



RAPID RESPONSE BY LABORATORY ANIMAL RESEARCH INSTITUTIONS DURING THE COVID-19 PANDEMIC: LESSONS LEARNED

► MARCH 9-10, 2021

A Virtual Workshop

Barney S. Graham, M.D., Ph.D.

Dr. Graham is Deputy Director of the NIAID Vaccine Research Center. He has a BA from Rice University, an MD from the University of Kansas School of Medicine, and a PhD in Microbiology & Immunology from Vanderbilt University School of Medicine where he also completed Internal Medicine residency, chief residencies, and a fellowship in Infectious Diseases. His primary interests are vaccine development for viral diseases, viral pathogenesis, mechanisms of immunity, and pandemic preparedness. He directs basic laboratory research, contributes to the pipeline of new VRC vaccines, and provides oversight of candidate VRC vaccines and antibodies in advanced development including those for HIV, Ebola, and Chikungunya. His laboratory explores the structural basis for antibody-mediated viral neutralization, investigates basic mechanisms by which T cells affect viral clearance and immunopathology, and has developed novel vaccines for RSV, influenza, Zika, and coronaviruses including the first COVID-19 vaccine and monoclonal antibody to enter clinical testing and that have now achieved Emergency Use Authorization.

Paul Duprex, Ph.D.

Paul Duprex is the Director of the Center for Vaccine Research (CVR), Professor of Microbiology and Molecular Genetics and Jonas Salk Endowed Chair for Vaccine Research at the University of Pittsburgh. He is a molecular virologist with nearly twenty five years' experience. His postgraduate training at the Pirbright Institute, Woking, England, UK focused on foot and mouth disease and he was awarded his PhD in 1994 from The Queen's University of Belfast, Northern Ireland, UK where he was a Lecturer/Senior Lecturer in Molecular Virology from 1999 until 2010.

During this time he worked for Johnson and Johnson (J&J) as Head of the Department of Emerging Sciences and Technologies at TransForm Pharmaceuticals, Lexington, MA. In 2010 he became an Associate, and then full Professor of Microbiology at Boston University (BU). As Director of Bioimaging at the BU NEIDL Institute he expanded his work on emerging infectious diseases. These interests continue at the BSL3+ Regional Biocontainment Laboratory in Pittsburgh, where he is the Director.

He works on human and animal respiratory viruses such as measles, mumps and SARS-CoV-2. His research focuses on understanding the molecular basis of viral pathogenesis and vaccine attenuation, with a view to developing rationally attenuated vaccines and novel therapeutic interventions. Developing strategies to increase the thermostability and optimize the delivery of live-attenuated vaccines are key elements in his research program. He is interested in barriers that restrict cross species transmission events, pandemic preparedness and understanding the evolutionary trajectories of viruses with a view to prediction.

Dr. Duprex is Editor-in-Chief of the Journal of General Virology and a Senior Editor of mSphere. He is a longstanding member of the American Society for Virology and The Microbiology Society. He is a Fellow of the American Academy of Microbiology.

Ian N. Moore, D.V.M., Ph.D., DACVP

Dr. Ian Moore is an Investigative Veterinary Pathologist and Section Chief for the Infectious Disease Pathogenesis Section (IDPS); the IDPS serves as a central research pathology core laboratory within the National Institutes of Health's (NIH) National Institute of Allergy and Infectious Diseases (NIAID). Dr. Moore's research, collaborations and publications span a broad range of infectious and allergic disease conditions including Influenza, Malaria, Zika, Tuberculosis, Human Norovirus, Coronaviruses, Eczema, and food allergies, to name a few.

Dr. Moore's doctoral research training was focused on the immunology and pathogenesis of different influenza virus subtypes in animal models. With this, he blends the knowledge of natural and experimental diseases of various veterinary species with his expertise as a veterinary pathologist with the collaborative expertise of NIH researchers in efforts to bridge the gaps in these correlated disease conditions in humans.

Franziska Grieder, D.V.M., Ph.D.

Dr. Franziska Grieder is the Director of the Office of Research Infrastructure Programs (ORIP), a program within the Office of the Director, the National Institutes of Health (NIH). She was appointed as ORIP Director in January 2013 after serving as the Division Director of Comparative Medicine programs since 2004. ORIP supports NIH extramural research infrastructure and related research programs, including supervision and management of the seven national primate research centers, primate breeding and resource-related projects, development of mammalian (including rodent) and non-mammalian animal model resources, pre- and post-doctoral training for veterinary scientists, other research projects, and the shared and high-end instrumentation program.

Dr. Grieder attended Veterinary School at the University of Zurich in Switzerland and subsequently earned both a MS and PhD degree in viral pathogenesis from the University of Wisconsin-Madison. She was a faculty member in the School of Medicine of the Uniformed Services University (USU) in Bethesda, Maryland, where – after her transition to NIH – she continues to serve as an Adjunct faculty member in the Department of Pathology. At USU, Dr. Grieder's research focused on viral pathogenesis using mouse models to investigate neuroimmune mechanisms.

Kurt Derfler, M.B.A.

Kurt Derfler is the Executive Director of Primate Operations for Charles River Labs. Prior to this role, he led Animal Operations for both Envigo Global Services and Covance Research Products. He received his MBA in Pharmaceutical Marketing and Management from Saint Joseph's University in 2014. He also served on the Board of Directors for the Pennsylvania Society for Biomedical Research from 2011-2016.

Stephen Festin, Ph.D.

Currently Director of Scientific and Commercial Development for Charles River Laboratories with responsibility for strategic identification, development and adoption of novel research models and life science technologies across the global Charles River Research Model and Services businesses. He has worked for Charles River since June of 2015. He has scientific expertise in Biochemistry, Molecular Biology and Genetics with experience in oncology basic research and commercial laboratory operations.

After a successful academic career as an experienced professional working at the science-business interface Steve has held scientific management positions including Vice President of Research, Operations Site Management (P&L), Laboratory Director and Director of Biomedical Research. He has identified, developed and commercialized several novel Life Science technologies including CRISPR-based technologies to scientific community over the last 16 years. Qualified and validated multiple platform technologies as in vivo platforms and lab services for regulatory compliant (GLP and GMP)

laboratories. Strategically developed and negotiated License, Access and Commercialization (LAC) in business across multiple research disease-focused divisions. Leveraged Lean, Six Sigma and Agile operations productivity and quality process improvement initiatives to establish, manage and restructure several molecular, in vivo, laboratories. Provided oversight of ongoing research projects and strategic business directions in the development of novel kinase/signaling pathway targets currently in Phase I trial for the treatment of pulmonary disease. In both his own laboratory and for commercial providers he has mentored dozens of graduate students, undergraduate students, employees to successful science careers

Steve earned a Bachelor of Science degree in Chemistry at Villanova University and completed PhD studies in Biochemistry and Molecular Biology at Albany Medical College, completed a post-doctoral fellowship at the National Cancer Institute and Assistant Professorship in Biology/Biochemistry at Hamilton College. Dr. Festin has published multiple scientific articles, given lectures and presentations in cancer research, peptide/protein chemistry, molecular diagnostics, genomics, bioinformatics and laboratory management. He managed corporate R&D, US and EU laboratory operations, business development, strategic planning and education initiatives. He leads subcommittees of scientific societies including The Endocrine Society and The American Association for Cancer Research and a number of regional scientific and business interest groups. Steve is also a proud member of the National Ski Patrol and US Rowing organizations.

Gale Galland, D.V.M., M.S., DACVPM

Gale graduated from the University of Georgia, College of Veterinary Medicine in 1986 and after 5 years in private practice and research, she joined the United States Public Health Service (USPHS), working for the Centers for Disease Control and Prevention. During her 21 years as a commissioned officer, she worked in a variety of positions including staff veterinarian for the Division of Parasitic Diseases and attending veterinarian and then branch chief for the Laboratory Animal Medicine Branch. In 2004, Gale moved to the Division of Global Migration and Quarantine (DGMQ) Zoonoses Team (ZT), utilizing her expertise with nonhuman primates, overseeing their importation for science, education, or exhibition. She was the DGMQ ZT Lead for 6 ½ years. Gale retired from USPHS in January 2013 and currently works part time with DGMQ focusing on the importation of nonhuman primates and part time as a clinical veterinarian in private practice.

Maureen Thompson, BSN, RN, COHN, RBP(ABSA)

Maureen Thompson is an Associate Director of Environmental Health and Safety Office for Emory University and the Safety Officer for the Yerkes National Primate Research Center. Maureen joined the Emory University EHSO team in September 1998.

Maureen has been responsible for the Environmental Health and Safety Program at the Yerkes National Primate Research Center where she provides guidance and oversight for regulatory compliance, environmental health and safety programs and training, safety inspections, risk assessments, and investigations related to employee injuries and exposures. Maureen is a member of the Emory University Institutional Biosafety and Research Safety Committees and represents the EHSO on the Institutional Animal Care and Use Committee.

Maureen received her Bachelor's degree in Nursing from Widener University in Pennsylvania. She is a Registered Nurse, Certified Occupational Health Nurse and a Registered Biosafety Professional with ABSA International.

For more than 35 years, Maureen has worked in the field of occupational health and safety where she has been instrumental in developing and implementing policies and procedures to support a safe and healthy work place.

Molly S. Sitt-Fischer, Ph.D., CPH, CBSP, SM(NRCM)

Molly is the University Biosafety Officer (BSO) and Alternate Responsible Official for Select Agents in the University of Pittsburgh Department of Environmental Health and Safety (December 2010-present). As BSO, she leads a lab safety team to support research safety programs for a large biomedical research with active high containment facilities, Select Agent research, and a Regional Biocontainment Laboratory. She received her BS in Molecular Biology from Allegheny College, her SM in Molecular Toxicology from the Massachusetts Institute of Technology, and her PhD in Environmental and Occupational Health from the University of Pittsburgh. Molly is a member of the charter class of public health professionals Certified in Public Health (CPH) by the National Board of Public Health Examiners, and completed a fellowship with the National Biosafety and Biocontainment Training program in 2010. She is a Certified Biological Safety Professional with ABSA International, as well as a Specialist Microbiologist in Biological Safety with the American Society for Microbiologists National Registry of Certified Microbiologists. As a member of ABSA since 2007, Molly served on the DIY Bio task force, and is a current member of the BSAT Community Advocate Committee. She enjoys contributing summaries to the LAI Database and sharing lessons learned with colleagues via publications and presentations.

Rebecca Lingenfelter, MSPH

Rebecca is the Associate Biosafety Officer and Alternate Responsible Official for Select Agents in the University of Pittsburgh Department of Environmental Health and Safety. As part of the lab safety team she provides expert biosafety support for research programs for a large biomedical research institution, and is the team's lead support for animal care and research programs. Ms. Lingenfelter received her MSPH from the Department of Environmental and Occupational Health at the Texas A&M Health Science Center School of Rural Public Health. She then completed a two-year fellowship with the National Biosafety and Biocontainment Training Program (NBBTP) in 2010. Prior to joining the University of Pittsburgh's EH&S department she serves as the Biosafety Officer at the Jackson Laboratory from 2010-2015.

James O'Reilly, B.A.

James O'Reilly is the president of the Massachusetts Society for Medical Research (MSMR), which was founded in 1953, making it the oldest non-profit organization in the country serving the biomedical research industry. MSMR's members include research hospitals, institutes, colleges and universities, biotechnology and pharmaceutical firms, professional associations and vendors from throughout New England and New York.

As president, Mr. O'Reilly heads MSMR's day-to-day operations, engaging with its members; tracking public policy and working to educate policymakers (legislators and regulators) on issues of importance to the medical research community; working with its Board of Directors; directing its annual awards and recognition programs; recruiting and developing new members; collaborating with allied organizations; writing and distributing member communications; and overseeing finances and administration.

Jim has more than 20 years of experience in non-profit association management, with a particular focus on government affairs and member advocacy. Prior to joining MSMR in June 2017 he spent nearly 15 years at Northeast Energy Efficiency Partnerships (NEEP) in Lexington, where he directed public policy, outreach and communications across an 11-state region of the country.

He also has experience with technology and trade groups, as well as a background in government service. He began his career as a newspaper reporter and editor after graduating from the College of the Holy Cross in Worcester, Mass. with a bachelor of arts in political science.

Eneida Hatcher, Ph.D.

Eneida Hatcher received her B.S. degree in Biology at Salisbury University, and her PhD in Microbiology from the University of Alabama at Birmingham in 2014. While at UAB in Elliot Lefkowitz's lab, Eneida studied poxvirus gene content and genomic evolution in an environment that encouraged internal and external collaboration. She continued her training as a postdoctoral fellow in the Lefkowitz lab researching horizontal gene transfer in poxviruses. Eneida joined Computercraft as a contractor for NCBI in 2015. In this position, she began work with the NCBI Virus group doing genomic data analyses, improving viral sequence data usability, and helping develop the annotation tool VADR. Eneida currently serves as the Product Owner for NCBI Virus, focusing on increasing the value of viral sequence data to better support research needs of the scientific community.

Koen Van Rompay, D.V.M., Ph.D.

Dr. Koen Van Rompay received his veterinary degree in 1989 from the University of Ghent in Belgium. A few months later he moved to the University of California, where he started research at the California National Primate Research Center and received a PhD in Comparative Pathology in 1994. He continued his career at that same institution, where he is currently a Full Research Virologist and Scientific Director of the Pathogen Detection Laboratory.

Koen's research has focused especially on using the simian immunodeficiency virus (SIV) –macaque model of HIV infection to study disease pathogenesis and to test novel intervention strategies, particularly drugs and vaccines. He has performed many studies in the infant macaque model of pediatric HIV infection. His preclinical research contributed to the development of tenofovir-based intervention strategies that are now commonly used to prevent or treat HIV infection. More recently, he has been involved in research in other nonhuman primate models of infectious diseases, including Zika virus, Chikungunya virus and SARS-CoV-2.

Isis Kanevsky, Ph.D.

Isis is an immunologist with > 20 years of experience in basic research and animal models of infectious disease. Isis received her Bachelors and Master's degrees in Animal and Biological Sciences from the University of Vermont. She continued her education and obtained a PhD in Veterinary Science and Immunology from Penn State University. To date, all her research experience was in large animal models (bovine and porcine), so for her post -doc she switched focus to small animal (rodent) models and study of human immunology / infectious disease at the Trudeau Institute in Saranac Lake, NY. After 3 years, Isis accepted a tenure track position at Virginia Tech in the department of Dairy Science where she received tenure in 2012. At Virginia Tech, her lab focused on investigation of host-pathogen interactions using in-vitro and in-vivo cell-culture and large and small animal models. Isis has contributed >25 peer reviewed publications and maintained a research program through securing funding (\$1,000,000+) from government and industry sources. Isis was awarded The 2012 Presidential Early Career Award in Science and Technology (PECASE) – highest honor bestowed by the U.S. government on outstanding scientists and engineers in the early stages of their independent careers. After 10 years as a professor, in 2016, Isis moved 'home' to NYC and accepted position as Principal Scientist in Bacterial Vaccines at Pfizer. At Pfizer, Isis is Director of the In Vivo immunopathology team supporting development of bacterial and viral vaccine, and anti-viral therapeutics through pre-clinical research.

Joyce Cohen, V.M.D., DACLAM

Joyce Cohen is the associate director of the Division of Animal Resources at the Yerkes National Primate Research Center. She is also an associate professor in Emory University School of Medicine's Division of Psychiatry and Behavioral Sciences and a diplomate of the American College of Laboratory Animal Medicine (DACLAM). Dr. Cohen joined the Yerkes Research Center in 2006 with responsibility for clinical medicine, colony management, residency training, research support, and

administration at the Yerkes Field Station. She was promoted to lead veterinarian at the field station in 2009 and appointed as assistant director of animal resources at the main center in early 2012. In her current role as associate director, she oversees the Division of Animal Resources, which includes Animal Care, Animal Records, Behavioral Management, Colony Management, Occupational Health and Safety, Research Resources and Veterinary Medicine. She received her veterinary medical degree from The University of Pennsylvania and her postdoctoral training in laboratory animal medicine at the Tri Institutional Program at Memorial Sloan Kettering Cancer Center, Weill Medical College, and Rockefeller University.

Michael J. Huerkamp, D.V.M., DACLAM

Michael Huerkamp is currently the executive director of the Division of Animal Resources at Emory University where he holds the academic rank of professor in the Department of Pathology and Laboratory Medicine. As director of the animal resources program, Dr. Huerkamp is the attending veterinarian at Emory and oversees animal husbandry and veterinary services programs delivered by a staff of 110 for a census of over 75,000 research mammals located in 9 buildings comprising 155,000 gross square feet of space. He is responsible for the health, safety, and research productivity of over 1,800 persons with animal research facility access. Dr. Huerkamp is a veterinarian and Diplomate of the American College of Laboratory Animal Medicine. He received his DVM from The Ohio State University College of Veterinary Medicine in 1984 and completed postdoctoral training in laboratory animal medicine at the University of Michigan in 1987.

CDR Temeri Wilder-Kofie, D.V.M., MPH, DACLAM

Dr. Temeri Wilder is a Facility Veterinarian at the National Institutes of Health in Bethesda, MD. She is a graduate of the Tuskegee University School of Veterinary Medicine (c/o 2006). Upon graduation, she worked as a Supervisory Veterinary Medical Officer with United States Department of Agriculture Food Safety Inspection Service for 2 years.

In 2008, she was commissioned into the United States Public Health Service as a Lieutenant (LT) and was the first resident accepted into the newly-established Centers for Disease Control and Prevention Laboratory Animal Medicine Residency Program (LAMRP). At the completion of the CDC LAMRP, Dr. Wilder became specialty board certified by the American College of Laboratory Animal Medicine in 2011 and joined the National Institutes of Health, National Institute of Allergy and Infectious Diseases Comparative Medicine Branch team in 2012.

Dr. Wilder is also a member of the Applied Public Health Team (APHT-3) which is a part of the National Response Plan's Emergency Support Function (ESF) #8. She participates in humanitarian missions as needed, as well as public health crises such as the Ebola Response Mission in Monrovia, Liberia and the current coronavirus pandemic. As a member of several professional organizations, Dr. Wilder is a strong advocate of student and animal facility staff mentorship, professional development and educating the community about laboratory animal medicine and how it is critical to the advancement of public health.

Jill Ascher, M.A., D.V.M., MPH, DACLAM

Jill Ascher is the director of the Division of Veterinary Resources at the National Institutes of Health (NIH). Dr. Ascher has over 25 years of experience in veterinary medicine including five years of experience at the Food and Drug Administration's (FDA's) Center for Biologics Evaluation and Research (CBER), where she most recently served as the deputy director of the Division of Veterinary Services. During her time at the FDA, Jill significantly increased social-housing of all social species in the animal facility and expanded training programs for veterinary staff and researchers who work with research animals in the facility. Her diverse career in veterinary medicine also includes over 15 years of experience in private practice in the U.S. and internationally and experience in industry, academia, and government. She holds licenses to practice in both the U.S. and the U.K. Some of her key career achievements include being a team leader in coordinating and carrying out the relocation of the FDA/CBER Laboratory Animal Program from the NIH Bethesda, Maryland campus to the FDA White Oak

campus in Silver Spring, Maryland. In addition, Dr. Ascher served as a lead veterinarian in setting up and managing the FDA Biosafety Level 3 animal research corridor including the Highly Pathogenic Avian Influenza Select Agent Research Laboratory. She organized and managed other special projects at FDA such as gnotobiotic mouse and humanized mouse programs, among others. Dr. Ascher was named by the FDA Office of the Director to serve on a special internal assessment team with the purpose of ensuring adoption of best practices in animal research colony management throughout the 7 FDA centers. Dr. Ascher earned her BS in microbiology from Cornell University, her MA in microbiology from Boston University School of Medicine and her DVM from Tufts University. She then completed a residency in laboratory animal medicine at the University of Rochester Medical Center while concurrently earning a MPH.

Lori Palley, D.V.M., DACLAM

Dr. Lori Palley has served as the Assistant Director of Veterinary Services in the Center for Comparative Medicine (CCM) at Massachusetts General Hospital (MGH) since 2012. She oversees a centralized group of veterinarians, veterinary technicians and program managers who provide clinical support, consultation and services for over 100,000 research animals housed in nine facilities comprising over 90,000 square feet. She is a voting member of the MGH IACUC and the Partners Institutional Biosafety Committee (PIBC).

Lori received her Doctor of Veterinary Medicine degree from Tufts University in 1987. After receiving her DVM, she completed a fourteen-month internship in small animal medicine and surgery at the Angell Memorial Animal Hospital. She completed postdoctoral training in laboratory animal medicine in the Division of Comparative Medicine (DCM) at the Massachusetts Institute of Technology (MIT) and became board certified by the American College of Laboratory Animal Medicine in 1995. Lori's background and work experience is varied and includes roles as a research scientist at MIT, research scientist / veterinarian in toxicology at Eli Lilly and Company and Astra Zeneca, as well as non-veterinary roles in customer support at Biogen and Boston Scientific.

Lucy Kennedy, D.V.M., DACLAM

Dr. Kennedy is the Assistant Director for Clinical Services and Assistant Attending Veterinarian University of Michigan's Unit for Laboratory Animal Medicine. She also currently oversees the Unit for Laboratory Animal Medicine's germ-free mouse facility. During her training, she worked in immunology labs studying the pathogenesis of *Helicobacter pylori* and mouse models of sepsis. As a clinical veterinarian, she collaborated on projects evaluating the effects of whole body radiation with ions that are found in space.

Now, as the managing director of the germ free mouse facility, Dr. Kennedy works with a core that produces over a thousand germ-free mice annually for use in studies investigating the role of the microbiome. This service has been a core component for over 300 experiments run by several U-M researchers from multiple fields of study.

Sean Maguire, V.M.D., M.S., MRCVS, DACLAM

Sean Maguire, VMD, MS, MRCVS, DACLAM is a Comparative & Translational Sciences Director & Associate Fellow at GlaxoSmithKline in Collegeville, Pennsylvania. Dr. Maguire received his veterinary degree from the University of Pennsylvania and earned his master's degree in chemistry from Lehigh University Bethlehem Pennsylvania. Dr. Maguire has extensive experience with animal care and use programs and in vivo animal models in drug discovery and development with a current focus on infectious diseases and primates. He is board certified in laboratory animal medicine and currently serves as an ad hoc Specialist for AAALAC.

Stephen Denny, D.V.M., M.S., DACLAM, DACVPM

Dr. Stephen Denny currently serves as the Director of the Office of Animal Care and Use, NIH. He received his Doctor of Veterinary Medicine degree from the University of Missouri prior to starting a 26 year career in the US Army Veterinary Corps which culminated in his service as the US Army Surgeon General's Consultant for Laboratory Animal Medicine. He is a Past President of the American Society of Laboratory Animal Practitioners and diplomate in the American College of Veterinary Preventive Medicine and the American College of Laboratory Animal Medicine. He holds a Master of Science degree in Laboratory Sciences from the University of Missouri and a Master of Strategic Studies degree from the US Army War College.