

WEDNESDAY, MARCH 14, 2018

UNDERSTANDING THE AREAS OF COMPLIANCE INTERSECTION: A GUIDE TO UNDERSTANDING AREAS OF COMPLIANCE BEYOND THE IACUC AND IBC™

KATE MELLOUK, As the Associate Vice President for Research Compliance, Kate is responsible for all non-financial research compliance issues at Boston University. That includes the Animal Sciences Center, Environmental Health and Safety, Charles River Campus IRB, Research Integrity, Export Controls, HIPAA Privacy, and multiple oversight Committees. Ms. Mellouk has been with the Office of Research Compliance at BU since 2006, serving as the Executive Director of Research Integrity & Assurance prior to being named Associate Vice President in July, 2013. Prior to her arrival at Boston University, she was a Research Compliance Manager at the University of Michigan.

ERIC T EVERETT, PhD is professor in the University of North Carolina at Chapel Hill Department of Pediatric Dentistry, the School of Dentistry's associate dean for research, and Institutional Research Integrity Officer. He has served on study sections for the NIH Center for Scientific Review and is associate editor of the European Journal of Oral Sciences. Everett's research program has focused on the identification of genes and pathways that play key roles during embryonic and postnatal development of craniofacial/oral/dental structures. Everett earned his M.S. in pathology from the University of Florida and his Ph.D. in molecular cell biology and pathobiology from the Medical University of South Carolina. Everett did his postdoctoral training in hematopoiesis at the Howard Hughes Medical Institute at Indiana University School of Medicine and a medical genetics fellowship in the Department of Medical & Molecular Genetics at the Indiana University School of Medicine. After spending eight years on the Indiana University faculty, Everett joined the UNC School of Dentistry faculty in 2004.

ABC's for IACUCs & IBCs: FRAMEWORKS FOR COMPLIANCE™

**KAREN KRUEGER, DVM, DACLAM, Director, Animal Resources
Boston Children's Hospital Chair, MSMR Program Committee**

Karen Krueger, DVM, DACLAM graduated from Tufts School of Veterinary Medicine and went through the residency program at MIT. She was a Clinical Veterinarian at Duke, working at the Duke Primate Center before becoming Associate Director of the animal care program at MGH and Director of animal care at Wyeth, Andover/Cambridge. For over the last decade she has been the Director of the Animal Care Resources Children's Hospital (ARCH) program here in Boston. Dr. Krueger had served as an ad-hoc consultant for AAALAC International.

**BARBARA GARIBALDI, DVM, DACLAM, Director of the Animal Research Facility at Beth Israel Deaconess Medical Center
Instructor, Department of Medicine, Harvard Medical School, Boston, MA**

Dr. Garibaldi is the Director of the Animal Research Facility at Beth Israel Deaconess Medical Center. She received her veterinary medical degree from Purdue University and completed postdoctoral work in laboratory animal medicine at the Massachusetts Institute of Technology. She is board certified in laboratory animal medicine. Dr. Garibaldi has completed a 12 year term as an AAALAC Council member and now serves as an Emeritus member to Council.

**TED MYATT, ScD, RBP, Practice Director – Life Sciences
Environmental Health & Engineering, Inc.**

Ted has extensive experience in the fields of biosafety, environmental health and safety (EH&S), research compliance, epidemiology, building mechanical systems, and exposure assessment. Prior to rejoining EH&E, Ted served as the Director of Research Integrity at the University of Rhode Island, overseeing all aspects of research compliance, including human subject research (i.e., Institutional Review Board), animal welfare (i.e., Institutional Animal Care and Use Committee), biosafety (i.e., Institutional Biosafety Committee), laboratory and chemical safety committee, export control compliance, conflict of interest, research misconduct, and responsible conduct of research (RCR) training. He has also served as the Director of the Partners HealthCare Institutional Biosafety Committee and the Biological Safety Officer at Brigham and Women's Hospital. He received a Bachelor's of Science in microbiology at the University of Illinois, a Master's of Environmental Management at Duke University, and a Doctorate of Science at the Harvard School of Public Health.

CHRISTINA NASCIMENTO, MS, CPIA, IACUC Manager
Brigham & Women's Hospital

Christina is the IACUC Manager at Brigham & Women's Hospital in Boston, Massachusetts. Christina earned her Bachelor's Degree in Pre-Veterinary Science and Biology at the University of Massachusetts, Amherst, Master's degree at UMASS Amherst concentrating in Molecular Genetics, and holds a CPIA certification from PRIM&R. As IACUC Manager, Christina oversees IACUC Office operations, while also implementing an eIACUC system and was part of the team opening a new state-of-the-art animal facility and establishing an entire animal care and use program for the institution. Christina served on the Harvard Medical Area/School IACUC for over 10 years, and is currently serving on the Brigham & Women's Hospital IACUC. After acting as the IACUC Inspection Officer at Harvard Medical School, Christina has over a decade of experience in IACUC policy and animal welfare, as well as managing a vast inspection and Post Approval Monitoring Program for dozens of animal facilities and satellites and hundreds of laboratory use areas. From her years as both an investigator and a veterinary technician, Christina has experience with a variety of species such as rodents, agricultural animals, aquatic species, cats, dogs, horses, and non-human primates. Outside of the office, Christina enjoys training young horses and is a licensed horseback riding instructor.

IACUC = Implementing Assurance Compliance Understanding and Confidence –
A NUTS AND BOLTS APPROACH TO IACUCS AND ANIMAL CARE AND USE PROGRAMS©

MARCY BROWN, BS, MA, CMAR, CPIA
Animal Welfare and IACUC Program Specialist
AAALAC, Intl ad hoc Specialist

Marcy is an Animal Welfare, IACUC, and Regulatory Specialist with experience in both academic and industry settings. Marcy is a Certified Professional IACUC Administrator (CPIA) and Certified Manager of Animal Resources (CMAR). She serves on the board of directors of the California Biomedical Research Association (CBRA) and as an AAALAC, International ad hoc Specialist. Marcy has also devoted significant time to presenting and co-facilitating presentations, workshops, and panels at PRIM&R's Annual IACUC meetings and CBRA's annual educational workshops, as well as faculty for American Association for Laboratory Animal Science (AALAS) and Massachusetts Society for Medical Research (MSMR) meetings. Marcy has a biology background, holds a Master of Arts degree from the University of California, Berkeley and is a certified Lean Six Sigma Black Belt. She is the 2016 recipient of the PRIM&R ARENA Legacy Award, which recognizes PRIM&R members who significantly promote the ethical conduct of research through mentoring, teaching, and leadership.

DEB FROLICHER, BS, CPIA
Director, IACUC Office
The Scripps Research Institute

Deb earned her Bachelor of Science degree in Agriculture/Animal Science and Nutrition at The Ohio State University, Columbus, OH and after graduation began working in biomedical research as a laboratory technician. In her 15 plus years in biomedical research she has worked with various animal models and a variety of species, including snakes, lizards, rodents, ducks, dogs, pigs, goats, cattle, and a colony of diabetic monkeys. She began her IACUC administrative career in the mid 90's. Deb's experience in the laboratory enables her to effectively interface with investigators and research staff to integrate IACUC review and oversight into their research programs. Currently, she is the director of the IACUC office at The Scripps Research Institute in La Jolla, CA. Deb earned CPIA certification in 2008 and served on the CPIA Council from 2010 through 2016, the last two years as Council Chair. She is a member of PRIM&R, SCAW, AALAS, and LAWTE.

THURSDAY, MARCH 15, 2018



Linda Carime Cendales, MD

Director, Duke Vascularized Composite Allotransplantation Program
Associate Professor of Surgery

Vascularized composite allotransplantation (VCA) refers to the transplantation of multiple tissues, such as skin, muscle, tendon, nerve, and bone, as a functional unit (e.g. a hand). Several recent advances in clinical organ transplant immunosuppression and experimental VCA have now made it feasible to consider clinical VCA for functional restoration in patients with the loss of one or both hands or large tissue defects that may not be reconstructed with autologous tissue. My research facilitates the translation of VCA from the bench to the bedside.

Our group has established preclinical models to understand VCA rejection in different tissues and to use that insight to minimize immunosuppression in VCA recipients who participate in clinical trials. We also organized the first public international consensus discussions conference in VCA at the Ninth Banff Conference on Allograft Pathology in Spain in 2007 resulting in the Banff VCA 2007 classification for skin allograft pathology. Additionally, we established a VCA Consortium to enable the comprehensive analysis of samples from patients in VCA clinical trials around the country.

Based on our studies of different immunosuppressive regimens in primates, we have been the first to show that belatacept prevents rejection in VCA in primates and controls rejection in humans. We are currently investigating this approach in a clinical trial of hand transplant recipients (NCT02310867). This clinical trial aims to determine the safety and efficacy of hand transplantation as a treatment for patients with limb loss. This study will also test the efficacy of belatacept to prevent rejection of the transplanted hand.

Education and Training

- Fellow, Translational Research, Emory University School of Medicine, 2009 – 2011
- Senior Clinical Fellow, National Institutes of Health, 2004 – 2006
- Fellow, Transplantation Surgery, National Institutes of Health, 2001 – 2004
- Clinical Fellow & Senior Fellow, Hand & Microsurgery, Christine M. Kleinert Institute, 1997 – 2001
- Chief Resident, Surgery, Hospital General Dr. Manuel Gea Gonzalez (Mexico), 1995 – 1996
- Internship/Junior Resident, Surgery, Hospital General Dr. Manuel Gea Gonzalez (Mexico), 1993 – 1995
- M.D., Universidad Autonoma Metropolitana (Mexico), 1992

LISA NEWBERN is Chief of Public Affairs for the Yerkes National Primate Research Center, one of only eight National Institutes of Health-funded national primate research centers. During her more than 20 years of communications experience, she has worked as a senior leader, strategist, program director and client services manager, all of which relied on her strategic focus and strong writing, media relations, community and educational outreach, special event, problem-solving and client service skills. As the Yerkes Research Center's lead communication officer, Newbern is responsible for educating the internal Emory community and the public about the distinct role the center holds in advancing science and improving health and well-being. To do this, she oversees all: media relations, the center's Web site, and community and educational outreach, including tours, open houses, speakers' bureau programs and special events. Her responsibilities also include issues management and emergency preparedness, the center's National Scientific Advisory Board, government affairs and FOIA requests, and special projects for the center director.

AMANDA M. DETTMER is a Senior Editor for Speaking of Research, an international advocacy group that provides accurate information about the importance of animal research in biomedical and veterinary science. She obtained her PhD in Behavioral Neuroscience from the University of Massachusetts Amherst, and for over 15 years has been studying nonhuman primate models of human development and disease. As an Editor for Speaking of Research, Dr. Dettmer is responsible for interacting with the public via blog posts, social media (Twitter, Facebook, Reddit, etc.), and media and professional conferences to promote greater understanding of the responsible, ethical, and highly-regulated use of animals in research, as well as the importance of animal research in scientific and medical advances.

Until recently, Dr. Dettmer maintained an active research program studying biobehavioral development in rhesus monkeys. As such, she is uniquely familiar with both the regulatory aspects of animal-based research as well as the need for effective public communication regarding the necessity of animals in research. She is currently working in Washington, DC, as the American Psychological Association's 2017-18 Executive Branch Science Policy Fellow.

SHELLEY LYNCH, PUBLIC INFORMATION OFFICER, FBI, CHARLOTTE OFFICE

Shelley Lynch joined the FBI as the Public Affairs Officer for the Charlotte Division in 2011. Ms. Lynch was called to Boston to work in the joint information center after the Boston marathon bombing and to Orlando to assist after the Pulse nightclub shooting. She has handled many high profile cases including the kidnapping and rescue of Frank Janssen, the father of a Wake County, N.C. prosecutor, the charges against former U.S. Army General David Petraeus, the arrest and conviction of former Charlotte Mayor Patrick Cannon and countless fugitive and missing children cases. She regularly coordinates with the FBI's National Press Office, other FBI field offices across the country, and state and local law enforcement agencies to develop and implement strategies to best communicate with and respond to media inquiries. Prior to her work in the FBI, she spent 16 years in the television news industry working at television stations in Augusta, GA and Charlotte, NC. She was a producer, executive producer, and interim news director during her TV career. Ms. Lynch uses her experience in television news to provide training to state and local law enforcement agencies regarding developing positive media relations.

EILEEN MORGAN currently serves as the Director, Division of Assurances in the Office of Laboratory Animal Welfare (OLAW) at the National Institutes of Health (NIH). Ms. Morgan previously served as a Senior Assurance Officer in the Division of Assurances within the Office of Laboratory Animal Welfare (OLAW). Eileen holds a B.S. in Technology Management from the University of Maryland and an associate degree in Animal Health Technology. She has 29 years of experience in animal models-based biomedical research and compliance oversight in the humane care and use of laboratory animals. Her experience includes service as Chief of the Facility Management Branch in the Division of Veterinary Resources, NIH Intramural Program, and positions at Johns Hopkins University School of Medicine, the American Red Cross, Holland Laboratory, Cleveland Research Institute, and Affinity Biotech, Inc. She has served as an Institutional Animal Care and Use Committee (IACUC) member and Chair.

KATHRYN HARRIS, PhD, is the Senior Outreach and Education Specialist (contractor) in the Program on Biosecurity and Biosafety Policy (PBBP) at the National Institutes of Health (NIH). Kathryn joined NIH in 2004. In her current role she develops national and regional programs of stakeholder relations, education, and outreach strategies relevant to the oversight of recombinant and synthetic nucleic acid molecule research and research that has dual use potential. In addition, she advises on biosafety and biosecurity policy issues.

She received her Ph.D. in biophysics from Cornell University and completed two years of postdoctoral training at Washington University in St Louis. Prior to joining NIH she was the Biological Safety Officer at Northwestern University. She is a registered biosafety professional was a founding member and first president of the Midwest Area Biosafety Network (MABioN).

DANIEL NELSON is Director of the Human Research Protocol Office for the National Health and Environmental Effects Research Lab (NHEERL), U.S. Environmental Protection Agency (EPA). He is also Adjunct Professor of Social Medicine and Pediatrics, and Faculty Associate in the Center for Bioethics at the University of North Carolina-Chapel Hill. Trained in medical physiology, Nelson previously held faculty appointments at the Mayo Clinic, the University of Rochester and UNC-Chapel Hill, where he directed the Institutional Review Boards for 16 years. A national leader in the field of human research protections, Nelson has served as past-president of the Applied Research Ethics National Association (ARENA); charter member of the Council for Accreditation and Site Visitor, Association for the Accreditation of Human Research Protection Programs (AAHRPP); charter member of the Council for Certification of IRB Professionals (CCIP); and consultant to the federal Office for Human Research Protections (OHRP). From 2004-2014, he chaired a subcommittee of the Secretary's Advisory Committee on Human Research Protections (SACHRP), which advises DHHS on the regulations that govern this area. In 2013 Nelson was honored by Public Responsibility in Medicine and Research (PRIMR) with the ARENA Legacy Award, for leadership and contributions to the field of research ethics.

ROSS HICKEY, JD, CIP, CIPA is the Assistant Provost for Research Integrity at USM. Ross is coordinating USM's work in the New England Ocean Cluster (NEOCH). He is an attorney and a member of the Maine Bar. Ross has built a nationally recognized

research compliance office that serves not only USM, but institutions throughout the State of Maine. He is contacted on a regular basis provide technical assistance to other local institutions on regulatory compliance matters. The Research Integrity Symposium hosted by Ross attracts attendees from all over the country to learn about regulatory and ethical considerations in research.

DR TONYA R HARGETT is currently the Director of Research Compliance and Ethics within the Division of Research and Economic Development, at North Carolina Agricultural and Technical State University. Dr. Hargett's career in the biomedical research field spans more than 28 years in various capacities throughout the UNC system. Dr. Hargett's experiences include directing undergraduate research, research compliance, developing programs, and training within the laboratory animal science field. Professionally Dr. Hargett serves as a Board Director and Executive Committee Member for the North Carolina Association for Biomedical Research; serves as the University Coordinator for the Leadership Alliance, several university committees. Dr. Hargett is a member of numerous professional organizations and serves on various non-profit boards.

F CLAIRE HANKENSON, DVM, MS is a laboratory animal veterinarian and serves as the Director for Campus Animal Resources and as the Attending Veterinarian for Michigan State University, East Lansing, Michigan. She holds a faculty appointment as a Professor of Laboratory Animal Medicine in the College of Veterinary Medicine. Dr. Hankenson earned her veterinary medical degree from Purdue University and a master's degree in microbiology from the University of Washington and Fred Hutchinson Cancer Research Center, Seattle, Washington. Previously, she has worked in academic and administrative roles at the University of Pennsylvania and the University of Michigan. Hankenson has an active research program in the study of rodent refinements for genotyping, humane endpoints and surgical preparation. She is a Diplomate of the American College of Laboratory Animal Medicine (ACLAM), is Past-President and a former Board Member for ACLAM, and currently resides on the Board for Public Responsibility in Medicine & Research (PRIM&R). Hankenson is an ad-hoc Specialist for AAALAC International.

ANGELA BIRNBAUM serves as the Director of Biosafety at Tulane University, and oversees a large university-wide biosafety program research including recombinant DNA, clinical trials, and research with high risk pathogens. She has years of experience working in academic institutions, including New York Medical College, Massachusetts Institute of Technology, and Harvard University as well as contract research organizations. Angela has a proven track record of biosafety and biosecurity program implementation, team building and integration, and a strong capacity to build sustainable biosafety programs for complex research programs. She also has a strong history of productive interactions with local, state, and federal regulatory agencies. Angela is a Registered Biosafety Professional, Certified Hazardous Material Manager, Certified Biosafety Professional, and a Specialist Microbiologist in the National Registry of Certified Microbiologists. She brings 16 years of experience implementing compliance services to BSL1/ ABSL1, BSL2/ ABSL2, BSL3/ABSL3, and BSL3/ABSL3-enhanced containment facilities for animal models including mouse, rat, rabbit, pig and non-human primates.

DAVID A. BORASKY JR., MPH, CIP serves as Vice President, IRB Compliance for the WIRB-Copernicus Group (WCG). He is responsible for leading the quality and compliance activities for the WCG IRBs. Borasky has 20 years' experience in managing IRBs. He has facilitated training activities on basic research ethics and IRB operations and management for IRB staff and has provided hands-on technical assistance to IRBs throughout North America, Africa, and Asia. He has served as a consultant for the Office for Human Research Protections, the US Department of Energy, the World Health Organization, and numerous other institutions. He currently serves as co-chair of the Subpart A Subcommittee of the DHHS Secretary's Advisory Committee on Human Research Protections. Borasky is a Certified IRB Professional and a former member of the board of directors of Public Responsibility in Medicine and Research (PRIM&R).

MARLEY J THRASHER has spent the last 17 years of her career moving into higher levels of responsibility in the learning and development (L&D) field. She has unique experience leading global training programs for public (NIH), private (AIG), not-for-profit (PRIM&R) and academic (NC State) organizations and is keenly adept at applying adult learning theory relevant to different learning cultures worldwide. Since 2009, Marley has focused on L&D for the research environment, working across multiple groups to create, facilitate and direct training for researchers, research staff, federal employees and other research professionals. Currently, Marley directs education and communications for research administration at NC State University, working with administrators and faculty to ensure compliance and research integrity. She is working towards her M.Ed. in Training and Development at NC State University with an expected graduation date of December 2019.

MARCY BROWN, BS, MA, CMAR, CPIA, is an Animal Welfare, IACUC, and Regulatory Specialist with experience in both academic and industry settings. Marcy is a Certified Professional IACUC Administrator (CPIA) and Certified Manager of Animal Resources (CMAR). She serves on the board of directors of the California Biomedical Research Association (CBRA) and as an AAALAC, International ad hoc Specialist. Marcy has also devoted significant time to presenting and co-facilitating presentations, workshops, and panels at PRIM&R's Annual IACUC meetings and CBRA's annual educational workshops, as well as faculty for American Association for Laboratory Animal Science (AALAS) and Massachusetts Society for Medical Research (MSMR) meetings. Marcy has a biology background, holds a Master of Arts degree from the University of California, Berkeley and is a certified Lean Six Sigma Black Belt. She is the 2016 recipient of the PRIM&R ARENA Legacy Award, which recognizes PRIM&R members who significantly promote the ethical conduct of research through mentoring, teaching, and leadership.

WILLIAM SO, PhD is currently a Policy & Program Specialist with the Federal Bureau of Investigation's (FBI) Weapons of Mass Destruction (WMD) Directorate, Biological Countermeasures Unit. In this capacity Will provides subject matter expertise, in the field of biological sciences, for matters dealing with FBI policy, national policy, response planning, and biosecurity. He has been in this position for the past four years, after serving one year as an Intelligence Analyst, and an additional one year prior to that as a Physical Scientist in FBI's Laboratory Division.

Will received his Ph.D. in Environmental Toxicology in 2005 and a Master of Science in Ecology from The George Washington University in 1997. Dr. So's experience includes policy, strategic guidance, and concept-of-operations related to biological crimes for both the FBI and the United States Government. He assisted and then later served as the project lead providing training on the Joint Criminal and Epidemiological Investigations model to over 3000 local, State, and Federal law enforcement and public health investigators. In recognition, he received two Merit Awards from the WMD Directorate. Will's current projects include bridging the gap between researchers/academics and law enforcement/security officials in matters related to biosecurity, dual-use, and pathogen security.

ANGELICA N MARTINS, PhD, RBP, Biosafety Officer, Office of Research Compliance, Research and Economic Development, University of North Carolina at Charlotte

Dr. Martins is the Biosafety Officer at UNC Charlotte. She holds a BS degree in Microbiology and Immunology, and a PhD in Genetics. Dr. Martins then completed four years of postdoctoral training at National Cancer Institute (NCI-Frederick). Dr. Martins has 15 years of experience studying Human Immunodeficiency Virus (HIV) and co-authored 16 research papers in leading peer-reviewed journals. She is a Registered Biosafety Professional (RBP) and member of Carolina Biological Safety Association (CaBSA).

FRIDAY, MARCH 16, 2018

COLLEEN BENNETT, MS, is Assistant Director of the Oversight & Outreach Office at Wake Forest School of Medicine. In this role, she works closely with the IACUC and Assistant Dean for Regulatory Affairs to develop, implement and recommend strategies to ensure that the animal research performed at WF meets the highest standards of animal welfare. This includes responsibilities for- training researchers in their regulatory responsibilities, quality assurance, the Post Approval Monitoring (PAM) program, and the oversight and investigation of non-compliant activities and adverse events. In addition, she is very involved in the WF Clinical and Translational Science Institute Community Engagement Program to promote biomedical science and biomedical career opportunities to k-12 teachers and students. She received her B.S. from Wilson College, Chambersburg PA and her M.S. Degree in Biology at Wake Forest University. She worked as a Laboratory Technician, Research Assistant, and Research Associate in the Dept. of Physiology and Pharmacology conducting research in the areas of hypertension and aging. In 2007, she left the laboratory for the position of Research Oversight Specialist for Animal Research. Over the past 10 years, she has developed a robust, collegial compliance program with a strong training component. Her approach to compliance is team oriented; with administrative, research, and veterinary staffs working together to produce an environment in which animal research is conducted with the highest regard for the welfare of the animals.

DORCAS P O'ROURKE, DVM MS, DACLAM is Professor and Chair of the Department of Comparative Medicine at the Brody School of Medicine, East Carolina University. She is a board certified laboratory animal veterinarian who serves as Attending Veterinarian for the East Carolina University animal care and use program. Dr. O'Rourke earned her veterinary and masters degrees at the Louisiana State University School of Veterinary Medicine, and was an LSU faculty member for four years. She spent 13 years at the University of Tennessee in Knoxville, first overseeing the College of Veterinary Medicine animal care facility, then as Attending Veterinarian for the entire campus. During that time, Dr. O'Rourke also served as consultant veterinarian for the Oak Ridge National Laboratories animal care and use program. Dr. O'Rourke has published in the laboratory animal medicine scientific literature, has presented talks nationally and internationally, and has served for over 16 years as a member and emeritus member of the AAALAC, International Council on Accreditation.

TERRENCE L. BOOS, PhD, SECTION CHIEF, DRUG & CHEMICAL EVALUATION SECTION, DIVERSION CONTROL DIVISION DRUG ENFORCEMENT ADMINISTRATION: Dr. Boos is the Section Chief of the Drug & Chemical Evaluation Section, Office of Diversion Control, Drug Enforcement Administration (DEA, U.S. Department of Justice). He joined the DEA in 2007 and has been in his current position since October 2012. The group initiates domestic control of drugs of abuse and provides support international drug and precursor control. Additionally, the group provides scientific support to federal, state, and local public health, law enforcement, and prosecutors related to drugs of abuse. Prior to joining DEA, Dr. Boos was a researcher at the National Institute on Drug Abuse.

SONIA HUNT

FBI, WMD

JEFF M. SEO, JD, LL.M joined Northeastern University in 2016 as its first Asst. Vice-Provost for Research Compliance where he is responsible for developing and managing the University's research compliance programs. Including compliance in areas such as grants management, export controls, financial conflicts of interest and research misconduct, among others. In doing so he is focused on the establishment and growth of the core elements of an effective compliance program as outlined in the Federal Sentencing Guidelines with an emphasis on outreach and education as well as the implementation of effective lines of communication. Prior to Northeastern, Jeff served in a similar capacity at Harvard Medical School for eight years as the Executive Director for the Office of Academic and Research Integrity. Jeff also serves as the Program Chair for the Research Administration Certification Program at Emmanuel College. His prior experience includes serving in the Office of General Counsel at Beth Israel Deaconess Medical Center and as a practicing attorney at boutique health law firm. Jeff received his Bachelor of Arts degree from the University of Rochester, a law degree from the New England School of Law and a Masters of Law degree from Loyola University Chicago.

DEB FROLICHER, BS, CPIA earned her Bachelor of Science degree in Agriculture/Animal Science and Nutrition at The Ohio State University, Columbus, OH and after graduation began working in biomedical research as a laboratory technician. In her 15 plus years in biomedical research she has worked with various animal models and a variety of species, including snakes, lizards, rodents, ducks, dogs, pigs, goats, cattle, and a colony of diabetic monkeys. She began her IACUC administrative career in the mid 90's. Deb's experience in the laboratory enables her to effectively interface with investigators and research staff to integrate IACUC review and oversight into their research programs. Currently, she is the director of the IACUC office at The Scripps Research Institute in La Jolla, CA. Deb earned CPIA certification in 2008 and served on the CPIA Council from 2010 through 2016, the last two years as Council Chair. She is a member of PRIM&R, SCAW, AALAS, and LAWTE.

WILLIAM STOKES, DVM, DACLAM, DACAW, BCES, FATS

ASSISTANT DIRECTOR, ANIMAL WELFARE OPERATIONS, USDA, APHIS, ANIMAL CARE

DANIEL VICK has spent his career guiding organizations through the complex web of export control regulations to help them thrive in a global environment. Daniel is currently the Director of the Office of Export Controls and Empowered Official for Duke University. In this role he is responsible for export compliance measures for the University and assists members of the Duke community with export and import transactions by identifying applicable regulations and collaborating on strategies for compliance. Prior to joining Duke, Daniel worked in both industry and academia in global trade related functions, from logistics to finance to compliance.

DEBORAH L. DUFFICY, DVM, MPH, DACVPM, Senior Staff Officer, Organisms and Vectors, Agriculture Select Agent Services (AgSAS), National Import Export Services, USDA, APHIS, Veterinary Services, obtained her Doctor of Veterinary Medicine degree from Colorado State University, and her Masters in Public Health from the University of Arizona. She is a diplomate of the American College of Veterinary Preventive Medicine. After two years in CDC's epidemic intelligence service, Deb moved to USDA as the Veterinary Services area epidemiologist for Wyoming for 5 years and then joined USDA Veterinary Services National Import Export Services staff in Organisms and Vectors permitting 3 years ago. Dr. Dufficy and her Organisms and Vectors colleagues, Dr. Abu Sayed and Dr. Troy Bigelow have been tasked with refocusing the scope of Organisms and Vectors permitting, defining and refining protocols, and producing educational materials for stakeholders.

WESLEY R JOHNSON, PhD, is a microbiologist with the Bureau of Industry and Security (BIS) at the U.S. Department of Commerce. He holds a BS and PhD in marine science and has an extensive background in microbial ecology, molecular microbiology, and pathogenomics. He has served for five years as a licensing officer and technical subject matter expert for the Chemical and Biological Controls Division of BIS, which implements the Export Administration Regulations for export of dual-use biological and chemical commodities and technologies. Dr. Johnson also serves as the biological technical expert for the Department of Commerce for the Australia Group multilateral export control regime, with a primary focus on synthetic biology and emerging biotechnologies.

KELÉ PIPER, MS, CIP, CHRC is a leading expert in research compliance with over 20 years of experience. In Kelé's current role at Beth Israel Deaconess Medical Center, a Harvard affiliate hospital, she serves as Director of Research Compliance. In this role, her primary responsibilities are to manage and oversee the research compliance program which includes bench, animal, and human subjects research. Current initiatives include controlled substances, lab safety, international research, research privacy, ClinicalTrials.gov. In recent years, she has spoken at conferences for organizations such as HCCA, PRIM&R, MSMR, MaHIMA, and the AAMC on topics to include controlled substances, ClinicalTrials.gov, risk-based monitoring, and research documentation in the electronic medical record. In her previous role, she led an initiative to create a process to assess institutional risk as it related to research as well as review and monitor QI ultimately reducing the burden on the local IRB. Additionally, Kelé works with a research team in the area of thyroid cancer and has been published in several scientific journals for her research work over the last 7 years.

PATRICIA CONDON is the Research Data Services Librarian at the University of New Hampshire. In this role, Patti collaborates with units across campus to develop services that accommodate the growing data management needs of the UNH research community. She has twenty years of experience researching, teaching, and working in the information fields. Patti earned her PhD in Library and Information Science from Simmons College, and her MLIS and MA in Anthropology from the University of Southern Mississippi. Her doctoral dissertation, *Digital Curation through the Lens of Disciplinarity: The Development of an Emerging Field*, was highlighted by American Libraries Magazine.

ELIZABETH KIPP CAMPBELL, PhD, CIP began her career as a researcher, obtaining her Master's and Doctoral degrees from the Pennsylvania State University where her research focus was on stress, illness and immune functioning in children. While an NIH post-doctoral fellow at the University of Minnesota, she became interested in the ethics of human research and was recruited to serve on the Institutional Review Board (IRB) there. She left academia to pursue a career full-time in this area, serving as the Director of the IRB at Children's Hospitals and Clinics of Minnesota and also volunteering as an Assistant Chair/Chair of a Biomedical panel on the University of Minnesota's IRB for 14 years. In 2010 she was recruited by Purdue University and served as their first Director of the Human Research Protection Program. Elizabeth left Purdue in 2015 to become the Director of the Office of Human Research Ethics at the University of North Carolina at Chapel Hill. She also serves on the Council for Certification of IRB Professionals.

TED MYATT, ScD, RBP, Practice Director – Life Sciences, Environmental Health and Engineering, Inc. has extensive experience in the fields of biosafety, environmental health and safety (EH&S), research compliance, epidemiology, building mechanical systems, and exposure assessment. Prior to rejoining EH&E, Ted served as the Director of Research Integrity at the University of Rhode Island, overseeing all aspects of research compliance, including human subject research (i.e., Institutional Review Board), animal welfare (i.e., Institutional Animal Care and Use Committee), biosafety (i.e., Institutional Biosafety Committee), laboratory and chemical safety committee, export control compliance, conflict of interest, research misconduct, and responsible conduct of research (RCR) training. He has also served as the Director of the Partners HealthCare Institutional

Biosafety Committee and the Biological Safety Officer at Brigham and Women's Hospital. He received a Bachelor's of Science in microbiology at the University of Illinois, a Master's of Environmental Management at Duke University, and a Doctorate of Science at the Harvard School of Public Health.

DANIEL EISENMAN, PhD, RBP, SM(NRCM), CBSP is Director of Biosafety Services for Advarra where he leads a commercial IBC service focusing on review of human gene transfer studies as well as providing biosafety training and consulting services. Prior to joining Schulman IRB, Dr. Eisenman served as Biosafety Officer at UNC Chapel Hill and the Medical University of South Carolina.

CHRISTINA NASCIMENTO, MS, CPIA, is the IACUC Manager at Brigham & Women's Hospital in Boston, Massachusetts. Christina earned her Bachelor's Degree in Pre-Veterinary Science and Biology at the University of Massachusetts, Amherst, Master's degree at UMASS Amherst concentrating in Molecular Genetics, and holds a CPIA certification from PRIM&R. As IACUC Manager, Christina oversees IACUC Office operations, while also implementing an eIACUC system and was part of the team opening a new state-of-the-art animal facility and establishing an entire animal care and use program for the institution. Christina served on the Harvard Medical Area/School IACUC for over 10 years, and is currently serving on the Brigham & Women's Hospital IACUC. After acting as the IACUC Inspection Officer at Harvard Medical School, Christina has over a decade of experience in IACUC policy and animal welfare, as well as managing a vast inspection and Post Approval Monitoring Program for dozens of animal facilities and satellites and hundreds of laboratory use areas. From her years as both an investigator and a veterinary technician, Christina has experience with a variety of species such as rodents, agricultural animals, aquatic species, cats, dogs, horses, and non-human primates. Outside of the office, Christina enjoys training young horses and is a licensed horseback riding instructor.

LYNELL DUPEPE, BS, CMAR, RLATG is the Associate Director of the Tulane University Department of Comparative Medicine in New Orleans, Louisiana. She has both CMAR and RLATG certifications as well as a Bachelor of Science degree in Animal Science. Lynell has been employed at Tulane University for 28 years and has a total of 35 years' experience in the field of Laboratory Animal Management. Lynell is responsible for the management of two animal facilities totaling 33,000 sq. ft., a member of the Tulane University HSC Emergency Management Team and is responsible for the implementation and continual revision of the Department of Comparative Medicine's Crisis and Emergency Response Plan. Lynell has given numerous talks on Emergency Preparedness in response to the Lessons Learned during Hurricane Katrina.

CECE BROTCHE-FINE, BS, MA, CPIA is now in her second decade of work in the pre-clinical research field, CeCe Brotchie-Fine has held diverse roles from husbandry through administration. She began her research journey working in the nutrition laboratory of the Smithsonian's National Zoological Park assisting with research on the metabolism of the Mojave Desert Tortoise (*Gopherus agassizii*). She first became involved with IACUCs during a position with a start-up biotech company. Her current role is Associate Director, Global Animal Welfare Compliance Due Diligence at Novartis Institutes for BioMedical Research in Cambridge, MA, where she is also the IACUC Chair. She has received a B.S. in Animal Science from the University of Massachusetts and M.A. in Psychology from Lesley University, and is currently enrolled in the M.S. in Bioethics program at Columbia University. CeCe is also a Certified Professional IACUC Administrator. For 7 years, she was the course facilitator for MSMR's On-Line Training Program for IACUC Members, and enjoys mentoring those new to the field.