Fun and Games (Animal Well-Being and the 3Rs Track) Joanna Makowska, Melanie Graham, Deb Hickman

Backup: Jeremy Bailoo, Tara Martin, Hanno Würbel

Decline: Gordon Burghardt (Alumni Distinguished Service Professor, Ecology & Evolutionary Biology, University of Tennessee Knoxville; see book The Genesis of Animal Play: Testing the Limits: https://mitpress.mit.edu/books/genesis-animal-play by. - IACUC17 debrief), Brianna Gaskill, Jamie Ahloy Dallaire, PhD, Universite Laval, Megan LaFollette, Purdue University, Kate Pritchett-Corning, Sergio Pellis, Vivien Pellis

What is animal play and what evolutionary role might it play? Can encouraging or engaging research animals in play reduce stress, improve acclimation to research procedures, or even facilitate the collection of better data? The speakers in this session will explore how animal play should be extended from enrichment and social housing to include how animals are engaged in research. During this session, speakers and attendees will:

- Discuss why animals play and how play factors into animal welfare
- Discuss how encouraging and engaging in play with animals can be a refinement to reduce stress associated with common research procedures
- Explore how an animal's natural drive to play and explore can be harnessed to enhance data collection and data quality

C2: Developing and Maintaining a Positive and Productive Communication Environment in an Animal Care and Use **Program** (Communication and Networking Track)

Grant Lyon, Janet Stemwedel - SF, Tanise Jackson Carol Clarke - resource person

Back-up: Jo Ann Henry (Grant); Donna Matthews Jerrell (Tanise)

CAROL TO BE CC'D ON PLANNING MEMO TO WORK WITH SPEAKERS ON REFINING SESSION.

An animal care and use program often brings together many different personalities and viewpoints. Diversity in the program is important for giving all stakeholders a voice, yet can create unintended tensions. Positive and productive communication is critical for fostering a cohesive animal care and use program and a culture of compliance. During this session, speakers and attendees will engage in small group work and mock exercises to:

- Identify the diversity that exists within their own animal care and use programs and share why diversity is important
- Review activities that can improve communication among stakeholders, including the IACUC, research teams, veterinary and husbandry staff, IACUC administration, and more
- Learn how to develop and maintain an environment that fosters positive and productive communication
- Explore situations that can compromise positive communication, and discuss ways to deal with difficult communication situations

C3: Issues of Adopting/Retiring Research Animals: Response to Adoption-Directed Legislation (Hot Topics and *Emerging Trends Track*)

Lyndon Goodley, Carolyn Allen Eric Hutchinson, Assistant Director, from Johns Hopkins could talk about retiring NHP (at AALAS he said that Hopkins is looking into how to create their own sanctuary)

Back-ups: Carey Allen, speaker from research animal rescue organization (Beagle Freedom Project, BeFreegle, Kindness Ranch, Cascade Beagle Rescue)--Sally?

Decline: Cindy Buckmaster, Natalie Bratcher

With more state and national legislative attention on research animal adoption, IACUCs and animal care and use programs need to consider what components should be included in their institution's approach. Before attending this session, attendees should be familiar with programs that have, or potentially will, house species that are likely to be covered by state and national legislations, and should have some awareness of the ethical concerns with adoption of purpose-bred animals. During this session, speakers and attendees will:

- Understand the current legislative environment and the drivers behind it
- Identify the ethical concerns to be considered with adoptions
- Share adoption program examples (e.g., goals, metrics, success stories)

explaining, and illustrating basic concepts, principles, regulations, policies, or best practices. Advanced: Assumes mastery of central ethical concepts and principles, the regulations, and the

processes of applying them to the day-to-day work of protocol review or research oversight

activities. Provides in-depth knowledge of an area and robust set of skills for addressing difficult

problems and navigating "grey areas," improving IACUCs, shaping institutional cultures, or

advancing careers. Attendees are expected to have sufficient experience and understanding to contribute to the discussion of and solution to difficult problems.

Tuesday, April 2: IACUC19

Icon Key Basic: Introduction of a topic for those with little or no knowledge; focus is on introducing,

Sessions span two time periods

CPL/ CPIA recertification credit

 \star Call for Session Proposals



Included in post-conference Pre-registration required





DIA

C4: Meeting the Challenges in IACUC Administration: Case Studies in Handling Complex Compliance Issues/Situations—Part II (IACUC Administration/Management and Process Track) Rosa Harmon Stacy Pritt, Neera Gopee Elizabeth Thoedorson (resource person)

Backup: Alan Ekstrand

Decline: Anna Hampton

Many IACUC administrators, members, and staff struggle with how to handle noncompliance and animal welfare concerns and what the IACUC should consider when reviewing these cases. In the second part of this two-part session, speakers and attendees will work through case studies on noncompliance and animal welfare concerns, and discuss possible ways to handle these complex situations. Attendees should have a sound working knowledge of the IACUC and the regulations before attending this session. Important to the session are well-versed IACUC administrators who can share their experiences handling noncompliance and animal welfare issues. During Part II of this session, speakers and attendees will:

- Discuss and analyze simulated, problematic scenarios about when animal welfare concerns are brought to the attention of the IACUC
- Share strategies for gathering information on and achieving resolution of noncompliance and animal welfare issues •
- Discuss what potential action could be taken to address repeat occurrences of noncompliance and animal welfare issues Note Part I of this session will take place on Tuesday April 2 from 3:15-4:30 PM (Session B4).

C5: IACUC Deliberations Using Wildlife Scenarios—Part I (Terrestrial Species) (Oversight of Non-typical Animals and Situations Track)

Bob Sikes, John Bryar

During this two-part session, speakers will actively engage the audience in examining challenges for the IACUC in reviewing field studies. Part I will focus specifically on research with terrestrial species, and ethical concepts and principles, regulations, and processes involved in terrestrial wildlife research will be examined. Attendees participating in this session should have direct experience in the use of these animals in the field, and are highly encouraged to attend sessions A5: IACUC Basics for the Use of Wildlife in Research and Education, and B5: The Role of the Attending Veterinarian in Review and Oversight of Wildlife Research, before attending this session. During Part I of this session, speakers and attendees will:

- Review whether activities fall under field studies exemptions ٠
 - Discuss how to list animal numbers and species •
 - Explore impacts of research activities on populations and communities
- Note: Part II of this session will take place on Wednesday April 3 from 3:15-4:30 PM (Session D5).

C6: How active Post-Approval Monitoring (PAM) Can Work at Smaller Institutions (Program Management Track) Chieko Azuma (Submitted CSP with no other suggested speakers; needs strong co-presenter), Felicia Ponce

Back-ups: Bruce Kennedy

Successful PAM processes can enhance compliance and facilitate research and teaching. Since smaller institutions may only have one to three administrative staff members to support the IACUC, establishment of an active PAM program can be difficult. However, since IACUC administrators are familiar with animal research protocols, monitoring the conduct of that research could be a natural extension of IACUC office function. This session will discuss the role of PAM in institutions with limited resources, and show how some PAM processes used at larger institutions may be incorporated into smaller programs without an excessive burden. During this session, speakers and attendees will:

- Discuss PAM methodologies that could be used at smaller institutions
- Share strategies for tying PAM methodologies and processes to routine IACUC administrative office functions
- Review how the PAM process can facilitate research and teaching while improving compliance

C7: How to Avoid Self-Imposed Administrative Burden From Inefficient or Over-Rigorous Protocol Forms and Review Practices (Protocol Review Track)

Sally Light, Sandy Wilkens,, Ben Clark Decline: Molly Greene

This session will highlight the regulatory obligations for protocol content and ways that institutions can use the protocol in concert with their post-approval monitoring (PAM) program, routine veterinary care policies, semi-annual inspections, and overall program description to strengthen their animal use program without disproportionate or duplicative emphasis on protocol content. During this session, speakers and attendees will:

- Briefly outline protocol review requirements in the USDA Animal Welfare Regulations, PHS Policy, US Government Principles, . and the Guide
- Through the use of examples, address common concerns driving requests for detail that exceeds the regulatory directives
- Determine how other tools, such as PAM programs, routine veterinary care policies, semi-annual inspections, and overall program descriptions can be used or be even better suited to address some of these concerns
- Share examples related to relieving administrative burden through the creation of a protocol form and review process that leverages the strengths of the other aspects of the program, rather than inefficiently duplicating efforts

Note: this session will be similar to the Decreasing Regulatory Burden: Is THAT Required? preconference program on April 1.

Tuesday, April 2: IACUC19

Icon Key

Sessions span two time periods

CPIA recertification credit \star













activities. Provides in-depth knowledge of an area and robust set of skills for addressing difficult problems and navigating "grey areas," improving IACUCs, shaping institutional cultures, or advancing careers. Attendees are expected to have sufficient experience and understanding to contribute to the discussion of and solution to difficult problems.

explaining, and illustrating basic concepts, principles, regulations, policies, or best practices. Advanced: Assumes mastery of central ethical concepts and principles, the regulations, and the

processes of applying them to the day-to-day work of protocol review or research oversight

Basic: Introduction of a topic for those with little or no knowledge; focus is on introducing,

CPL/

C8: Strategies for Successfully Training the IACUC (Qualifications and Training Track)

Ken Gordon, Jennifer F. Iwamoto – in planning memo note to have them focus on identifying needs and developing methods that fit that need Back-ups: Holly McEntee from Wisconsin, Molly Greene, Marky Pitts, Mary Lou James published in ILAR re: training strategies for the IACUC, which covers the topic from recruitment and orientation through continuing education Decline: Samantha Augustowski

The Animal Welfare Act and Regulations holds institutions responsible for ensuring personnel involved in animal care, treatment, and use are qualified to perform their duties, including IACUC members. This responsibility, in part, can be fulfilled through the provision of training. The *Guide* charges institutions with the responsibility of providing a suitable orientation and appropriate resources to assist IACUC members in understanding their roles and responsibilities and evaluating issues brought before the committee. Determining the best way to present this information can be daunting. Attendees will hear about successful IACUC member training programs at various institutions and share their own examples and experiences. During this session, speakers and attendees will:

- Share successful strategies, learning approaches, and formats for IACUC member training, including potential topics for training
- Discuss how and when to utilize various learning strategies (e.g., active learning, didactic, on-line, etc.)
- Review potential obstacles to a successful training program and how to address them
- Develop implementation strategies to bring back to your institution

6:15-7:15 PM

IACUC19 Welcome Reception

Celebrate the opening of IACUC19. During this time, attendees can meet the conference Supporters and Exhibitors. Light refreshments will be served.

6:15-7:15 PM

Meet the IACUC19 Poster Authors

Visit the authors of posters featured in the IACUC19 Poster Program and learn more about their innovative and important work in the field. Presentation of the posters promotes interdisciplinary sharing and collaboration, and facilitates the exchange of ideas, information, and practical strategies for managing the many challenges faced by animal care and use professionals.

7:15-8:15 PM

Young Professionals Networking Reception

Connect with other young professionals interested in research ethics and animal care and use, and relax after a busy day at the conference at an off-site location (forthcoming). A complimentary drink ticket will be provided in your registration materials. All attendees are welcome, but drink tickets will be provided for young professional registrants only.

Basic: Introduction of a topic for those with little or no knowledge; focus is on introducing, explaining, and illustrating basic concepts, principles, regulations, policies, or best practices.
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Icon Key

CPIA CPIA recertification credit



CPIA

7:00 AM-12:30 PM On-Site Check-In Open

7:00 AM-8:00 AM Attendee Breakfast

Breakfast will be provided by PRIM&R in the Grand Ballroom Foyer, and open seating will be in Grand Ballroom J-K (for those not wishing to attend the 7:00 AM session on the current status of the 21st Century Cures Act).

7:00 AM-8:00 AM

Breakfast Session: Reducing Burden on Investigators Using Animals in Research: Current Status of the 21st Century Cures Act

Pat Brown (NIH), <mark>Carol Clarke (USDA)</mark>

Back-up: Brianna Gaskill (FDA) Betty Goldentyer (USDA), Estella Jones (FDA)

The breakfast for this session will be served outside the room in the Grand Ballroom Foyer.

A section of the 2016 21st Century Cures Act directed the NIH, in collaboration with USDA and the FDA, to complete a review of applicable regulations and policies for the care and use of laboratory animals and make revisions, as appropriate, to reduce administrative burden on investigators while maintaining the integrity and credibility of research findings and protection of research animals. The Act instructs NIH to: (1) seek the input of experts, if appropriate; (2) identify ways to ensure applicable regulations and policies are not inconsistent, overlapping, or unnecessarily duplicative; (3) take steps to eliminate or reduce identified inconsistencies, overlap, or duplication among such regulations and policies; and (4) take other actions, as appropriate, to improve the coordination of regulations and policies with respects to research with laboratory animals.

This panel will consist of the Working Group Chair and senior representatives from NIH and USDA, who will present a historic timeline of how the current report, entitled "Reducing Administrative Burden for Researchers: Animals Care and Use in Research," was developed. Discussion of the Working Group's analysis of documents, the listening sessions and meetings it held, its evaluation of public comments from a Request for Information, and the Working Group's proposed actions for the three agencies will illustrate how the report's key findings were developed. The efforts of the Working Group and others within the federal government led to the proposal of recommendations intended to reduce the administrative burden associated with research activities with laboratory animals while maintaining appropriate protections and scientific integrity. The speakers will point out the key portions of the report that would directly impact investigators and IACUCs. This panel will be of great interest to all attendees and will include time for questions from the audience.

8:00-8:15 AM

Welcome and PRIM&R Membership and CPIA® Updates

8:15-9:15 AM

Keynote Address by Melanie Graham, MPH, PhD, Associate Professor, Department of Surgery Program; Director, Preclinical Research Center, University of Minnesota: Why the Animal Experience Matters for Tomorrow's Cures: the Intersection of Research, Welfare, and Public Policy

9:15-9:45 AM

Beverage Break With the Supporters and Exhibitors

Join us for coffee in the exhibit hall. PRIM&R would like to thank InfoEd Global for helping support this break.

9:45-11:00 AM

Panel II: Alternatives—Are We There Yet?

Moderator: Sally Thompson-Iritani

Panelist 1: Ed Kelly (c), https://sop.washington.edu/people/edward-kelly/; http://casistissuechip.blogspot.com/; University of Washington, Chips in Space (Fifty years ago it was Chimps in Space) – this is a nice segue where we have done replacement Panelist 2: Helena Hogberg: alternatives but also could give interesting perspective on the adoption of in silco tools - and differences academia presents versus industry, and what logically follows from this

Panelist 3: Mary Zelinksi (present on your work as a researcher focusing on fertility and contraception in monkeys, as well as the complex hormonal environment) backup: Jonah Sacha; Shui-lok hu from UW and Hans Peter Kiem from Fred Hutch Decline: Warren Casey (uc)- https://www.niehs.nih.gov/research/atniehs/dntp/assoc/niceatm/staff/casey/index.cfm; toxicology focused - ICCVAM, NICEATM, Tom Hartung , Beth Buffalo (uc)- https://buffalomemorylab.com/; NHP neuroscientist studying aging and memory, Nancy Haigwood

IACUCs are required to review whether there has been proper consideration of the 3Rs, and more specifically replacements for animal models with non-animal alternatives. Scientific progress in looking for alternatives in order to answer some complex questions and evaluate disease processes has had a significant impact on our reliance of whole body systems for some areas of research, but there are still areas where animal models are necessary. Panelists will discuss some of the advances in the development of alternatives, including: 1) organ-on-a-chip and the initiative to send these chips into space in 2019 (CRS-17 (SpaceX)), and how the knowledge gained will be used to inform decisions about physiology in space; 2) the use of in vitro systems to evaluate early toxicity and chemical hazards to inform policy without the use of animal models. There will also be discussion about areas where we are still heavily reliant on animal models because of the need for a whole body system to answer scientific questions.

Basic: Introduction of a topic for those with little or no knowledge; focus is on introducing, explaining, and illustrating basic concepts, principles, regulations, policies, or best practices.
 Advanced: Assumes mastery of central ethical concepts and principles, the regulations, and the processes of applying them to the day-to-day work of protocol review or research oversight activities. Provides in-depth knowledge of an area and robust set of skills for addressing difficult problems and navigating "grey areas," improving IACUCs, shaping institutional cultures, or advancing careers. Attendees are expected to have sufficient experience and understanding to contribute to the discussion of and solution to difficult problems.

Icon Key

- Sessions span two time periods
 - Call for Session Proposals



Breakout Session Series D, 11:15 AM-12:30 PM

D1: State of the Art Laboratory Animal Analgesia for Rodents

(Animal Well-Being and the 3Rs Track)

Daniel Pang, DVM, University of Montreal Veterinary School; Lon Kendall, DVM, University of Colorado

Back-up: Decline: Jennifer Smith, DVM, Henry Ford, Jennie Lofgren

The IACUC is obliged to weigh the objectives of a study against potential welfare concerns. This session will review how IACUCs can use current literature to improve overall expectations related to optimal analgesia, justification of analgesia withholding from a scientific perspective, and how untreated pain/distress may affect data. Attendees should have a basic understanding of current trends in analgesia and of USDA Pain Category E. During this session, speakers and attendees will:

- Use specific examples to discuss individual and collective responsibilities, the development and validation of humane intervention points and endpoints (including category E endpoints), and the implementation and assessment of specific measures for minimizing pain and distress
- Explore the use of observation to optimize animal welfare

D2: Developing and Implementing Proactive Communication Strategies Surrounding the Use of Animals in Research (Communication and Networking Track)



Advanced

Ken Gordon , Amanda Carson Banks Back-ups: Ken Gordon, Chris Braunger

Decline: Allyson Bennett

Institutions and organizations that develop and implement proactive communication strategies surrounding the use of animals in biomedical research provide vital tools in dealing with the lack of understanding on the part of their staff and the public of how animal based research is conducted and the dynamic oversight process that regulates this activity. Adopting a transparent and proactive strategy to communicate with public audiences about animal research can benefit organizations by minimizing reactive responses when things go wrong and help to foster more positive public understanding of animal research. Before attending this session, attendees should have a good understanding of the regulations governing animal care and use in research, and be able to speak to the value of institutional programs. During this session, speakers and attendees will:

- Explain why a proactive communication strategy is beneficial to the organization and animal research in general
- Discuss the resources available that can help institutions and organizations develop a proactive communication program
- Identify key messages for an effective communication plan
- Provide examples of effective communication strategies with internal and external audiences
- Review tips for how to communicate in a variety of situations, such as planned press releases, social media, and interviews

D3: The Green Mile: Considerations for Humane Euthanasia (Hot Topics and Emerging Trends Track)

Deb Hickman, Kate Pritchett-Corning, Tracy Thompson - send planning memo without her, she's part of the shutdown

Euthanasia of animals used in research activities remains a challenge and requires a number of ethical considerations for researchers, animal care staff, veterinary staff, and IACUC members. This session intends to continue the conversation regarding appropriate and humane methods of euthanasia, including upcoming revisions to the AVMA Guidelines for use of CO2, challenges faced when wild animals in research activities require euthanasia in the field, the IACUC's role in evaluating proposed methods, and considerations for holding conditions prior to euthanasia, ensuring the entire process is as humane as possible. This session will also discuss the relation of euthanasia and compassion fatigue by examining ways to mitigate and address the impacts of euthanasia on research and animal care and use care staff. During this session, speakers and attendees will:

- Discuss the revisions to the AVMA Guidelines for CO2 euthanasia criteria, as well as how animal welfare may be impacted or improved
- Evaluate methods of euthanasia commonly used in wildlife research
- Examine ways to address and mitigate compassion fatigue and the impact of euthanasia on research and animal care and use care staff

Note: This session will also take place on Wednesday April 3 from 11:15 AM-12:30 PM (Session A9).

Basic: Introduction of a topic for those with little or no knowledge; focus is on introducing, explaining, and illustrating basic concepts, principles, regulations, policies, or best practices. Advanced: Assumes mastery of central ethical concepts and principles, the regulations, and the processes of applying them to the day-to-day work of protocol review or research oversight activities. Provides in-depth knowledge of an area and robust set of skills for addressing difficult problems and navigating "grey areas," improving IACUCs, shaping institutional cultures, or advancing careers. Attendees are expected to have sufficient experience and understanding to contribute to the discussion of and solution to difficult problems.

Icon Key

Sessions span two time periods CPL CPIA recertification credit \star

Call for Session Proposals



Wednesday, April 3: IACUC19 Breakout Session Series D, 11:15 AM-12:30 PM

D4: Helpful Tips for Implementing a Web-Based Protocol Management System (IACUC Administration/Management and Process Track)

Jori Leszczynski, CeCe Brotchie Fine (Novartis)

Back-ups: Elain K. Kim, Stacy Pritt, Cyndi Rosenblatt, Aubrey Schoenleben, Jesse Kittel (University of Michigan)

Web-based solutions are widely used to manage the protocol review and approval process. Speakers and attendees will discuss, compare, and contrast their experiences with the process of implementing a web-based protocol management system, from planning and implementation to continuing maintenance, and will participate in an extensive question and answer session. Before attending this session, attendees should have a basic understanding of IACUC functions and responsibilities, and protocol review workflow. During this session, speakers and attendees will:

- Explore the pros and cons of using a web-based protocol management system
- Share strategies for selecting a system that best fits your needs, taking into account committee, research, and institutional needs
- Describe the steps and personnel involved in system development and implementation
- Discuss post-implementation needs, including routine data transfer to other online systems, report generation, updating forms based on new regulations, etc.

D5: IACUC Deliberations Using Wildlife Scenarios—Part II (Aquatic Species) (Oversight of Non-Typical Animals and Situations Track)

George Sanders,<mark>,</mark> Doreen Bartlett (resource person), <mark>Rebecca Henry</mark>

Back-up: Jeff Wyatt (from Bob Sikes), Vincent Politano (from Sally), Maybe: Elaine Kim, Preston Van Hooser, Laurence Istvan (from Sally) Tara Chestnut – PhD – Biologist for Mt Rainer National Park <u>tara_chestnut@nps.gov;</u> Dede Olson – PhD – USFWS Biologist

Dede -FS Olson <u>dedeolson@fs.fed.us;</u> Jonah Plovia-Scott – PhD – Researcher – WSU (Vancouver Campus) jonah.piovia-scott@wsu.edu; Jenny Pramuk – PhD - Animal Curator – Woodland Park Zoo Jennifer.Pramuk@Zoo.org

Decline: Mike Murray, Phil Harris, Katie Haman, Jonah Plovia-Scott

During this two-part session, speakers will actively engage the audience in examining challenges for the IACUC in reviewing field studies. Part II will focus specifically on research with aquatic species, and ethical concepts and principles, regulations, and processes involved in aquatic research will be examined. Attendees participating in this session should have direct experience in use of these animals in the field, and are highly recommended to attend sessions A5: IACUC Basics for the Use of Wildlife in Research and Education session, and B5: The Role of the Attending Veterinarian in Review and Oversight of Wildlife Research. During Part II of this session, speakers and attendees will:

- Review whether activities fall under field studies exemptions
- Discuss how to list animal numbers and species
- Explore impacts of wildlife research activities on populations and communities

Note Part I of this session will take place on Tuesday April 2 from 4:45-6:00 PM (Session C5).

D6: Reproducibility, Environment, and Design—Implications for Research Outcomes (Program Management Track) Larry Carbone, Ben Weigler, Animal Resources Director, University of Nevada-Reno

A number of variables influence reproducibility of animal models, including, but not limited to environment, experimental design, and choice of statistical power. There is often reluctance to change the status quo, even if there are implications for improved animal welfare, due to the potential effect on the reproducibility of results. During this session, speakers and attendees will:

- Address issues surrounding reproducibility, including attrition in drug discovery and development, translation of animal
- studies to human outcomes, and ways to identify models more or less likely to translate
- Consider how optimal animal welfare can be balanced with potential research outcomes
- Discuss where IACUCs fits into this equation and how they can improve lines of communication between them and
 researchers

D7: Harm-Benefit Analysis in Protocol Review and Assessing Study Design (Protocol Review Track) George Babcock, Kathy Laber

Back-up: Chris Newcomer, Jeff Everitt,

Decline: Jerry Collins

A central responsibility expected of IACUCs is to be institutional advocates for laboratory animals. This includes deliberating on projects that involve pain or distress, where the *Guide* states that "the IACUC is obliged to weigh the objectives of the study against potential animal welfare concerns" (8th edition, page 27). This could be done through a harm-benefit analysis. Before attending this session, attendees should have thorough knowledge of the regulations and have reviewed the AALAS-Federation for Laboratory Animal Science Associations (FELASA) report. During this session, speakers and attendees will:

- Review the AALAS-FELASA working group report on harm-benefit analysis
- Debate how IACUCs can compare known animal harm versus unknown harm/benefit to current and future patients based on medical advances
- Discuss how this relates to study design and reproducibility, ensuring that harm is minimized while also producing beneficial results
- Explore what IACUCs can do within the scope of their charge if study design is not appropriate, or investigators rely on historical precedent for their procedures

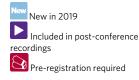
Basic: Introduction of a topic for those with little or no knowledge; focus is on introducing, explaining, and illustrating basic concepts, principles, regulations, policies, or best practices.
 Advanced: Assumes mastery of central ethical concepts and principles, the regulations, and the processes of applying them to the day-to-day work of protocol review or research oversight activities. Provides in-depth knowledge of an area and robust set of skills for addressing difficult problems and navigating "grey areas," improving IACUCs, shaping institutional cultures, or advancing careers. Attendees are expected to have sufficient experience and understanding to contribute to the discussion of and solution to difficult problems.

Icon Key

Sessions span two time periods



Call for Session Proposals







Advanced



Wednesday, April 3: IACUC19

Breakout Session Series D, 11:15 AM-12:30 PM

D8: Strategies for Evaluating the Effectiveness of Training Programs (Qualifications and Training Track)

lichelle Stickler, Amy Chuang (VCU, participated in iCare, built a robust, data driven education program

The OLAW program evaluation checklist suggests that IACUCs should be evaluating the effectiveness of their training programs. This session will discuss what might be meant by the phrase "evaluate effectiveness," and what kind of data can be used to demonstrate a training program is being evaluated. During this session, speakers and attendees will:

- Discuss what components of a robust training program should be evaluated
- Identify the goals of a training program evaluation and different types of evaluation strategies to complement goals •
- Describe what type of data can be used to support a training program evaluation •

D9: Timing and Substance: How to Respond When Things Go Wrong (Communication and Networking Track) Sally Thompson-Iritani, Buddy Capuano



The combined effect of Murphy's Law, human fallibility, and moving targets for ethical, veterinary, and regulatory standards, is that things go wrong—in animal research as in any other area of human endeavor. How animal research program participants respond makes all the difference. This session will focus on how to use the process of identifying and addressing problems to improve the animal care and use program, instead of only ensnaring the program in ever increasing and counterproductive regulatory burden. Specific topics to be addressed include what to do with the findings that come from AAALAC International site visits, and what to do about problems that are self-identified. This session will be useful to participants from any institution, although speakers will address a few VA-specific points as well. During this session, speakers and attendees will:

- Consider how the timing of the responses can impact their efficacy and how much administrative burden is involved
- Examine the requirements for self-reporting and the need to make sure that compliance supports improved animal care and use

12:30-1:45 PM

Attendee Open Lunch Period

During this time, attendees will eat lunch on their own. Learn more about dining options in the hotel and area here.

Breakout Session Series E, 1:45-3:00 PM

E1: Non-Animal Alternatives: Barriers to Implementation (Animal Well-Being and the 3 Rs Track) Ed Kelly; Helena Hogberg: Mary Zelinski

This session is a follow-up to the panel on the same topic (Panel II: Alternatives—Are We There Yet?). During this session, speakers and attendees will:

Discuss in more detail why, while the search for alternatives has yielded important knowledge on the reliance of whole body • systems, animal models are still necessary in certain types of research

E2: IACUC Chair Roles and Responsibilities Beyond the IACUC Meeting (Communication and Networking Track) Wayne Barbee, VCU; Jane Sullivan

Back-up: George Babcock

The IACUC has responsibility for all aspects of an animal care and use program. An engaged chair should take an active role in collaborating with the attending veterinarian and IACUC administrator to thoroughly evaluate the animal care and use program and ensure it is fully within regulatory compliance and implementing best practices. This session will address various ways in which chairs can become more engaged in the overall animal care and use program through didactic presentation and discussion among participants. During this session, speakers and attendees will:

Briefly review the components and key players of the animal care and use program

Basic: Introduction of a topic for those with little or no knowledge; focus is on introducing,

explaining, and illustrating basic concepts, principles, regulations, policies, or best practices. Advanced: Assumes mastery of central ethical concepts and principles, the regulations, and the

processes of applying them to the day-to-day work of protocol review or research oversight

activities. Provides in-depth knowledge of an area and robust set of skills for addressing difficult

problems and navigating "grey areas," improving IACUCs, shaping institutional cultures, or

advancing careers. Attendees are expected to have sufficient experience and understanding to contribute to the discussion of and solution to difficult problems.

- Describe the IACUC's role in evaluating the entirety of the animal care and use program from protocol review to animal facilities and veterinary care
- Provide examples of situations where chair involvement can be of benefit to the animal care and use program
- Discuss the role of an actively engaged IACUC chair in ensuring the animal care and use program is fully compliant with regulations, while helping investigators facilitate research

Icon Key



PIA Basic

Advanced

Sessions span two time periods CPL CPIA recertification credit \star

Call for Session Proposals



CPIA Basic

advancing careers. Attendees are expected to have sufficient experience and understanding to contribute to the discussion of and solution to difficult problems.

Wednesday, April 3: IACUC19 Breakout Session Series E, 1:45-3:00 PM

E3: Use of Pet Animals for Research—Impacts of the One Health Initiative (Hot Topics and Emerging Trends Track) Chris Newcomerresurce persons: Carol Clarke, Lon Kendall (c) Backup speakers: Lon Kendall, Philippe Baneux, Valerie Bergdall

Decline: "Steven Soloman, FDA

READING MATERIALS: LV Kendall et al. Institutional animal care and use committee review of clinical studies. J Am Vet Med Assoc 253 (8): 980-984, 2018; R Page et al. Conduct, oversight, and ethical considerations of clinical trials in companion animals with cancer: report of a workshop on best practice recommendations. J Vet Intern Med 30 (2): 527–535, 2016, doi: <u>10.1111/ivim.13916</u>; PJR Baneux et al. Issues related to institutional animal care and use committees and clinical trials using privately owned animals. ILAR J 55 (1): 200–209, 2014, <u>https://doi.org/10.1093/ilar/ilu005</u>

While pets with "spontaneous" or "natural" diseases and injuries have always represented opportunities to learn more about conditions that also afflict man, growing appreciation by physicians and pharmaceutical companies in how those pets may advance both human, as well as veterinary medicine, has increased interest and funding for mutual benefit. At the same time, universities with both an IACUC for laboratory animals and a veterinary school may be asked to expand IACUC oversight to clinical research on pets. Such a combination presents novel and sometimes poorly defined compliance responsibilities. Before attending this session, speakers should familiarize themselves with the reading that will be available in late March once session materials are posted online. Before attending this session, it is recommended that attendees read three articles that will be posted in late March. During this session, speakers and attendees will:

- Provide background and overview of the One Health Initiative
- Discuss implementation of research activities involving pet animals and challenges encountered at institutions conducting these activities
- Address ambiguity in compliance responsibilities and identify approaches to engaging the IACUC while minimizing burden

E4: Effectively Identify, Track, and Report Departures—Meeting OLAW and USDA Requirements (IACUC Administration/Management and Process Track)

Neera Gopee, Richelle L. Scales, Elizabeth Meek

This session will actively engage the audience in a discussion on departures from OLAW and USDA Requirements. Before attending this session, attendees should have familiarity with exceptions from regulations and IACUC office management. During this session, speakers and attendees will:

- Discuss the meaning of "departure" based on the PHS Policy and Animal Welfare Act and Regulations
- Review OLAW's and USDA's reporting requirements for departures
- Evaluate case studies and scenarios surrounding departure reporting
- Outline ways to track departures for reporting purposes

E5: Oversight Challenges in Agricultural Research (Oversight of Non-Typical Animals and Situations Track)

Susan Harper, Robert Gibbens

Researchers who conduct agricultural research frequently encounter unique challenges when trying to develop standards that balance optimum welfare with other management considerations that are important to herd/flock/population management. This session will focus on strategies to identify acceptable practices, and monitor their quality and effectiveness relative to animal care for studies that are conducted under simulated production conditions. During this session, speakers and attendees will:

- Provide an overview of resources available to assist individuals managing agricultural research programs
- Discuss strategies for developing standards that are appropriate for the species, facilities, and research
- Present options to assess the effectiveness of practices involving agricultural species

E6: Institutional Responsibility and Oversight of Other Animals on Campus (Program Management Track) Jori Leszczynski, Lyndon Goodly, Elaine Kim

Back-ups: Josh Gulley (for Lyndon - someone from University of Illinois Urbana-Champaign (see article in the Scientist - https://www.thescientist.com/news-opinion/the-challenges-of-bringing-service-dogs-into-the-lab-64812), CSU has display animals that they cover, so Elaine Kim or Lon Kendall would be great. From U of I Urbana Champagne, the article had Josh Gulley as the "IACUC Head" and Lyndon Goodly is the Director of their animal facility (they have a few other vets – Sarah Allison, Jennifer Criley and Helen Valentine that also might be able to come); Kathy Branson is the IACUC administrator at University of Illinois

With the increase of emotional support animals, assistance animals, and animals used for therapy, what are institutions able to do to ensure animals and people are safe in restricted areas? This session will explore what legal and other responsibility the institution has regarding animals on campus that are not under the traditional IACUC structure (e.g., therapy dogs, emotional support animals, animals used for display, etc.), as well as the rights of service dogs and where these animals are permitted to be at an institution, including if they could be permitted in laboratories or vivariums. During this session, speakers and attendees will:

- Outline the existing laws regarding assistance and emotional support animals
- Discuss the policies and infrastructure institutions can have in place to review requests and who should participate
- Explore what restrictions can be placed on assistance animals into restricted areas, such as laboratories and vivariums

Sessions span two time periods

- CPIA CPIA recertification credit
- Call for Session Proposals









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Wednesday, April 3: IACUC19 Breakout Session Series E. 1:45-3:00 PM

E7: Universal Protocol Form (Protocol Review Track) Bill Greer - SF, Axel Wolff (resource person), Ron Banks

Back-ups: Kim Stocking

Decline: Monte Matthews

There has been recent discussion about a universal protocol form that would be mandated for institutions to use. This session will provide a platform fora discussion about the pros and cons of such a form, ideas on what the form could contain, and how this could be implemented across the country given the varied electronic and paper systems that currently exist. During this session, speakers and attendees will:

- Discuss the pros and cons of implementing a universal protocol form
- Share ideas on what the form could contain and how it would allow for the varied research at all institutions
- Consider how a universal form could be implemented

E8: Implementing Customer Service Into Your IACUC Program (IACUC Administration/Management and Process Track)

Rachel Murray (CSP author), Sally Light

This session will focus on ways to incorporate and implement customer service into your program from all angles (i.e., how the IACUC administrator/coordinator can provide customer service to and build bridges between their IACUC, the research community, and the veterinary services program). During this session, speakers and attendees will:

- Define customer service in animal care and use programs
- Explore how the IACUC administrator/coordinator can provide customer service to the IACUC and the research community

Discuss ways to build bridges between the various stakeholders in the animal care and use program

Note: this session will be similar to the Decreasing Regulatory Burden: Is THAT Required? preconference program on April 1.

E9: External Collaborations—How Do You Do Due Diligence? (IACUC Administration/Management and Process Track) Kate Pritchett Corning, Harvard University (has both the industry and academic perspective) Birgit Leidermann as an Interpharma representative (shared audits of suppliers)

Back-up: Gary Borkowski (or we can include as a resource person) Decline: Chris Dillon at MPI

When sponsoring animal research at an external institution, how does an IACUC assure they have performed due diligence? Is AAALAC International accreditation of the external partner sufficient as a standard of great animal welfare? Is IACUC review needed if the external partner's IACUC reviews the work? Before attending this session, attendees should have a basic understanding of IACUC functions and responsibilities, and protocol review workflow. During this session, speakers and attendees will:

- Define due diligence and how it supports animal welfare goals
- Discuss what program elements are needed to assure appropriate standards of animal welfare are being met
- Explore pros and cons of reviewing a reviewed study

3:00-3:15 PM

Beverage Break

3:15-4:30 PM

Panel III: Engaging the Public Over the Use of Animals in Research

Moderator: Taylor Bennett (c)

Panelist 1: Leland Shapiro – personal story, (back-up: Steven Gilbert) (uc); Panelist 2: Wendy Jarrett (c) – UK concordat success with openness and transparency; Panelist 3: Logan France (c)

Decline: Don Tapscott Anthony D. Williams (uc) – wikinomics – this is a fascinating topic about trying to bring the public into our world to problem solve and bring new ideas. Contests for design of animal homes possibly

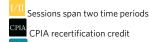
What are the benefits of openness and transparency about animal research? Are there new ways the field can approach transparency that are interactive and allow people to participate with novel ideas? How do we include the public in the conversation rather than talking at them? This panel will share ideas and experience for how IACUC professionals and research staff can work with the public to advocate for ethical and responsible animal research. Attendees will hear about how a patient benefited from animal research, the success the United Kingdom (UK) had with the UK Concordat, and how to engage with the public to join in advocacy going forward.

Thursday, April 4: NWABR Regional IACUC/IBC Conference

Visit this page for the agenda and more information on the NWABR Regional IACUC/IBC Conference

Basic: Introduction of a topic for those with little or no knowledge; focus is on introducing, explaining, and illustrating basic concepts, principles, regulations, policies, or best practices.
 Advanced: Assumes mastery of central ethical concepts and principles, the regulations, and the processes of applying them to the day-to-day work of protocol review or research oversight activities. Provides in-depth knowledge of an area and robust set of skills for addressing difficult problems and navigating "grey areas," improving IACUCs, shaping institutional cultures, or advancing careers. Attendees are expected to have sufficient experience and understanding to contribute to the discussion of and solution to difficult problems.

Icon Key



Call for Session Proposals







