

PRECONFERENCE COURSES: **TUESDAY JUNE 11, 2019**

3:00 PM - 6:00 PM

FUNDAMENTALS OF IBCS AND THE NIH GUIDELINES Kathryn Harris, Ph.D., RBP

This workshop provides an introductory overview of the history, function, and administration of Institutional Biosafety Committees (IBCs). Learn about the activities of the NIH OSP, the content of the NIH Guidelines for Research Involving Recombinant and Synthetic Nucleic Acid Molecules, and the function, administration, and responsibilities of IBCs under the NIH Guidelines. What is a humanized mouse and how is it created? Why are they

WEDNESDAY JUNE 12, 2019

8:00 AM - 12:00 PM PROMOTING BIOSAFETY AND BIOSECURITY THROUGH EFFECTIVE GOVERNANCE Kathryn Harris, PhD, RBP

This highly interactive class will focus on the importance of ensuring institutions have robust and comprehensive biosafety and biosecurity governance structures in place. Information will be provided about some of the tools and best practices institutions can employ to strengthen their biosafety and biosecurity programs. Participants should come prepared to engage in discussion, information sharing, and Q & A with other participants. PARTICIPANT SHARING OF BEST PRACTICES

8:00 AM - 12:00 PM

OCCUPATIONAL HEALTH AND SAFETY IN ANIMAL PROGRAMS: AN OVERVIEW AND CASE STUDY Helen Diggs, MEd, DVM, DACLAM, Senior Director, AAALAC International; John N. Norton, DVM, PhD, DABT, DACLAM

During AAALAC site visits of animal facilities and programs, deficiencies are frequently found involving occupational health and safety. Prevent this from happening at your institution! This workshop will combine an AAALAC site visitor's perspective with a facility director's experiences. Dr. Diggs will present AAALAC International's expectations for Occupational Health and Safety Programs, and Dr. Norton will follow-up with a "recipe for success" for implementing these expectations in an animal program. Best practices based on the "Eighth Edition of the Guide for the Care and Use of Laboratory Animals" will be explored.

WHY ALEXANDRIA, VA?

Located minutes from Washington, DC, Alexandria offers brick sidewalks and preserved 18th- and 19th- century buildings that will send you back in history. Outside the door of our hotel is Kings Street known for boutiques and specialty shops. Founding fathers dined at Gadsby's Tavern, which is a museum with period objects, photographs and the site of our networking dinner. Travel back in time to celebrate and make history at the 10th Occupational Health Colloquium.

Other Notable Features

- Experience history where it happened Gadsby's Tavern Museum, Stabler-Leadbeater Apothecary Museum, Caryle House, or George Washington's Mount Vernon.
- •Torpedo Factory See a naval munitions factory converted into an art center located on the banks of the Potomac River!
- •The Tiny Spite House Go see the skinniest historic house in America at 7 feet wide!
- •Oldest Farmers' Market in the U.S Visit a 260+ year Old Town Farmer's Market. The oldest continuously-run farmers market in the US!
- •Ghost Tour Founded in 1749, go on Alexandria's haunted history ghost tour led by a lantern-carrying costumed guide! Explore graveyards, haunted neighborhoods and historic hot spots.
- New Additions there are many new additions to Alexandria in 2019! These include, a new waterfront park area, electric bike tours, and new beer gardens!

CONFERENCE: **WEDNESDAY JUNE 12, 2019**

1:00 PM WELCOME

HUMANIZED MICE AS RESEARCH TOOL: A DEEP DIVE INTO THE SCIENCE AND THE SAFETY CONSIDERATIONS Scott Kitchen, PhD, Director, UCLA CFAR/JCCC Humanized Mouse Core Laboratory; Timothy Mandrell, DVM, DACLAM, Consultant

useful, and what are some of the current research projects using them? Dr. Kitchen will address the science behind the creation of these mice and how mice bearing human cells are used in biomedical research. Dr Mandrell will then lead a discussion about occupational health and safety considerations for researchers, animal care staff, and

INTERACTIVE ACTIVITY:

Audience teams will review information from IBC and IACUC protocols involving humanized mice. They will need to ask the researcher, Dr. Smart, questions about his protocols, and make recommendations on health and safety procedures.

Participants are invited to share ideas regarding IBC best practices at their institutions. Topics may include community member recruitment strategies, meeting facilitation, protocol review, interaction with principal investigators, member training, and occupational health. In addition, with regards to Human Gene Therapy, the group will discuss the steps that are being taken to ensure IBCs can take on challenges with reduction in RAC oversight. Steering committee members will

5:00 PM CONCLUSION

5:30 PM RECEPTION IN THE COURTYARD



THURSDAY JUNE 13, 2019

8:00 AM

IBC OVERSIGHT OF TRANSLATIONAL RESEARCH: CHANGES IN PERSPECTIVE WHEN RDNA MOVES FROM THE LAB TO THE CLINIC

Team from Duke University: Richard Frothingham, MD, IBC Chair, Wayne Thomann, DrPH, Director, Occupational and Environmental Safety, Pat Condreay, PhD, Safety Manager, Antony Schwartz PhD, Director of Biological Safety, Carol Epling, MD, Director, **Occupational Health**

This half-day session will describe the development, by a Duke University investigator, of a recombinant chimeric poliovirus that showed promise as an oncolytic virus treatment for glioblastoma multiforme in cell culture and animal models; and eventually was proposed for human clinical trials. The Duke IBC will share experiences from their rare opportunity to oversee a wide spectrum of issues surrounding a single recombinant virus for more than 15 years.

Over the course of the session the following aspects will be explored:

- The evolution of the focus of oversight by the Duke University IBC from issues of laboratory biosafety to those of informed consent and biosafety in a clinic setting
- How Occupational Health expertise on the IBC has influenced approaches to evaluation of recombinant virus research and facilitated institutional preparedness for emerging issues related to novel therapies
- The challenges that novel therapeutic approaches such as PVS-RIPO present in the evolving regulatory environment for human gene transfer clinical trials

INTERACTIVE ACTIVITY:

Throughout the morning, participants will be asked to provide perspectives from their experiences with challenging registrations and contribute to sharing sound oversight practices.

THE FUTURE OF HGT RESEARCH OVERSIGHT Kathryn Harris, Ph.D., RBP

This presentation will describe the changes taking place at NIH in Human Gene Transfer Research Oversight

IBC CASE STUDIES

A. IBC OVERSIGHT OF HUMAN/CRISPR TRIALS Ellyn Segal, PhD, Biosafety Manager, Stanford University

The previous time span from bench to bedside for human gene transfer using viral vectors was 20 years; the time span from bench to bedside for CRISPR based human clinical trials was 5 years. This accelerated time scale necessitates an in-depth comprehension of a technology that has yet to be thoroughly understood and presents an IBC with numerous unknowns relating to review and oversight. This session will provide a discussion of the state-of-the-art human gene transfer clinical trials currently being performed and discuss some of the scientific questions associated with these trials.

STAY THE WEEK!

9 Sunday:

PM: Pre-Conference

AM: Pre-Conference

10 Monday:

Occupational Health Colloquium

11 Tuesday:

Occupational Health Colloquium

PM: Optional Workshop: **Pre-Conference**

12 Wednesday:

AM: Pre/Post-Conference

13Thursday:

IBC Conference

PM: IBC Conference

For More Information on the Occupational Health Colloquium, visit: www.eagleson.org/conferences/OCC.

B. IBC OVERSIGHT OF PRION-LIKE PROTEINS Susan Vleck, PhD, Stanford University

IBC oversight of infectious agents includes prion protein work as a BMBL-designated BSL2 (or sometimes BSL3) agent. A growing body of data regarding proteins associated with neurodegenerative proteinopathies indicates that these proteins may act in a similar manner to prions. These so-called prion-like proteins misfold and aggregate, are capable of cell-to-cell and cross-species transmission, and may be similarly resistant to common methods of protein degradation. This session will discuss the expansion of IBC oversight beyond the "accepted" list of infectious proteins, touching on issues of risk assessment, decontamination and disposal, and biosafety review.

5:00 PM CONCLUSION

5:30 PM OPPORTUNITY TO TOUR D.C. MONUMENTS BY **BICYCLE**



REGISTRATION INFORMATION

Register online at www.eagleson.org/IBC or call 207-490-1076

CONFERENCE

before May 1, 2019 **\$7**95 after May 1, 2019 **\$845**

Conference fees include attendance at all conference sessions, Wednesday night reception and lunch on Thursday.

CONFERENCE WORKSHOPS

Fundamentals of IBCs and the NIH Guidelines \$245/\$295 Promoting Biosafety and Biosecurity through Effective Governance **\$245/\$295**

Occupational Health and Safety in Animal Programs \$245/\$295

PROMOTIONS:

Attend both the Occupational Health and IBC conferences; save \$400.*

Bring a colleague from your institution and get a 30% discount!**

*Promotions cannot be combined.

**Both registrations must be from the same institution and paid for at the same time. The discount is applied to the lesser registration. Call to register.

CANCELLATION POLICY

Individuals who cancel more than 15 business days prior to the conference date will receive a full refund. For cancellations made 6 to 15 business days before the start of the program, a 50% refund will be given. For cancellations made 5 business days or less prior to the conference date, no refunds will be given. Notification of cancellation must be received in writing. Substitutes for a registered attendee may be made at any time.

Register now for IBC Conference!

- Explore best practices for facilitating safe, cutting-edge science.
- Interact with colleagues to share creative, practical solutions to common challenges.
- Develop strategies and tools for running an effective and efficient program.
- Learn from case studies by scientists, safety professionals, and veterinarians from UCLA, Stanford, and Duke Universities.

