



HARVARD ANIMAL LAW & POLICY PROGRAM

Future Directions for Laboratory Animal Law in the United States: Pre-Workshop Webcast and Workshop

In the United States, two major federal laws apply to vertebrate animals used in laboratory research. The first of these two statutes, the Animal Welfare Act (AWA, under the US Department of Agriculture), celebrated its fiftieth anniversary in 2016. The second statute, the Health Research Extension Act of 1985 (also referred to as the Public Health Services Act, or PHS Act), which is similar to the AWA, applies specifically to work funded by the US Public Health Service (i.e., agencies under the Department of Health and Human Services). Understanding laboratory animal law is necessary and fundamental for all researchers relying on results from animal research, laboratory animal veterinarians, institutional officials, Institutional Animal Care and Use Committee (IACUC) members and veterinarians in training. They require familiarity with both the scope and particulars of these laws. Different parties interested in or impacted by laboratory animal laws can have significantly different perspectives about the scope or efficiency of the regulations or their implementation.

The Roundtable on Science and Welfare in Laboratory Animal Use of the Institute for Laboratory Animal Research, the Animal Law and Policy Program and the Petrie-Flom Center for Health Law Policy, Biotechnology and Bioethics of the Harvard Law School will convene a pre-workshop webcast and a workshop to discuss the future of federal laboratory animal law in the United States.

On **January 17, 2018, noon EST**, the [pre-workshop webcast](#) will provide an overview of applicable laws and regulations governing the care and use of laboratory animals.

On **January 26, 2018**, the [workshop](#) will examine how technological advances, such as CRISPR/Cas9, may impact the current legal framework, including our ability to sustainably support laboratory animal welfare.

Pre-workshop Webcast

Laws and Regulations Governing the Care and Use of Laboratory Animals: An Overview

January 17, 2018 12 noon EST

<http://nas-sites.org/ilar-roundtable/roundtable-activities/future-of-animal-law/>

Presenter: Margaret Foster Riley, University of Virginia School of Law



Margaret (Mimi) Foster Riley teaches food and drug law, health law, animal law, bioethics, regulation of clinical research and public health law. Riley has written and presented extensively about health care law, biomedical research, genetics, reproductive technologies, stem cell research, animal biotechnology, health disparities and chronic disease. She serves as chair of UVA's Embryonic Stem Cell Research Oversight Committee and as legal advisor to the Health Sciences Institutional Review Board, which is responsible for reviewing all human subject research at UVA involving medically

invasive procedures. She served on the National Research Council Committee on Revisions to the Common Rule for the Protection of Human Subjects and has advised numerous committees of the Institute of Medicine and the Virginia Bar. Before coming to Virginia, Riley was an associate with Pepper Hamilton & Scheetz in Philadelphia, where she worked primarily in complex securities, commercial and mass tort litigation. Prior to that position, she was a litigation associate with Rogers & Wells in New York. Riley received her law degree from Columbia University and her bachelor of arts from Duke University.

Future Directions for Laboratory Animal Law in the United States: A Workshop

January 26, 2018

Harvard Law School

Milstein East (2036), Wasserstein Hall (WCC)

1585 Massachusetts Avenue, Cambridge, MA 02318

Agenda

8:30am -9:00 **Registration**

9:00-9:15 **Welcoming Remarks**

- Lida Anestidou – Institute for Laboratory Animal Research, National Academies of Sciences, Engineering and Medicine
- Carmel Shachar - The Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics at Harvard Law School
- Chris Green - Animal Law and Policy Program, Harvard Law School (*organizing committee member*)

9:15-10:00 **Keynote Presentation**

Bernadette Juarez, US Department of Agriculture - Animal and Plant Health Inspection Services

Moderator: Chris Green

10:00-11:00 **Revision**

The laws, regulations and policies that govern the use of animals in laboratories create a complex and not always consistent system. In this panel, we will hear different perspectives about how this system currently operates, and how it might be changed. As we look to the future, what aspects of federal laws should or could be changed? Do the goals as currently set out in federal laws need to be changed? If so, to what and how?

- Richard Born, Harvard Medical School
- Delcianna J. Winders, PETA Foundation & Elisabeth Haub School of Law at Pace University

Moderator: Anne Deschamps, Federation of American Societies for Experimental Biology (*organizing committee member*)

11:00-11:15 **Break**

11:15-12:15 **Reach - Part 1: Expanding Laboratory Animal Laws to Other Species and Other Research Purposes**

This session will address whether current federal laws, regulations and policies addressing animals in research setting should be expanded to cover currently exempted species, including animals in agricultural research. Speakers will also

discuss the possible impact on the resources required for implementation of such laws, regulations and/or policies.

- Steven M. Niemi, Harvard University (*organizing committee co-chair*)
- Lawrence B. Schook, University of Illinois

Moderator: Szczepan Baran, Novartis (organizing committee member)

12:15-1:15 pm **Lunch**

1:15-2:15 **Reach - Part 2: Expanding Laboratory Animal Laws to New Technologies and Organizations and Other Animal Owners**

The development of new genetic technologies and the growing involvement of veterinary clinics in animal research have created uncertainty and potential gaps in the regulatory oversight of animal use in basic science and pre-clinical trials. This session will examine challenges posed by the emergence of gene drive research - which seeks to develop genetically modified animals in the lab for intentional release into wild populations - and the growing practice of recruiting private individuals' sick pets into clinical studies on both human and animal diseases.

- Lisa Moses, Harvard Medical School & MSPCA-Angell Animal Medical Center
- Kenneth Oye, MIT

Moderator: Elizabeth Heitman, University of Texas Southwestern Medical Center (organizing committee member)

2:15-3:15 **Resolution**

This session will address significant and/or interesting potential legal conflicts related to laboratory animals that may arise in coming years.

- Jerrold Tannenbaum, UC Davis School of Veterinary Medicine
- Nathan W. Herschler, New England Anti-Vivisection Society

Moderator: Richard L. Cupp, Pepperdine University School of Law (organizing committee member)

3:15-4:00 **Closing Comments and General Discussion**

Paul A. Locke, Johns Hopkins University (*organizing committee co-chair*)

4:00 **Adjourn**