

**NATIONAL INSTITUTES OF HEALTH**  
NIH Workshop on Ensuring the Continued Responsible Oversight of  
Research with Non-Human Primates

December 28, 2016

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## Overall Summary

On September 7<sup>th</sup> 2016, the National Institutes of Health (NIH) held a workshop titled “Ensuring the Continued Responsible Oversight of Research with Non-Human Primates” with leading experts in science, ethics, policy and animal welfare. This workshop was convened in response to congressional interest and aligned with the agency’s continued interest in ensuring the NIH continues to have robust policies and practices for supporting both cutting edge science and the highest ethical standards of animal care and use. At the workshop, NIH leadership received broad input from researchers, bioethicists, veterinarians and policymakers from both inside and outside the NIH representing a wide array of professionals knowledgeable in the care and use of non-human primates.

The workshop explored the state of NIH-supported biomedical and behavioral research involving non-human primates, and provided an overview of the current oversight framework governing the conduct of this research and the associated ethical underpinnings. Discussions were carried out to better understand how non-human primates uniquely contribute to the biomedical research enterprise and how ethical and welfare concerns associated with their use are addressed by relevant policies and practices.

There are many scientific and ethical considerations surrounding research with non-human primates; the NIH takes our stewardship responsibilities for these animals very seriously. Although numerous policies and procedures reflecting the ethical principles of scientific rigor, appropriateness of the model, and the primacy of animal welfare are already in place, the NIH recognizes that research with non-human primates deserves an ongoing reflection and discourse. The intention of this workshop was to hear from and engage broad communities in a constructive conversation on the ethical use of these valuable resources. The document below reflects the thoughtful and productive discussions that occurred at the workshop.

## Established Framework Overseeing the Health and Welfare of Animals

Upholding the highest standards of animal welfare and funding the best science go hand-in-hand. This includes ensuring that an animal model is appropriate to the research proposed. These precepts have been codified in research policy for many decades and are a central value of all biomedical research funded by the NIH.

There are a number of relevant laws, regulations, and policies governing the welfare of animals used in research that are applicable to research conducted and funded by the NIH. These include: the Animal Welfare Act, a Federal law that regulates the treatment of animals in research, exhibition, transport, and by dealers<sup>1</sup>, and the Public Health Service (PHS) Act, as amended by the Health Research Extension Act (HREA) of 1985 (P.L. 99-158, Sec.495), requiring the NIH Director to establish guidelines for the proper care and treatment of animals to be used in biomedical and behavioral research,<sup>2</sup> and requiring that research institutions establish and maintain proper measures to ensure the appropriate care and use of all animals involved in

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<sup>1</sup> Animal Welfare Act – <https://awic.nal.usda.gov/government-and-professional-resources/federal-laws/animal-welfare-act>

<sup>2</sup> <https://grants.nih.gov/grants/olaw/references/hrea1985.htm>

research, research training, and biological testing activities conducted or supported by the PHS.<sup>3</sup> The PHS endorses the "U.S. Government Principles (USG Principles) for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training" developed by the Interagency Research Animal Committee.<sup>4</sup>

The NIH has established numerous policies, procedures, and protocols to ensure that all federal regulations and ethical principles are addressed in NIH-supported studies. All NIH research involving animals requires review by a local Institutional Animal Care and Use Committee (IACUC) of the scientific justification for the use of animals, as well as the appropriateness of the species, number of animals requested, alternatives to their use, general care, and approaches to avoid or minimize discomfort, distress, and pain. The NIH Office of Laboratory Animal Welfare (OLAW) oversees all agency supported research activities that involve vertebrate animals, ensures that NIH-funded institutions comply with animal welfare laws and policies, and investigates and acts on allegations related to violation of animal care standards in NIH-funded studies.

### **Rationale for Workshop**

In the House Committee on Appropriations Report accompanying the Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Bill, 2016, (H. Rept. 114-195)<sup>5</sup>, the Committee on Appropriations of the 114<sup>th</sup> U.S. Congress requested the following:

“The Committee is aware that prominent experts and animal advocacy organizations have raised concerns about the scientific and ethical justifications for maternal deprivation studies involving baby monkeys being conducted in both intramural and extramural NIH funded laboratories. The Committee is further aware that the NIH Office of Laboratory Animal Welfare opened an investigation in response to these allegations on September 9, 2014. The investigators consulted with research investigators, the USDA, non-human primate center scientists, veterinarians, animal care staff and other relevant experts. As a result of the investigation, several modifications were made to the protocol and several procedures removed. Accordingly, the Committee requests NIH to conduct a review of its ethical policies and processes with respect to non-human primate research subjects, in consultation with outside experts, to ensure it has appropriate justification for animal research protocols and to provide an update on these efforts in the fiscal year 2017 budget request.”

In response to this request, the NIH provided an update in the fiscal year (FY) 2017 Congressional Justification<sup>6</sup> and hosted a workshop on September 7, 2016 that convened experts in science, policy, ethics, and animal welfare to review the ethical policies and oversight framework governing the use of non-human primates in NIH-funded biomedical and behavioral research. Workshop participants also explored the state of the science of research involving non-

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<sup>3</sup> Public Health Service Act – <https://grants.nih.gov/grants/olaw/references/phspol.htm>

<sup>4</sup> <https://grants.nih.gov/grants/olaw/tutorial/relevant.htm#2b>

<sup>5</sup> <http://appropriations.house.gov/uploadedfiles/hrpt-114-hr-fy2016-laborhhsed.pdf> (see page 72)

<sup>6</sup> [https://officeofbudget.od.nih.gov/pdfs/FY17/30-SIs%20\(002\).pdf](https://officeofbudget.od.nih.gov/pdfs/FY17/30-SIs%20(002).pdf) (see page 181)

human primates. The NIH sought a diverse, balanced panel of experts that could facilitate a thorough and productive dialogue about responsible research using non-human primates.

The NIH remains confident that the oversight framework for the use of non-human primates in research is robust and has provided sufficient protections to date. However, we also believe that periodically reviewing agency policies and processes ensures that our oversight framework evolves in a manner consistent with emerging scientific opportunities, public health needs, ethical considerations, and animal welfare standards.

## Public Engagement

The general public's input was solicited throughout the planning process and during the workshop. The activity was announced on a public blog post in May 2016,<sup>7</sup> and a draft agenda followed in August 2016.<sup>8</sup> Both requested public feedback<sup>9</sup> on the workshop's content and possible participants. The workshop proceedings were videocast live and archived for future reference on the NIH Videocast website.<sup>10</sup> Comments submitted by the public were provided in real time to the session moderators to be raised during the discussion periods and during a workshop session dedicated to public comments. All public comments submitted in advance of and during the workshop via the online comment form are available on the NIH website.<sup>11</sup>

## Summary of Session I: State of the Science

### Presentations and Panel Discussion

The first set of presentations reviewed the current state of the science in a variety of fields using non-human primates as research models. During this session, workshop participants were tasked with discussing why, when, and how non-human primates should be involved in biomedical and behavioral research. The purpose of this session was to provide context to the discussion of appropriate use of non-human primates in NIH-funded research. Speakers (identified in the workshop agenda<sup>12</sup>) were asked to limit their remarks so the majority of the time could be reserved for discussion.

### *HIV/AIDS and Other Infectious Diseases*

Infectious disease researchers discussed how non-human primates have been used in addressing infectious diseases and understanding how the immune system adapts, developing vaccines against numerous existing and emerging infectious diseases, as well as addressing other diseases that do not naturally occur in rodent models (e.g. tuberculosis). They noted that, compared to other animals, persistent infections are more faithfully replicated in non-human primates. One important example is non-human primate models of HIV: these models more accurately mimic

<sup>7</sup> <http://osp.od.nih.gov/under-the-poliscope/2016/05/ensuring-continued-responsible-research-non-human-primates>

<sup>8</sup> <http://osp.od.nih.gov/event/2016-09-07-130000-2016-09-07-210000/nih-workshop-ensuring-continued-responsible-oversight-research-non-human-primates>

<sup>9</sup> <http://grants.nih.gov/grants/rfi/rfi.cfm?ID=58>

<sup>10</sup> <https://videocast.nih.gov/>

<sup>11</sup> <http://osp.od.nih.gov/event/2016-09-07-130000-2016-09-07-210000/nih-workshop-ensuring-continued-responsible-oversight-research-non-human-primates>

<sup>12</sup> [http://osp.od.nih.gov/sites/default/files/Workshop%20Agenda\\_0.pdf](http://osp.od.nih.gov/sites/default/files/Workshop%20Agenda_0.pdf)

the immune deficiency and clinical manifestations of AIDS compared to other animal models, and the most widely-used HIV therapies first showed promise in non-human primate models of disease.

Workshop presenters also reported on the benefits of using non-human primates in research on microbial threats including other emerging infectious diseases. They discussed the fact that researchers used non-human primates to understand how the Zika virus replicates and causes disease during pregnancy, and how non-human primate research is essential to explore and compare multiple approaches to treat microbial threats. These treatments include small molecule drug development, vaccine design and delivery, immunotherapy, and genetic analysis as methods to respond to and protect against infectious diseases.

### *Social, Cognitive, and Behavioral Research*

Presenters described the benefits of using non-human primate models in social, cognitive, and behavioral research. They noted that, unlike other animal models, non-human primates share some of the same complex social behaviors with humans. They highlighted that such similarities can often shed light on neurobiological and behavioral aspects of complex social behaviors in humans. The presenters provided as an example recent evidence demonstrating that a similar neural network in humans and macaques is activated when individuals coordinate with others using social cues.<sup>13</sup> Presenters also discussed two therapeutic advances being tested using non-human primate research models: administration of the hormone oxytocin to promote pro-social behaviors,<sup>14</sup> and transcranial magnetic stimulation as a therapy to treat depression.

### *Regenerative Medicine*

Presenters then discussed the use of non-human primate models to explore regimens for organ and tissue regeneration due to the similarity of organ size, physiology, structure, function as well as immune system between these animals and humans. The presenters provided as one example research examining the ability of stem cells to regenerate heart tissue: stem cell-derived cardiomyocytes have been shown to enhance the cardiac function in macaques following an induced myocardial infarction.<sup>15</sup> The presenters ended by noting that restorative functionality cannot be typically obtained in other relevant animal models (e.g., pigs) due in part to issues related to immunosuppression, which is necessary for the long-term survival of transplanted organs, tissues, and cells.

### *Reproductive Biology*

Researchers in this part of the workshop discussed how non-human primates are appropriate models to address human fertility because they share key characteristics of human endocrine function not seen in other mammals. They noted a number of reproductive research discoveries using non-human primate models, including: a better understanding of ovarian and testicular function, physiology of the uterus and vagina, establishment of pregnancy and menopause, as

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<sup>13</sup> Kaiser and Feng. Modeling psychiatric disorders for developing effective treatments. *Nat Med.* 2015 Sep; 21(9):979-88 & Brent et al. Genetic origins of social networks in rhesus macaques. *Sci Rep.* 2013;3: 1042.

<sup>14</sup> Putnam et al. Oxytocin enhances gaze-following responses to videos of natural social behavior in adult male rhesus monkeys. *Psychoneuroendocrinology.* 2016 Oct; 72:47-53. doi: 10.1016/j.psyneuen.2016.05.016.

<sup>15</sup> Chong et al. Human Embryonic Stem Cell-Derived Cardiomyocytes Regenerate Non-Human Primate Hearts *Nature.* 2014 Jun 12; 510(7504): 273–277.

well as causes and consequences of preterm labor and other disorders related to fertility. The presenter also noted that researchers and clinicians have utilized non-human primate models for therapeutic research in this field, such as identifying the developmental defects associated with thalidomide and providing evidence of efficacy for recombinant human gonadotropins for use during *in vitro* fertilization.

### *Neurobiology and Social Functions*

The presenters discussed how studying disorders of social functions in which individuals have problems connecting with others (e.g., autism, schizophrenia, etc.) requires getting inside the brain in a way not currently possible in humans. It was highlighted that unlike non-human primates, small animal models do not mirror human social interactions well enough to be an appropriate model for this type of research. This makes non-human primates an ideal model to study human social disorders. Another presenter further enforced the idea that non-human primates are critical models to study the nervous system in general. It was discussed that computer disease models must be refined using animal models. For example, you can have multiple computer models, but to elucidate which model is the best simulator of a specific condition, animal models must be used. Although cell-based disease models can be very useful, they do not reflect the complexity of the neural circuitry in human brains. Non-human primates remain the best model to study higher order functions. An example of where the use of non-human primates was critical in developing a promising therapeutic technology is the development of deep-brain stimulation for the treatment of Parkinson's disease. Another example that was discussed at length was the visual system of non-human primates, which is the most relevant model for studying human disorders of vision, eye movement, and neural processing of sight. Presenters stressed that in any study, animal models should be carefully matched to the problem being investigated.

### Group Discussion

During the discussion, participants were challenged with the question, "How can we do better?" in the use and consideration of non-human primates in research. Participants expressed the need for more data sharing, such as making different datasets from the same animal more accessible among researchers. They also expressed the need to make negative data more acceptable for publishing. The group agreed that improving researcher access to data would reduce experimental redundancy and improve data utilization by allowing multiple members of the research community to evaluate the study in detail, learn from the outcomes, and address reproducibility concerns. They suggested that a registry of studies with non-human primates could be a forum to publish both positive and negative results. Finally, the group agreed that scientists should better communicate and engage with the public and patient advocates to explain how their research with non-human primates is moving science forward in meaningful ways to improve the health of humans and other animals.

The group also discussed the housing needs of non-human primates involved in their studies. One expert suggested the idea of moving primates out of smaller individual lab environments into larger regional or national primate centers. Though the groups acknowledged a number of benefits to this scenario, concerns were also raised about the loss of diverse expertise and intellectual richness that may accompany consolidation of non-human primate research into large

centers. On a related topic, many public comments focused on the need for social housing as non-human primates are social animals. Researchers are required by federal regulations to maximize the social interaction through paired or group housing of these animals whenever possible, unless specific health contraindications or scientific justification exists.

Finally, the group discussed how investigators and funders can best refine, replace, and reduce non-human primates as much as possible in research. Workshop participants raised the point that the diversity of non-human primate species available for research has been reduced over time. Currently, rhesus macaques are the predominant non-human primate species used in research. They noted that if alternative non-human primate species are identified, made available, and genetically characterized, then new models may be developed to potentially replace macaques as a means to better address biomedical and behavioral questions relevant to human health.

## **Session II: Oversight of NIH-Supported Research Using Non-Human Primates**

### Presentations and Panel Discussions

The afternoon discussion turned towards understanding the current ethical principles governing the research use of non-human primates and how these ethical principles are incorporated into the existing oversight framework at the federal level. In particular, participants discussed how scientific justification and ethical issues are considered when determining the use of non-human primates in individual research studies. Presenters at this session highlighted that any use of non-human primates in research must involve weighing the probability and magnitude of potential benefit (to health, scientific knowledge, or both) against the risk to research animals. The session also examined data on pain and distress experienced by the animals, and discussed strategies to minimize any adverse events incurred on research animals.

#### *Comments from the US Department of Agriculture*

The Animal and Plant Health Inspection Service (APHIS) and the Animal Welfare Information Center (AWIC) representatives from the US Department of Agriculture (USDA) summarized the regulatory requirements under the Animal Welfare Act (AWA).

The APHIS representative discussed the regulatory requirements under the AWA to promote the psychological well-being of non-human primates and minimize pain and distress during research, teaching, and testing. Findings from surveys on non-human primate social housing as well as data on non-human primate usage were also provided. A comparison of the 2000/2001 USDA survey on social housing to the 2014 survey conducted by the National Association of Biomedical Research and the Association of Primate Veterinarians revealed an increase in social housing from 65 percent to 85 percent.

Data on non-human primate usage compiled from the Annual Reports submitted to APHIS from 2013-2015 revealed an average of 111 Federal facilities and 1089 non-Federal facilities using non-human primates during this period. According to the reports, non-human primates that experienced pain and distress requiring the use of pain relieving drugs (Category D) in Federal facilities ranged from 16-21 percent of the total non-human primates used during this period.

Similarly, the percentage for non-Federal facilities ranged from 25-27 percent. Non-human primates in Federal facilities that experienced unrelieved pain and distress with scientific justification (Category E) ranged from four to five percent of total animals used. The percentage for non-Federal facilities remained consistent at one percent throughout.

The AWIC was created to serve as a resource for information on methods of experimentation that could reduce or replace animal use and minimize pain and distress to animals. As an information resource, the AWIC helps researchers fulfill the AWA regulatory requirement to consider alternatives. The AWIC representative discussed the ‘3Rs’ principles as described by Russell and Burch in their 1959 publication ‘Principles of Humane Experimental Technique’ and provided examples such as: “replacement” of non-human primates with less sentient models when possible, “reduction” in the number of animals utilized to achieve results of a given amount and precision, and “refinement” of experimental procedures to minimize pain and distress. Information provided by the AWIC also helps prevent unintended duplication of animal studies. Sample literature searches revealing alternatives to procedures using non-human primates were provided. A graph highlighting the increase in literature searches conducted for social housing, enrichment, and psychological well-being from 1980-2014 was also provided. The representative suggested conditions related to social housing could be improved if more housing and psychological well-being information is reported (or required) in publications.<sup>16</sup>

#### *Perspective from Office of Laboratory Animal Welfare*

The Director of OLAW described the oversight framework for NIH-supported research, including a history of the statutes that govern the use of animals in research. First, all funded research must adhere to legislation outlined in the AWA and the HREA. The HREA established standards for animal health and welfare in NIH funded research. Moreover, these standards and framework evolve as new scientific knowledge is gained over time. Implementation of the HREA focuses on local IACUCs and acknowledges that science is not static, with standards that must always evolve.

OLAW’s director also described research requirements outlined in the PHS Policy on Humane Care and Use of Laboratory Animals, which complements the AWA, and provides guidance on IACUC function, while recognizing that research must avoid or minimize discomfort, distress, and pain consistent with sound experimental design. The USG Principles, developed in 1985 and adopted by all U.S. agencies, require that research with animals is relevant to human health and has the promise to be beneficial, provides an ethical framework, and requires use of the minimum number of animals necessary to obtain valid results. The Principles dictate that non-animal simulation models must be used where appropriate in lieu of animals; adverse events (e.g., discomfort, pain, and distress) must be minimized or avoided whenever possible; and justifications and intended benefits must be provided for all species involved in the research.

The OLAW representative also described the NIH-required standards in the *Guide for the Care and Use of Laboratory Animals*<sup>17</sup> which states that the decision to use animals requires critical

<sup>16</sup> <https://www.nal.usda.gov/awic/environmental-enrichment-nonhuman-primates-resource-guide-social-housing>

<sup>17</sup> The PHS Policy requires institutions to use the *Guide for the Care and Use of Laboratory Animals (Guide)*, developed by the National Academies of Science, as a basis for developing and implementing an institutional program for activities involving animals. <https://grants.nih.gov/grants/olaw/Guide-for-the-Care-and-use-of-laboratory-animals.pdf>.

thought, judgement, and analysis and that the use of non-human animals is a privilege, expected to only be performed if there is a benefit to humans. The IACUCs weigh the objectives of the study with the amount of distress, discomfort, pain or injury that the animal experiences as well as review the justification for the use of animals in research. The Guide also recommends using the least sentient species possible to achieve the aims of the research, the fewest number of animals, and to minimize adverse events associated with research.

The OLAW representative described NIH policies to ensure the ethical use of animals in NIH-funded research, which are outlined in the NIH Grants Policy Statement, Instructions to Applicants, and guidance to peer reviewers. Furthermore, the NIH recently updated the Guidance for the Review of the Vertebrate Animals Section of the NIH Grant Applications and Contract Proposals.<sup>18</sup> Applicants must justify the need for the species selected, justify why alternatives are not appropriate, and describe the interventions to minimize any discomfort, distress, pain or injury. All NIH-convened Scientific Review Groups review this information in applications and contract proposals prior to Institutes or Centers awarding funds.

### *Ethicist Perspective*

The ethicist's perspective on this topic described funders' and oversight committees' responsibilities to ensure that there is an acceptable ethical cost-benefit relationship in research involving non-human primates (and other species). He indicated that only a slim majority of the public still believes research with animals that can improve the human condition justifies it as ethical<sup>19</sup>, despite advances in research animal care and well-being that have occurred over the past few decades. He described the current requirement that when animals are used in research—specifically in situations with research-induced pain, discomfort, and morbidity—then that research must be thoroughly justified by a greater benefit to humans and other animals than the cost inflicted. A balance must exist between research-induced adverse effects with, or preferably outweighed by, the potential benefits to the health of human or other animals as well as the advancement of knowledge or the good of society. The speaker concluded by noting that an ethical and scientific imperative exists such that the potential benefits to such research must yield high quality reproducible data (both positive and negative), be published, as well as address how and when this information will advance knowledge or the good of society.

### *Role of Veterinary Science*

The speaker began her presentation by noting that veterinarians must be involved in NIH-supported research activities using non-human primates and other animals, and described a number of advances in veterinary science for research animals. For example, current animal care approaches have evolved to hierarchically engage technicians, veterinarians, specific behavioral personnel, and researchers in the daily care and use of animals. Protocols involving positive reinforcement training, such as the use of clicker and reward based training, represent an example of how animal health experts are minimizing the stress associated with experimental or routine physical assessment of non-human primates. Enhancements to standard behavioral management practices provide additional opportunities to express species-typical behaviors. The veterinarian discussed these examples, and noted that many others over recent years have led to noticeable improvements in outcomes related to animal husbandry (e.g., introduction outcomes)

<sup>18</sup> [https://grants.nih.gov/grants/olaw/vertebrate\\_animal\\_section.htm](https://grants.nih.gov/grants/olaw/vertebrate_animal_section.htm)

<sup>19</sup> <http://www.pewinternet.org/2015/07/01/chapter-7-opinion-about-the-use-of-animals-in-research/>

and have enhanced the quality of life for animals involved in research.<sup>20</sup> She also raised the point that continued funding for the science of animal welfare is needed to sustain improvements to animal well-being, body condition scoring, orthopedics, cardiology, colony management, feeding and foraging, hematology, and clinical pathology.

Following this presentation, workshop participants further discussed the public comments submitted that related to the social housing of non-human primates involved in research activities. They noted that paired or group housing is the most optimal approach sought for the health and well-being of the animals involved, in addition to exhibiting typical species behavior compared to environmental enrichment. They also noted that, when considering social housing practices, investigators weigh issues related to indoor or outdoor paired or group housing, adjoining enclosures for social interactions, health and safety of the animals including limiting disease transmission, as well as the compatibility, emotionality, and temperament of certain pairs or groups. The speaker presented a number of photographs illustrating examples of ideal research housing, currently being used, that provided appropriate enrichment and social interaction opportunities.

#### *Role of Investigators and the IACUC*

Researchers consider many factors when planning for a research study, especially when non-human primates are involved. This includes, but is not limited to, avoiding unnecessary duplication, justifying the significance and innovation, informing IACUC members about the current state of the science, as well as remaining knowledgeable about the field. The workshop presenter discussed recent efforts focusing on enriching the environment for non-human primates through the availability of stimuli such as toys, edibles, foraging, music, visuals, social housing, exercise activities, as well as daily contact with familiar human care-takers. In addition to these actions to enrich the environment, the presenter discussed that a researcher must still explain the necessity and justification for the use of animals throughout their research endeavors.

#### Group Discussion

The afternoon discussion began with the questions raised: how does one address scientific necessity for using non-human primates in research without discussing the ethics?

One participant suggested that unnecessary research is unethical, but doing research that is necessary does not automatically make it ethical. Whatever the benefit may be, it must outweigh the moral cost to the non-human primate involved.

Other participants requested clarity about what makes something ethically permissible in response to that argument and how subjective terms like ‘necessity,’ ‘worthy scientific knowledge,’ and ‘ethics’ should be defined. In particular, they discussed scenarios in which research is necessary from a scientific or public health perspective, but would still not be considered ethically acceptable. As one example, they discussed the experience of the Institute of Medicine Committee that produced the recent report on the use of chimpanzees in research, where half of the Committee members felt there was justification for the use of chimpanzees to

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<sup>20</sup> Baker et al. Survey of 2014 Behavioral Management Programs for Laboratory Primates in the United States. *Am J Primatol.* 2016 Jul; 78(7): 780–796

develop a vaccine against the hepatitis C virus, while the other half did not. The members who disagreed indicated there was not enough justification to use animals, when much of the necessary testing could be performed in humans. Workshop discussion of this example led to additional discussion of the minimum ethics needed for a study—for example, at what point does research justify significant post-operative pain in non-human primates.

In contrast, many participants expressed concern that a requirement to clearly address potential human health benefits in basic research can be difficult or impossible, as investigators cannot always predict the outcome of a research project. However, they noted that basic research is critical to future breakthroughs overall. For example, basic research has been crucial to understanding human perception and movements. As many groundbreaking innovations at the basic research level were not associated with a particular disease state in mind, workshop participants stressed that scientific knowledge must be considered along with human benefit when reviewing and assessing a research project. A powerful example of this is deep-brain stimulation to treat Parkinson's disease. The fundamental knowledge gained through basic research, not in the context of a specific disease, in non-human primates significantly contributed to the development of deep-brain stimulation technology. Additional discussion during this session focused on how the best non-human primate model for a given disease can be identified without relying heavily on previous experiments using other non-human primate or other animal models.

Workshop participants also discussed the public comments surrounding the IACUCs, including IACUC functions, processes for ensuring that the necessary ethical and scientific expertise is represented and for balancing cost/benefit relationship, similarities and differences from Institutional Review Boards (IRBs), and IACUCs effectiveness in addressing animal welfare issues. Participants indicated that the IACUCs focus on animal welfare concerns and will usually defer to the scientific review of proposals and veterinarians when evaluating the scientific justification and experimental quality. Participants noted that even the best IACUCs find it difficult to assess the potential benefits of a research activity, and subsequently focus on the harms and costs. Though many recent enhancements have been made to the IACUCs in the oversight of research animals, there has not been an assessment of the effectiveness of these actions. That being said, many of the workshop participants praised the current state of IACUC actions and processes. The discussant also raised a number of issues to be considered by all stakeholders: for example, continuing to improve the understanding of the ethical considerations for research involving non-human primates, and developing ways to improve and optimize training opportunities.

Besides the points noted above, workshop participants also discussed: the paradigm of animal management should be expanded to include non-human primate mental health beyond stereotypies and self-injurious behavior; non-experimental adverse rearing practices (maternal deprivation) should be avoided to prevent the development of animal psychopathologies; and the community must understand and provide guidance on how to utilize best practice interventions when behavioral pathologies emerge in animals.

## Summary of Public Comments

As noted above, public comments were invited in advance of and during the workshop as well as shared with the moderators to be raised during the group discussions. Investigators, animal welfare organizations, international organizations, and public citizens submitted comments for consideration. Below is a summary of comments received from the public:

- General themes:
  - Emphasis on the need for alternative models
  - Expressed opposition to any use of non-human primates as immoral or unjustified
  - Requests for additional discussion on the stress or psychological well-being of animals
  - Moving away from animal research would yield a competitive advantage to other countries
- Recommendations aimed at NIH:
  - Explore better communication strategies with the public
  - Consider an Institute of Medicine-like review of the cost-benefit analysis of primate research
  - Review best practices on husbandry from zoos
- Concerns about organization of the workshop:
  - Concerns about conflicts of interest
  - Mostly focused around the status quo and not pushing for change

**Appendix 1: Common Acronym List**

APHIS	USDA Animal and Plant Health Inspection Service
AWA	Animal Welfare Act of 1985
AWIC	USDA Animal Welfare Inspection System
Guide	Guide for the Care and Use of Laboratory Animals
HREA	Health Research Extension Act of 1985
HIV	Human Immunodeficiency Virus
IACUC	Institutional Animal Care and Use Committee
NIH	National Institutes of Health
OLAW	NIH Office of Laboratory Animal Welfare
USDA	United States Department of Agriculture

## Appendix 2: Workshop Agenda

### NIH Workshop on Ensuring the Continued Responsible Oversight of Research with Non-Human Primates

Wednesday, September 7, 2016  
National Institutes of Health  
Bethesda, MD

Objective: to explore the current state of the science of NIH-supported research involving non-human primates (Session I) and discuss existing animal welfare regulations and policies (Session II).

- 9:00am Welcome and Opening Remarks  
Francis S. Collins, M.D., Ph.D., Director, National Institutes of Health  
Carrie Wolinetz, Ph.D., Associate Director for Science Policy, National Institutes of Health
- 9:15am Session I: State of the Science of NIH-Supported Research Involving Non-Human Primates (5 Panel Presentations – 15 minutes each)  
Moderator: David O'Connor, Ph.D., Professor of Pathology and Laboratory Medicine, University of Wisconsin, Madison
- Nancy Haigwood, Ph.D., Director and Senior Scientist at the Oregon National Primate Research Center, Oregon Health & Science University
  - William Newsome, Ph.D., Professor of Neurobiology and Psychology, Stanford School of Medicine
  - Michael Platt, Ph.D., Professor of Neuroscience, Psychology and Marketing, University of Pennsylvania
  - Charles Murry, M.D., Ph.D., Professor of Pathology, Bioengineering and Medicine/Cardiology, University of Washington
  - Teresa Woodruff, Ph.D., Professor and Vice Chair for Research of Obstetrics & Gynecology, Northwestern University
- 10:45am BREAK
- 11:00am Group Discussion  
How do non-human primates uniquely contribute to our understanding of basic biological processes and disease states?  
What are the emerging scientific opportunities and/or public health needs for which non-human primates research models may be required?  
Why and how does a researcher decide to use a non-human primate model?
- 12:30pm LUNCH

- 1:00pm      Session II: Oversight of NIH-Supported Research Using Non-Human Primates (5 Panel Presentations – 15 minutes each)  
Moderator: Margaret Foster Riley, J.D., Professor of Law at the University of Virginia School of Law
- Carol Clarke, D.V.M., D.A.C.L.A.M., Research Staff Officer at the Animal and Plant Health Inspection Service and Kristina Adams, M.S., Coordinator in the Animal Welfare Information Center, U.S. Department of Agriculture
  - Patricia Brown, V.M.D., M.S., D.A.C.L.A.M Director of the Office of Laboratory Animal Welfare, U.S. Department of Health and Human Services
  - Ernest Prentice, Ph.D., Associate Vice Chancellor for Academic Affairs, University of Nebraska Medical Center
  - F. Claire Hankenson, D.V.M., M.S., D.A.C.L.A.M., Director of Animal Resources and Attending Veterinarian, Michigan State University
  - Nancy Ator, Ph.D., Director of the Division of Behavioral Biology, Johns Hopkins University
- 2:15pm      BREAK
- 2:30pm      Group Discussion  
What are the policies and processes in place regarding the ethical use of non-human primates in NIH-supported research?  
How does the current oversight framework address ethical and welfare concerns of using non-human primates in NIH-supported research?  
What is the laboratory and veterinary science evidence base underlying current welfare standards and practices?
- 4:15pm:      Public Comments
- 4:45pm:      Closing Remarks  
Carrie Wolinetz, Ph.D., Associate Director for Science Policy, National Institutes of Health
- 5:00pm:      Adjourn

**Appendix 3: Workshop Participants (in alphabetical order)**

- Christian Abee, D.V.M., M.S., D.A.C.L.A.M., Professor and Chair in the Department of Veterinary Sciences, University of Texas MD Anderson Cancer Center
- (Speaker) Kristina Adams, M.S., Coordinator, Animal Welfare Information Center, U.S. Department of Agriculture
- David Amaral, Ph.D., Chair and Director of Research, MIND Institute, University of California at Davis
- Richard Andersen, Ph.D., Professor of Neuroscience, Caltech
- (Speaker) Nancy Ator, Ph.D., Director of the Division of Behavioral Biology, Johns Hopkins University
- Kathryn Bayne, M.S., Ph.D., D.V.M., D.A.C.L.A.M., D.A.C.A.W., C.A.A.B., Executive Director, Association for Assessment and Accreditation of Laboratory Animal Care International
- Tom Beauchamp, Ph.D., Professor of Philosophy and Senior Research Scholar at the Kennedy Institute of Ethics, Georgetown University
- Charles Bradberry, Ph.D., Senior Investigator in the Preclinical Pharmacology Section, National Institute on Drug Abuse
- (Speaker) Patricia Brown, V.M.D., M.S., D.A.C.L.A.M., Director of the Office of Laboratory Animal Welfare, U.S. Department of Health and Human Services
- Larry Carbone, D.V.M., Ph.D., D.A.C.A.W., D.A.C.L.A.M., Interim Director of the Institutional Animal Care and Use Program, University of California San Francisco
- (Speaker) Carol Clarke, D.V.M., D.A.C.L.A.M., Research Staff Officer at the Animal and Plant Health Inspection Service, U.S. Department of Agriculture
- Francis S. Collins, M.D., Ph.D., Director, National Institutes of Health
- Mahlon DeLong, M.D., Professor of Neurology, Emory University
- John Dennis, D.V.M., M.S., D.A.C.L.A.M., Director of Veterinary Services at the Center for Biologics Evaluation and Research, Food and Drug Administration
- Asgi Fazleabas, Ph.D., Professor and Associate Chair for Research of Obstetrics, Gynecology, and Reproductive Biology, Michigan State University

- Joanne Flynn, Ph.D., Professor of Microbiology and Molecular Genetics, University of Pittsburgh
- Genoveffa Franchini, M.D., Senior Investigator, National Cancer Institute
- Michael Goldberg, M.D., Professor of Brain and Behavior in Neuroscience, Neurology, Psychiatry, and Ophthalmology, Columbia University Medical Center
- Christine Grady, M.S.N., Ph.D., Chief of the Department of Bioethics, NIH Clinical Center
- (Speaker) Nancy Haigwood, Ph.D., Director and Senior Scientist at the Oregon National Primate Research Center, Oregon Health & Science University
- (Speaker) F. Claire Hankenson, D.V.M., Director of the MSU Campus Animal Resources and Attending Veterinarian, Michigan State University
- Kathy Hudson, Ph.D., Deputy Director for Science, Outreach, and Policy, National Institutes of Health
- Jeff Kahn, Ph.D., M.P.H., Director of Berman Institute of Bioethics, Johns Hopkins University
- Sabine Kastner, M.D., Ph.D., Professor of Psychology, Princeton University
- Allan Kirk, M.D., Ph.D., F.A.C.S., Professor and Chair of Surgery, Duke University Medical Center
- Jeffrey Lifson, M.D., Director, AIDS and Cancer Virus Program, Leidos Biomedical Research Inc., Frederick National Laboratory
- Janet McNicholl, M.D., Preclinical Team Lead of the Division of HIV/AIDS Prevention Laboratory Branch, U.S. Centers for Disease Control and Prevention
- John Morrison, Ph.D., Director, California National Primate Research Center and Professor of Neurology, University of California at Davis
- LaVonne Meunier, D.V.M., D.A.C.L.A.M., D.A.C.A.W., Director of Veterinary Medicine and Attending Veterinarian, GlaxoSmithKline
- (Speaker) Charles Murry, M.D., Ph.D., Professor of Pathology, Bioengineering and Medicine/Cardiology, University of Washington
- Christian Newcomer, V.M.D., M.S., D.A.C.L.A.M., Independent Consultant on Research Animal Care and Use

- (Speaker) William Newsome, Ph.D., Professor of Neurobiology and Psychology, Stanford School of Medicine
- Steven Niemi, D.V.M., D.A.C.L.A.M., Director of the Office of Animal Resources, Harvard University
- (Moderator) David O'Connor, Ph.D., Professor of Pathology and Laboratory Medicine, University of Wisconsin, Madison
- Kyle Orwig, Ph.D., Associate Professor of Obstetrics, Gynecology, and Reproductive Sciences, and Molecular Genetics and Biochemistry, University of Pittsburgh
- (Speaker) Michael Platt, Ph.D., Professor of Neuroscience, Psychology and Marketing, University of Pennsylvania
- Linda Porrino, Ph.D., Professor and Chair of Physiology and Pharmacology, Wake Forest School of Medicine
- (Speaker) Ernest Prentice, Ph.D., Associate Vice Chancellor for Academic Affairs, University of Nebraska Medical Center
- (Moderator) Margaret Foster Riley, J.D., Professor of Law, University of Virginia School of Law
- Jeffrey Rogers, Ph.D., Associate Professor of Molecular and Human Genetics, Baylor College of Medicine
- Doug Rosene, Ph.D., Professor of Anatomy and Neurobiology, Boston University
- Steven Schapiro, Ph.D., Associate Professor of Veterinary Sciences, Michale E. Keeling Center for Comparative Medicine and Research, University of Texas MD Anderson Cancer Center
- Krishna Shenoy, Ph.D., Professor of Electrical Engineering, Stanford University
- Peter Strick, Ph.D., Professor and Chair of Neurobiology, University of Pittsburgh
- Carrie Wolinetz, Ph.D., Associate Director for Science Policy, National Institutes of Health
- (Speaker) Teresa Woodruff, Ph.D., Professor and Vice Chair for Research of Obstetrics & Gynecology, Northwestern University
- Joanne Zurlo, Ph.D., Senior Scientist, Johns Hopkins Bloomberg School of Public Health

## Appendix 4: Workshop Participant Biographies

### **CHRISTIAN R. ABEE, D.V.M., M.S., D.A.C.L.A.M.**

Dr. Christian R. Abee is the Doctor R. Lee Clark Professor of Comparative Medicine, chair of the Department of Veterinary Sciences, and director of the Michale E. Keeling Center for Comparative Medicine and Research at the University of Texas MD Anderson Cancer Center in Bastrop, Texas. He received his B.S. in veterinary science and his D.V.M. from Texas A&M University and his M.S. in comparative medicine at the Wake Forest University School of Medicine. He is a Diplomate of the American College of Laboratory Animal Medicine and has served on the board of directors of the National Association for Biomedical Research (NABR), the Scientists Center for Animal Welfare (SCAW), and other organizations, including the Association of Primate Veterinarians (APV) and the American College of Laboratory Animal Medicine (ACLAM). Dr. Abee directs two national research resources of non-human primates supported by grants from the National Institutes of Health.

### **KRISTINA ADAMS, M.S.**

Kristina Adams received a B.S. in zoology from Miami University in 1995 and worked as a large mammal keeper at the Baltimore Zoo (now the Maryland Zoo in Baltimore) for four years. After leaving the zoo, Ms. Adams pursued a graduate degree in animal and avian sciences from the University of Maryland, College Park. In 2001, she received an M.S. after completing her thesis on social and spacing behavior in scimitar-horned oryx herds maintained at the National Zoo's Conservation Research Center in Front Royal, Virginia. She worked as a behaviorist and environmental enrichment technician at the NIH Veterinary Resources Program (now the Division of Veterinary Resources) for two years, developing behavioral management programs for a variety of laboratory animal species including nonhuman primates. In 2003, she became a technical information specialist at the Animal Welfare Information Center (AWIC), which is part of the U.S. Department of Agriculture's National Agricultural Library (NAL). Currently, Ms. Adams is the program lead for the Animal Health and Welfare Program at NAL and coordinator of AWIC.

### **DAVID AMARAL, PH.D.**

Dr. David Amaral is currently a University of California, Davis Distinguished Professor of Psychiatry and Neuroscience and the Beneto Foundation Chair and founding research director of the MIND Institute. He was educated at Northwestern University, the University of Rochester (where he received a joint Ph.D. in psychology and neurobiology), and Washington University. He spent 13 years at the Salk Institute for Biological Studies. He coordinates a comprehensive, multidisciplinary analysis of children with autism, called the Autism Phenome Project, to define different types of autism. He is the director of Autism BrainNet, sponsored by the Simons Foundation and Autism Speaks, that solicits postmortem brain tissue to facilitate autism research. In April 2015, Dr. Amaral became editor-in-chief of *Autism Research*, the journal of the International Society for Autism Research.

**RICHARD ANDERSEN, PH.D.**

Dr. Richard Andersen, the James G. Boswell Professor of Neuroscience at Caltech, studies neural mechanisms of sight, hearing, balance, touch, and action, as well as the development of neural prosthetics. Dr. Andersen obtained a Ph.D. from the University of California, San Francisco and completed a postdoctoral fellowship at the Johns Hopkins Medical School. He was a faculty member of the Salk Institute and MIT before coming to Caltech. Dr. Andersen is a member of the National Academy of Sciences, the National Academy of Medicine, and the American Academy of Arts and Sciences. He has received a McKnight Foundation Scholars Award, a Sloan Foundation Fellowship, a Visiting Professorship at the College de France, and the Spencer Award from Columbia University. He has served as director of the McDonnell/Pew Center for Cognitive Neuroscience at MIT and of the Sloan-Swartz Center for Theoretical Neurobiology at Caltech, as well as being a member or chair of various government advisory committees.

**NANCY A. ATOR, PH.D.**

Dr. Nancy A. Ator is professor of behavioral biology in the Department of Psychiatry and Behavioral Sciences at the Johns Hopkins University School of Medicine, director of the Division of Behavioral Biology in that department, and chair of the Johns Hopkins University Animal Care and Use Committee. She received her B.A., M.S., and Ph.D. from the Department of Psychology at the University of Maryland in College Park and did her postdoctoral work at Johns Hopkins in the division she now directs. Her area of scientific expertise is the experimental analysis of behavior and the behavioral pharmacology of centrally acting drugs. She has over 40 years of experience in the care of and behavioral research with pigeons, rats, and non-human primates. She has served on committees involving the care and use of animals in research in her professional organizations and serves on the Board of Trustees of AAALAC International.

**KATHRYN BAYNE, M.S., PH.D., D.V.M., D.A.C.L.A.M., D.A.C.A.W., C.A.A.B.**

Dr. Kathryn Bayne is executive director for AAALAC International, a private nonprofit organization that promotes the humane treatment of animals in science through voluntary assessment and accreditation programs. Prior to this position, she worked at the National Institutes of Health, leading a research program on non-human primate psychological well-being and environmental enrichment programs for primates, dogs, cats, and swine. She is a certified applied animal behaviorist and is internationally renowned for her work in laboratory animal behavior and welfare. Dr. Bayne has held several leadership positions, including service as president of the American College of Laboratory Animal Medicine, the Association of Primate Veterinarians, and the District of Columbia Veterinary Medical Association. She is past chair of the American Veterinary Medical Association's Animal Welfare Committee and was the inaugural chair of the American Society of Laboratory Animal Practitioner's Animal Welfare Committee. Dr. Bayne was the 2009 recipient of the American Veterinary Medical Association's Animal Welfare Award.

**PATRICIA BROWN, V.M.D., M.S., D.A.C.L.A.M.**

Dr. Patricia Brown currently serves as the director of the National Institutes of Health Office of Laboratory Animal Welfare (OLAW). Her office oversees the use of animals in all Public Health Service (PHS)–and National Science Foundation–supported research by providing guidance and interpretation of the PHS Policy on Humane Care and Use of Laboratory Animals, monitoring compliance with the policy, evaluating allegations or indications of noncompliance with federal animal welfare requirements, and supporting educational programs that further the humane care and use of research animals. She received her undergraduate degree in animal science from the Pennsylvania State University and her veterinary degree from the University of Pennsylvania. She joined NIH in 1986, serving in several clinical and management positions in the intramural research program before joining OLAW in 2006 as its director.

**LARRY CARBONE, D.V.M., PH.D., D.A.C.L.A.M., D.A.C.A.W.**

Dr. Larry Carbone is senior veterinarian at the University of California San Francisco (UCSF) and the Interim Director of UCSF's IACUC office. He has worked in laboratory animal care for 35 years, in the academic setting, including care of primates on neurobiology studies. Larry holds a DVM degree from Cornell University, where he also received his Ph.D. in History of Science/Veterinary Ethics. He is a Diplomate of the American College of Laboratory Animal Medicine and the American College of Animal Welfare. He has researched and written extensively on welfare and pain management for laboratory animals, including his 2004 book: *What Animals Want: Advocacy and Expertise in Laboratory Animal Welfare Policy*.

**CAROL CLARKE, D.V.M., D.A.C.L.A.M.**

Dr. Carol Clarke received her bachelor's degree in the natural sciences from Johns Hopkins University and her DVM from the Tuskegee School of Veterinary Medicine. After receiving her DVM, she practiced small animal medicine in New York City for 13 years before entering the laboratory animal medicine training program at SmithKline Beecham Pharmaceuticals. Upon completion of the program, she entered the National Institutes of Health in 1998 as the primate facility attending veterinarian for the Veterinary Resources Program. In 2001, she accepted a position with the Comparative Medicine Branch of the National Institute of Allergy and Infectious Diseases (NIAID) and became a Diplomate of the American College of Laboratory Animal Medicine in 2005. During her 10 years with NIAID, she served as Institutional Animal Care and Use Committee (IACUC) coordinator, vice chair of the Rodent Gnotobiotic Committee, and chief of shared and central facility operations. In addition, she prepared all U.S. Department of Agriculture, OLAW, and AAALAC annual reports. Dr. Clarke accepted a position with the USDA in 2011 and currently serves as the research program manager for animal care at the headquarters of the Animal and Plant Health Inspection Service (APHIS). Her duties include writing policies, lecturing at conferences, conducting inspections, reviewing public complaints, and representing the USDA on various committees. She also served as the project officer for Module #26: Nonhuman Primate Transportation, which was developed for the APHIS National Veterinary Accreditation Program.

**MAHLON DELONG, M.D.**

In a series of pioneering physiologic non-human primate studies, Dr. Mahlon DeLong identified parallel brain circuits involving the cerebral cortex and the basal ganglia and thalamus that serve movement, executive, and mood/reward functions. His studies helped characterize the circuit disturbances underlying parkinsonism in NHP models and demonstrated the abolition of parkinsonism with focal inactivation of nodes of the basal ganglia motor circuit. These studies, which provided novel targets, physiologic guidance and a clear rationale for surgical approaches, contributed to the revival and development of neurosurgical treatments for Parkinson's and other movement disorders. He has received numerous awards for his contributions to the field. Most recently, he was awarded a Breakthrough Prize in Life Sciences (2014) for his pioneering work on the basal ganglia and Parkinson's disease, and he shared the Lasker-DeBakey Clinical Medical Research Award (2015) with Alim Benabid. Dr. DeLong is the W.P. Timmie Professor of Neurology at Emory University.

**JOHN DENNIS, D.V.M., M.S., D.A.C.L.A.M.**

Dr. John Dennis is attending veterinarian for the Food and Drug Administration's White Oak campus and the director of veterinary services for the Center for Biologics Evaluation and Research. Prior to joining FDA, he was head of laboratory animal medicine and director for the National Cancer Institute's Bethesda animal program; previously, he was a staff veterinarian at Duke Medical Center. He completed an NIH postdoctoral fellowship at Penn State College of Medicine and is board certified in laboratory animal medicine. He has a D.V.M. from North Carolina State University and a biology degree from the College of William and Mary. For more than 22 years, Dr. Dennis has cared for and overseen non-human primates used as models to study neuroscience, pharmacology, transplantation, and infectious disease.

**ASGI FAZLEABAS, PH.D.**

Dr. Asgi Fazleabas is professor, associate chair for research, and director of the Center for Women's Health Research at Michigan State University. His laboratory has two main focus areas: implantation biology and endometriosis. The first looks at the cellular and molecular dialogue between the early embryo and the uterine endometrium that is required for the establishment of pregnancy. His laboratory was the first to demonstrate that chorionic gonadotropin, the embryonic signal in the primate, acts directly on the uterus in vivo. These studies have led to the more recent studies that focus specifically on the role of Notch-1 during decidualization. Data from the laboratory also suggests that altered Notch signaling is evident as a consequence of endometriosis. The altered Notch signaling has a significant impact on an aberrant decidualization response in the eutopic endometrium and promotes lesion development at ectopic sites. In conjunction with these studies, his laboratory has also identified specific microRNAs that are altered in both the ectopic and the eutopic tissues of baboons and women with endometriosis. These studies have specifically focused on target genes that are regulated by microRNAs 451, 29c, and 21, which contribute to endometriosis-related pathologies. Dr. Fazleabas has received numerous prestigious awards and has more than 200 peer reviewed publications, multiple book chapters, and reviews.

**MICHAEL E. GOLDBERG, M.D.**

Dr. Michael E. Goldberg is the David Mahoney Professor of Brain and Behavior in the Departments of Neuroscience, Neurology, Psychiatry, and Ophthalmology at the Columbia University College of Physicians and Surgeons. He is a graduate of Harvard College, Harvard Medical School, and the Harvard-Longwood Neurology Program. He was a postdoctoral staff associate at the National Institute of Mental Health under Dr. Robert H. Wurtz. Before coming to Columbia in 2001, he had been an investigator in the Laboratory of Sensorimotor Research of the Intramural Program of the National Eye Institute since its founding in 1978. He is a pioneer in the study of the physiology of cognition using the awake, behaving rhesus monkey as a model system, with important contributions to our understanding of visual attention and spatial perception. He is a member of the National Academy of Sciences and a past president of the Society for Neuroscience. Dr. Goldberg is also an active clinical neurologist, specializing in general hospital neurology at the Columbia University Medical Center.

**JOANNE L. FLYNN, PH.D.**

Dr. JoAnne Flynn earned a B.S. in biochemistry from the University of California at Davis in 1982. She earned her Ph.D. in microbiology and immunology from the University of California at Berkeley in 1987, where she studied the pathogenesis of cystic fibrosis isolates of *Pseudomonas aeruginosa* under Dr. Dennis Ohman. Dr. Flynn's first post-doc was with Dr. Magdalene So at the Scripps Clinic Research Institute in La Jolla, California, developing on salmonella vaccine vectors against various parasitic diseases, including malaria. In 1990, she joined the lab of Dr. Barry Bloom at the Albert Einstein College of Medicine as a Howard Hughes Research Associate, beginning her studies in tuberculosis. Dr. Flynn joined the faculty of the Department of Molecular Genetics and Biochemistry (now Microbiology and Molecular Genetics) at the University of Pittsburgh School of Medicine in 1994. She was promoted to associate professor in 2000 and to full professor in 2006. Dr. Flynn has been a member of the Interdisciplinary Graduate Programs for 19 years and was director of the Molecular Virology and Microbiology Graduate Program for five years. She is also the program director on an NIH T32 Training Grant. She has numerous grants from NIH and the Bill and Melinda Gates Foundation, among others. She was an editor at *Infection and Immunity* from 2004 to 2014 and is currently a section editor for *PLOS Pathogens*. Dr. Flynn has served on numerous grant review study sections and on committees for national organizations, and she is currently a member of the National Institute of Allergy and Infectious Diseases Board of Scientific Counselors. She is also a member of Council for the American Association of Immunologists (AAI), and a Fellow of the American Academy of Microbiologists. She has published more than 150 papers and collaborates with scientists worldwide. Her research in tuberculosis is focused on immunology, host-pathogen interactions, vaccines, drugs, and animal models, and she has developed and used the non-human primate as a model for tuberculosis over the past 16 years.

**NANCY L. HAIGWOOD, PH.D.**

Dr. Nancy L. Haigwood is a professor of pathobiology and immunology and director of the Oregon National Primate Research Center at Oregon Health & Science University. She earned her B.S. in zoology with honors and her Ph.D. in microbiology and immunology at the

University of North Carolina at Chapel Hill; she did postdoctoral work at Johns Hopkins University, followed by 17 years in the biotechnology sector. From 1997 to 2007, she was a professor of microbiology and pathobiology at the University of Washington and a member at the Center for Infectious Disease Research in Seattle. Since 1986, her research has focused on HIV and AIDS. Her group studies the role of antibodies in mother-to-child transmission, as well as immunotherapies and novel vaccines in non-human primate models. Dr. Haigwood serves as a board member of Cascade AIDS Project in Portland and a member of the board of scientific counselors for the Vaccine Research Center at NIH. She was elected a Fellow of the American Academy of Microbiology in 2014.

#### **F. CLAIRE HANKENSON, D.V.M., M.S., D.A.C.L.A.M.**

Dr. F. Claire Hankenson is the director of Campus Animal Resources and the attending veterinarian at Michigan State University in East Lansing. In addition, she is a professor of laboratory animal medicine in the Department of Pathobiology and Diagnostic Investigation at the university's College of Veterinary Medicine. Dr. Hankenson obtained her veterinary degree from Purdue University. Following veterinary school, she completed her laboratory animal medicine residency and graduate work (M.S., microbiology) at the University of Washington, Seattle. She became a Diplomate of the American College of Laboratory Animal Medicine (ACLAM) in 2002. Dr. Hankenson's current position combines administrative service, regulatory input, clinical effort, and collaborative research. Dr. Hankenson has been active on committees within AALAS since 2002, serves on ACLAM's executive board (currently as president), and is an ad hoc consultant/specialist with AAALAC.

#### **JEFFREY KAHN, PH.D., M.P.H.**

Jeffrey Kahn is the Andreas C. Dracopoulos Director of the Johns Hopkins Berman Institute of Bioethics. He is also Robert Henry Levi and Ryda Hecht Levi Professor of Bioethics and Public Policy and a professor in the Department of Health Policy and Management in the Johns Hopkins University Bloomberg School of Public Health. His research interests include the ethics of research, ethics and public health, and ethics and emerging biomedical technologies. He speaks widely both in the U.S. and abroad and has published four books and more than 125 articles in the bioethics and medical literature. He is an elected Fellow of the Hastings Center and has chaired or served on committees and panels for the National Institutes of Health, the Centers for Disease Control and prevention, and the Institute of Medicine/National Academy of Medicine, where he is currently chair of the Board on Health Sciences Policy. His education includes a B.A. in microbiology (UCLA, 1983), an M.P.H. (Johns Hopkins, 1988), and a Ph.D. in philosophy (Georgetown, 1989).

#### **SABINE KASTNER, M.D., PH.D.**

Dr. Sabine Kastner is a professor of neuroscience and psychology in the Princeton Neuroscience Institute and Department of Psychology and serves as the scientific director of Princeton's neuroimaging facility. Dr. Kastner earned her M.D. in 1993 and Ph.D. in 1994 and received postdoctoral training at the Max Planck Institute for Biophysical Chemistry and the National Institute of Mental Health before joining the faculty at Princeton University. She studies the

neural basis of visual perception, attention, and awareness in the healthy, adult primate brain, as well as in patients with brain lesions and during development. Dr. Kastner serves on several editorial boards and is a senior editor for *eLife*. Dr. Kastner engages in a number of outreach activities, such as fostering the careers of young women in science, promoting neuroscience in schools and public education (as chief editor of *Frontiers for Young Minds*), and exploring the intersection of visual neuroscience and art.

#### **ALLAN D. KIRK, M.D., PH.D., F.A.C.S.**

Dr. Allan D. Kirk is a professor of surgery, pediatrics, and immunology at Duke University. He serves as chair of the Department of Surgery and surgeon-in-chief for the Duke University Health System. He is the editor-in-chief for the *American Journal of Transplantation*. Dr. Kirk received his M.D. and Ph.D. in immunology at Duke, and he completed a surgery residency at Duke. He completed an organ transplant fellowship at the University of Wisconsin. Dr. Kirk served as a senior investigator at NIH and as chief of the Transplantation Branch for NIDDK from 2001 to 2007. In 2007, he moved to Emory University, as professor and vice chair for surgical research. Since 2014, he has been in his current position at Duke. His work has focused on translational development of anti-rejection therapies in organ transplantation. He has published more than 250 manuscripts in the peer-reviewed literature, and he maintains a clinical kidney transplant practice and a laboratory effort with active NIH, FDA, and Department of Defense funding.

#### **JANET M. McNICHOLL, M.D., M.MED. SC., M.B.**

Dr. McNicholl is currently a Medical Scientist, Team Lead, Pre-Clinical evaluation Team, Laboratory Branch, Division of HIV/AIDS Prevention, National Centers for HIV, Hepatitis TB and STD Prevention, Centers for Disease Control and Prevention. Dr. McNicholl was educated in Ireland, where she received degrees in general science, medical science (immunology), and medicine and worked as a resident and registrar. She completed fellowships in allergy/immunology and rheumatology at Johns Hopkins University and Emory University and is board certified in internal medicine and rheumatology. She was on faculty at Emory University before becoming a medical scientist and HIV Immunology Section Chief at the Centers for Disease Control (CDC) in 1992. From 2004 to 2009, she was chief of CDC's HIV/STI Laboratory in Thailand. Since 2009, she has been the team lead for preclinical evaluations in CDC's Division of HIV/AIDS. She has been a co-principal investigator, collaborator, and consultant on many AIDS and immunology-related NIH grants and has supervised doctoral students and research fellows at Emory, CDC-Atlanta, and CDC-Thailand. In Thailand, she assisted with national and regional HIV-related trainings in diagnostics, CD4 counts, flow-based immune assays, ELISPOT assays, viral loads, HIV resistance, and STI testing. She has experience implementing quality management, including leading CDC's Thailand Laboratory to be the first overseas CDC laboratory accredited by the College of American Pathologists. Her research has focused on autoimmunity, human genetics, and T-cell responses to HIV and HIV vaccines in humans, macaques, and small animals. In Thailand, she participated in human HIV phase I, II, and III trials on microbicides, vaccines, oral pre-exposure prophylaxis, HIV treatment, and pharmacokinetics, and she worked on national and regional studies on HIV prevalence, incidence and drug resistance. This work was conducted in

collaboration with Thai and regional ministries of health and the U.S. NIH HIV Prevention and Microbicide networks. Currently, she continues human HIV prevention research with CDC-Thailand and animal HIV prevention research related to vaccines and other biomedical preventions with partners in NIH, academia, and industry. She is particularly interested in how host immunity affects vaccines, other biomedical preventions, and HIV risk factors in influencing HIV acquisition or disease.

**LAVONNE MEUNIER, D.V.M., D.A.C.L.A.M., D.A.C.A.W.**

Dr. LaVonne Meunier is director of veterinary medicine and attending veterinarian at GlaxoSmithKline Pharmaceuticals. She received her D.V.M. from the University of Minnesota, then practiced small animal medicine for eight years before becoming involved in laboratory animal medicine. She is a Diplomate of the American College of Laboratory Animal Medicine and a charter Diplomate of the American College of Animal Welfare. She is currently the president of Association of Primate Veterinarians.

**JOHN H. MORRISON, PH.D.**

Dr. John Morrison's research program focuses primarily on the neurobiology of aging and neurodegenerative disorders, particularly as they relate to cellular and synaptic organization of the cerebral cortex. Within this broad arena, his lab works specifically on the interactions between endocrine factors (e.g., estrogen, stress steroids) and aging and the synaptic determinants of cognitive aging from the perspective of synaptic health. His laboratory is particularly interested in age-related alterations in structural and molecular attributes of the synapse that compromise plasticity and lead to cognitive decline. Since 1985, the NIH has funded Dr. Morrison's research without interruption, including a grant on the neurobiological basis of cognitive aging that has been designated an NIH MERIT Award. Dr. Morrison has published more than 300 articles on cortical organization, the cellular pathology of neurodegenerative disorders, the neurobiology of cognitive aging, and the effects of stress on cortical circuitry. He has trained dozens of postdocs and graduate students. He was the dean of basic sciences and the Graduate School of Biomedical Sciences at the Icahn School of Medicine at Mount Sinai before coming to the University of California, Davis, in October 2015 as professor of neurology and director of the California National Primate Research Center.

**CHARLES E. MURRY, M.D., PH.D.**

Dr. Charles E. Murry received his B.S. in chemistry from the University of North Dakota, followed by M.D.-Ph.D. training at Duke University, where he studied myocardial ischemia-reperfusion injury. He did residency training in pathology at the University of Washington (UW), followed by fellowships in vascular biology and diagnostic cardiovascular pathology. He is currently a professor of pathology, bioengineering, and medicine/cardiology at the UW. Dr. Murry's research focuses on stem cell biology, emphasizing differentiation of the human cardiovascular system and using these cells to study diseases and regenerate damaged tissues. His group is a world leader in heart regeneration and is working toward a clinical trial using cardiomyocyte therapy. Dr. Murry is interim director of the UW Institute for Stem Cell and

Regenerative Medicine, director of the UW Medicine Heart Regeneration Program, and co-director of the UW Center for Cardiovascular Biology. He has received numerous awards for teaching and scientific achievement.

**CHRISTIAN E. NEWCOMER, V.M.D., M.S., D.A.C.L.A.M.**

Dr. Christian E. Newcomer is the recently retired executive director of AAALAC International and has been involved in AAALAC International's peer review activities for the past 30 years. He is a 1977 graduate of the School of Veterinary Medicine at the University of Pennsylvania. Following a large animal veterinary internship at the Pennsylvania State University, he completed training in laboratory animal medicine at the University of Michigan and became board certified in the American College of Laboratory Animal Medicine (ACLAM) in 1982. During his career, he held academic and leadership positions in laboratory animal medicine at the Massachusetts Institute of Technology (1981–1987), Tufts-New England Medical Center and Tufts University School of Veterinary Medicine (1987–1994), the University of North Carolina at Chapel Hill (1994–2001), the Veterinary Resources Program at NIH (2001–2003), and Johns Hopkins University (2003–2008). He is a past president of ACLAM and of the American Association for Laboratory Animal Science. Dr. Newcomer currently serves on the board of directors as treasurer for Public Responsibility in Medicine and Research.

**BILL NEWSOME, PH.D.**

Dr. Bill Newsome is an investigator of the Howard Hughes Medical Institute and professor of neurobiology at the Stanford University School of Medicine. He received a B.S. in physics from Stetson University and a Ph.D. in biology from the California Institute of Technology. Dr. Newsome is a leading investigator in systems and cognitive neuroscience. He has made fundamental contributions to our understanding of the neural mechanisms underlying visual perception and simple forms of decision making. Among his honors are the Rank Prize in Optoelectronics, the Spencer Award, the Distinguished Scientific Contribution Award of the American Psychological Association, the Dan David Prize of Tel Aviv University, the Karl Spencer Lashley Award of the American Philosophical Society, and the Champalimaud Vision Award. His distinguished lectureships include the 13th Annual Marr Lecture at the University of Cambridge, the 9th Annual Brenda Milner Lecture at McGill University, and, most recently, the Distinguished Visiting Scholar lecture at the Kavli Institute of Brain and Mind, University of California, San Diego. He was elected as a member in the National Academy of Sciences in 2000 and to the American Philosophical Society in 2011. Dr. Newsome recently co-chaired the NIH BRAIN working group, charged with forming a national plan for the coming decade of neuroscience research in the United States.

**STEVEN M. NIEMI, D.V.M., D.A.C.L.A.M.**

Dr. Steve Niemi is director, Office of Animal Resources, and lecturer in the department of organismal and evolutionary biology, Harvard University Faculty of Arts Sciences. With over 35 years' experience in biomedical research and commercial biotechnology, he has held senior management positions in contract drug and device development, biotech start-ups in gene therapy and genomics, and laboratory animal care and assurance. Dr. Niemi is a Diplomate and

past president of the American College of Laboratory Animal Medicine, and he has served on numerous boards and national task forces addressing medical product development and lab animal welfare. He earned an A.B. in biology from Harvard College and a D.V.M. from Washington State University, then received a U.S. Public Health Service National Research Service Award while a postdoctoral fellow at the Massachusetts Institute of Technology. He later completed the Program for Management Development at the Harvard Business School.

#### **DAVID O’CONNOR, PH.D.**

Dr. David O’Connor received his B.S. from the University of Illinois at Urbana Champaign and his Ph.D. from the University of Wisconsin–Madison. He is a professor of pathology and laboratory medicine in the University of Wisconsin–Madison School of Medicine and Public Health and the associate director for research services at the Wisconsin National Primate Research Center. His research focuses on the interplay of genetics, immunity, and pathogenesis of RNA viruses such as HIV and Zika virus.

#### **KYLE E. ORWIG, PH.D.**

Dr. Kyle Orwig joined the faculty of the University of Pittsburgh in 2003. He is a professor of obstetrics, gynecology, and reproductive sciences and director of research in the Division of Reproductive Endocrinology and Infertility. Dr. Orwig has been continuously funded by NIH and other sources for research focused primarily on stem cells and spermatogenic lineage development in rodents, monkeys, and men. He is the founding director of the Fertility Preservation Program at the University of Pittsburgh Medical Center. In this capacity, he is keenly interested in understanding the effects of chemotherapy and radiation on fertility. His group is actively developing stem cell technologies to preserve and restore the fertility of cancer patients. A second major area of research in the Orwig lab is determining the genetic basis of infertility and developing patient-specific gene therapies. In the current era of personalized medicine, this research stimulates thinking about the safety and feasibility of cutting-edge genome editing approaches, as well as their ethical, legal, and social implications.

#### **MICHAEL L. PLATT, PH.D.**

Dr. Michael Platt, the James S. Riepe University Professor at the Perelman School of Medicine, received a B.A. from Yale and a Ph.D. from the University of Pennsylvania, both in anthropology, and did a postdoctoral fellowship in neuroscience at New York University. He has been supported by NIH, the Klingenstein Foundation, the McDonnell Foundation, the Broad Foundation, the Simons Foundation, the Department of Defense, and others. He has authored over 130 papers, which have been cited over 4,000 times. Dr. Platt is director of the Wharton Neuroscience Initiative, former president of the Society for Neuroeconomics, former director of the Duke Institute for Brain Sciences, and former director of the Duke Center for Cognitive Neuroscience. He has received the Williams Research Prize and the Master Teacher Award from the Duke University School of Medicine. His work has been featured in the *New York Times*, *Washington Post*, *Wall Street Journal*, *Newsweek*, and *National Geographic*, as well as on ABC TV, NPR, CBC, BBC, and MTV.

**LINDA J. PORRINO, PH.D.**

Dr. Linda J. Porrino is currently professor and chair of the Department of Physiology and Pharmacology at Wake Forest School of Medicine. She received her Ph.D. from New York University and completed postdoctoral training at the National Institute of Mental Health. She joined the faculty at Wake Forest University in 1990. Her research, supported by two NIH grants, focuses on the use of brain imaging methods to visualize the effects of chronic drug use on brain structure and function. She is the past president of the College on Problems of Drug Dependence and has served on the Advisory Council of the National Institute on Drug Abuse. She is the author of more than 150 peer-reviewed publications and serves as an editor of *Drug and Alcohol Dependence*. Dr. Porrino has participated in numerous study sections and continues to serve as a mentor to graduate students, residents, fellows, and faculty.

**ERNEST D. PRENTICE, PH.D.**

Dr. Ernest D. Prentice is the associate vice chancellor for academic affairs at the University of Nebraska Medical Center (UNMC). He is the institutional official for both the UNMC Human Research Protection Program and the UNMC Animal Care and Use Program. Dr. Prentice is a frequent contributor to the literature on the ethics and regulation of both human and animal research and is a frequent speaker at meetings on various aspects of research ethics. Currently, Dr. Prentice is the chair of the CITI External Advisory Board and immediate past-president of the Scientists Center for Animal Welfare. From 2003 to 2007, he served as the chair of the HHS Secretary's Advisory Committee on Human Research Protection. In 2003, Dr. Prentice received the Harry C. Roswell Award for promoting laboratory animal welfare. In 2013, he received the Association of Clinical Research Professionals' Global Conference top speaker award and received the top speaker award for 2016 from MAGI.

**MARGARET FOSTER RILEY, J.D.**

Margaret (Mimi) Foster Riley is a professor at the University of Virginia (UVA) Law School, has a secondary appointment at the Medical School, and is affiliated with the Batten School of Public Policy. Ms. Riley has written and presented extensively about bioethics, research ethics, health care law, and food and drug law. She directs UVA's animal law program. She serves on a number of UVA's institutional review boards and has served on several National Academies committees devoted to research ethics. Ms. Riley has advised numerous committees of the Institute of Medicine, the National Institutes of Health, the National Science Foundation, the Food and Drug Administration, and the Virginia Bar. She received her bachelor's degree from Duke University and her law degree from Columbia University.

**JEFFREY ROGERS, PH.D.**

Dr. Jeffrey Rogers is an associate professor in the Human Genome Sequencing Center and the Department of Molecular and Human Genetics, Baylor College of Medicine. He serves as chair of the NIH National Primate Center's Working Group for Genetics and Genomics and is a core scientist for the Wisconsin National Primate Research Center. Dr. Rogers's research focuses on the genetics and genomics of non-human primates, with emphasis on neurogenetics and

behavioral genetics in primate models of psychiatric disorders. In collaboration with various colleagues, Dr. Rogers has published numerous articles on the genetics of individual differences in behavior among macaques, baboons, and other primates, targeting risk factors in mental illness. His work also includes genetic analyses of variation in primate neuroanatomy. Dr. Rogers has led or participated in several projects generating whole-genome assemblies for primates used in biomedical research, and he is currently conducting genome sequencing studies to discover and characterize SNPs and other genomic variation across several species, including macaques, baboons, and mouse lemurs. These studies are designed to identify novel genetic models of human disease.

#### **STEVEN J. SCHAPIRO, PH.D.**

Dr. Steven J. Schapiro is associate professor of comparative medicine in the Department of Veterinary Sciences of the University of Texas MD Anderson Cancer. He is the chief of the Section of Primate Behavior and Environmental Enrichment. For more than 25 years, his research group has been conducting studies focused on the behavior and welfare of captive rhesus monkeys and chimpanzees, including collaborative research projects funded by NIH and the National Science Foundation. A relevant emphasis of his research program is to provide non-human primates with opportunities to voluntarily participate in their own care. He is a co-founder of the Primate Training and Enrichment Workshop and the founder of the Primate Behavioral Management Conference. He is the editor of the forthcoming *Handbook of Primate Behavioral Management*, to be published by Taylor & Francis. He is a past-president and former treasurer of the American Society of Primatologists, and the current treasurer and vice president for membership of the International Primatological Society.

#### **KRISHNA SHENOY, PH.D.**

Prof. Krishna Shenoy is a professor of electrical engineering, bioengineering, and neurobiology at Stanford University. He is also a Howard Hughes Medical Institute investigator. Prof. Shenoy directs the Stanford Neural Prosthetic Systems Lab and codirects the Stanford Neural Prosthetics Translational Laboratory. His honors and awards include a Burroughs Wellcome Career Award in the Biomedical Sciences, a Sloan Fellowship, a McKnight Technological Innovations in Neurosciences Award, an NIH Director's Pioneer Award, the 2010 Stanford University Postdoc Mentoring Award, and election as a Fellow of the American Institute for Medical and Biological Engineering (AIMBE) College of Fellows.

#### **PETER L. STRICK, PH.D.**

Dr. Peter L. Strick is the founding scientific director of the University of Pittsburgh Brain Institute, as well as Thomas Detre Chair and distinguished professor of the Department of Neurobiology. Dr. Strick earned a B.S. and Ph.D. from the University of Pennsylvania and was a staff fellow in the Laboratory of Neurophysiology at the National Institute of Mental Health. In 1976, Dr. Strick moved to the VA Medical Center in Syracuse, New York, and joined the Departments of Neurosurgery and Physiology at the State University of New York Upstate Medical Center. In 2000, Dr. Strick moved to the University of Pittsburgh School Of Medicine. Dr. Strick was elected to the American Academy of Arts and Sciences in 2004 and to the

National Academy of Sciences in 2012. His research focuses on the generation and control of voluntary movement by the cortical motor areas, the motor and cognitive functions of the basal ganglia and cerebellum, the neural basis for the mind-body connection, and unraveling the complex neural networks that comprise the central nervous system.

#### **TERESA K. WOODRUFF, PH.D.**

Dr. Teresa Woodruff is the Thomas J. Watkins Professor of Obstetrics and Gynecology, the vice chair of research (OB/GYN), the chief of the Feinberg School of Medicine's Division of Reproductive Science in Medicine, and professor of molecular biosciences at the Weinberg College of Arts and Sciences at Northwestern University. She is an internationally recognized expert in ovarian biology and, in 2006, coined the term "oncofertility" to describe the merging of two fields: oncology and fertility. She now heads the Oncofertility Consortium, an interdisciplinary team of biomedical and social scientist experts from across the country. Dr. Woodruff also serves as the founding director of the Women's Health Research Institute. Dr. Woodruff was awarded the Presidential Award for Excellence in Science, Mathematics, and Engineering Mentoring in 2011 by President Obama for her work with the Women's Health Science Program. In addition to her academic stewardship, she also served as the president of the Endocrine Society from 2013 to 2014. Dr. Woodruff leads a large group of scientists, postdoctoral fellows, graduate students, undergraduates, visiting scholars, and technicians who together make up the Woodruff Lab.

#### **JOANNE ZURLO, PH.D.**

Dr. Joanne Zurlo's current interest is in the integrity of animal models for human disease, from scientific, ethical, and translational perspectives. Included in this interest is the need to implement appropriate care and welfare guidelines for animals used in research to ensure that the animal models are providing scientifically valid data that can be used to extrapolate to human disease. Intrinsic to this process is the understanding of animal behavior, specifically the necessity for animals to express species-specific behaviors in a captive environment. From 2000 to 2010, she was the director of the Institute for Laboratory Animal Research (ILAR) at the National Academy of Sciences, where she oversaw the development of expert reports related to the use of animals in research, including the eighth edition of the *Guide for the Care and Use of Laboratory Animals*. When she rejoined the Hopkins faculty in 2010, she continued her efforts to bring scientists and veterinarians together to share information and encourage research into the welfare of laboratory animals. Included in these activities were two workshops devoted to the use of dogs in biomedical research and testing, several workshops on refinement of laboratory animal practices (both in the U.S. and in Europe), and most recently, a series of workshops focused on facilitating the social housing of social laboratory animal species. Her work, both at ILAR and at Hopkins, has emphasized a need for international cooperation and harmonization in the area of laboratory animal care. She will be co-chairing the 2017 World Congress on Animals and Alternatives in the Life Sciences, which will have as one focus the appropriate use of animal models.

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