

INSTITUTE OF MEDICINE AND NATIONAL RESEARCH COUNCIL

OF THE NATIONAL ACADEMIES

Forum on Neuroscience and Nervous System Disorders
Committee on Science, Technology, and Law
Institute for Laboratory Animal Research

U.S. and European Animal-Research Regulations: Impact on Neuroscience Research

July 26-27, 2011
Kavli Royal Society International Centre, Chicheley Hall
Buckinghamshire, UK

Background: Numerous regulations, laws, directives, and policies are in place to ensure the ethical use of animals in medical and life-sciences research. These regulations are intended to ensure the humane care and use of animals in research and that practical steps are taken to use the smallest number of animals to give significant results while ensuring that each individual animal experiences minimum pain or distress. The goal of the workshop is to bring together researchers, legal scholars, administrators, and other key stakeholders to discuss current trends and differences in animal regulations. Particular attention will be paid to identifying potential implications of new regulations on neuroscience research. The workshop will also provide an opportunity for international dialog around engaging the public regarding animal use in research and the development of core principles and outcomes for animal care and use.

Meeting Objectives:

With particular reference to neuroscience research, to:

- Identify and discuss international differences in animal-research regulations
 - Discuss current and emerging issues
- Discuss legal trends and activity in the courts that may impact research
- Examine the implications of regulations on the neuroscience research enterprise
- Discuss current communication strategies regarding animal research
- Explore the feasibility of developing a set of global core principles and outcomes for animal care and use.

DAY ONE

8:00 a.m. Breakfast

8:30 a.m. Welcome, Introductions and Objectives

COLIN BLAKEMORE, *Co-Chair*
ARTHUR SUSSMAN, *Co-Chair*

8:45 a.m. Animal Research in the Neurosciences

COLIN BLAKEMORE

SESSION I: CURRENT REGULATIONS AND EMERGING ISSUES

Session Objective: Highlight current animal-research regulations, policies and guidance. Review differences in approaches to regulations and practices exemplified by US and EU and new regulation currently being proposed in emerging regions (e.g. Asia and South America). Include a review of current and emerging issues in animal-research regulations.

9:15 a.m. Overview and Session Objectives

JUDY MACARTHUR CLARK, *Session Chair*

9:25 a.m. Europe

KARIN BLUMER
Scientific Affairs
Novartis, Switzerland

9:50 a.m. US

TAYLOR BENNETT
Senior Scientific Advisor
National Association for Biomedical Research

10:15 a.m. Asia

JIANFEI WANG
Director, Laboratory Animal Science
GlaxoSmithKline, R&D China

10:40 a.m. South America

EKATERINA RIVERA
Professor, Biological Sciences Institute
University of Goias

11:05 p.m. Panel discussion with speakers and participants:

- What is the basis for regulatory differences between countries?
- What are emerging key issues surrounding animal-research regulations?

12:00 p.m. LUNCH

SESSION II: IMPACT OF LEGAL TRENDS ON ANIMAL RESEARCH

Session Objective: Discuss changes to laws regarding animal rights on regulations and research. Explore emerging laws and legal strategies that have the potential to directly influence the use of animals in medical research.

1:15 p.m. Overview and Session Objectives

ARTHUR SUSSMAN, *Session Chair*

1:25 p.m. Animal rights laws

- Examine the interplay between the legal system and animal use regulatory system.
- What are the potential implications of changes to the legal rights of animals on regulations? Research?
- What are current trends, US vs. European differences?

MARGARET FOSTER-RILEY
Professor
University of Virginia, School of Law

1:45 p.m. Freedom of Information and Openness

- How are these laws being used by the animal rights movement?
- Are there limitations to the type of information that can be obtained?
- Can greater transparency lead to less effort needed in response to FOI demands?

MARGARET SNYDER
Health Scientist Administrator
Office of Extramural Research
National Institutes of Health

2:05 p.m. State Sunshine Laws

- How are these laws being used by the animal rights movement?
- Are there limitations to the type of information that can be obtained?
- Can greater transparency reduce requests for information?

RICHARD CUPP
John W. Wade Professor of Law
Pepperdine Law School

2:15 p.m. Discussion with speakers and participants

2:40 p.m. BREAK

SESSION III: THE IMPACT OF REGULATIONS ON ANIMAL-BASED NEUROSCIENCE RESEARCH

Session Objective: Discuss the impact of current regulations, policies, guidance and economic considerations on the conduct of animal-based neuroscience research. Consider the role that animals have played in neuroscience research; the benefits achieved but also the costs. Include examination of the administrative load and economic cost associated with animal research regulations and response of researchers and funders to cost implications.

3:10 p.m. Overview and Session Objectives

ROBERTO CAMINITI, *Session Chair*

3:20 p.m. Panelists:

Use of rodent models in neuroscience

BILL YATES
Professor
University of Pittsburgh

When should NHP be used as animal models?

ROGER LEMON
Sobell Chair of Neurophysiology
UCL Institute of Neurology

The ethical and practical dilemmas of research on NHP

STUART ZOLA
Director
Yerkes National Primate Research Center

Administrative and economic cost

CHARLES J. HECKMAN
Professor
Northwestern University Feinberg School of Medicine

4:40 p.m. Discussion with speakers and participants:

- How has the implementation of current and new regulations impacted the speed and quality of research, positively and negatively?
- Has the pressure for reduction of numbers, use of 'lower' species, reduction of cost and replacement of animals distorted the balance of neuroscience research in ways that impede the rate of discovery?
- How can we assess costs to animals, especially cumulative severity in long term animal studies, including NHPs?
- How can administrators and scientists work together to balance the economic costs of animal research regulations while maintaining public confidence?

5:30 p.m. ADJOURN

DAY TWO

8:00 a.m. Breakfast

SESSION IV: IMPACT OF 3Rs ON THE NEUROSCIENCE RESEARCH ENTERPRISE

Session Objective: Examine experiences of applying all the 3Rs (replacement, refinement, reduction) in neuroscience research, including consideration of opportunities for enhanced scientific outcomes as well as welfare benefits and potential limitations. Examine the influence that non-researchers and others have on neuroscience researchers working with animals. Consider the role of systematic reviews, or the review and synthesis of all relevant studies by the application of scientific strategies,

8:30 a.m. Overview and Session Objectives

COLIN BLAKEMORE, *Session Chair*

8:40 p.m. Panelists:

Replacement strategies in neuroscience research: Focus on spinal cord injury

SUE BARNETT
Professor of Cellular Neuroscience
University of Glasgow

Refinement and reduction strategies: improving models of disease and using translational approaches in epilepsy and Parkinson's disease.

GAVIN WOODHALL
Reader in Neuropharmacology
Aston University

The Role of Systematic Reviews

ANNE MURPHY
Associate Professor
University of California, San Diego

Future Considerations and Impact of 3Rs

JACKIE HUNTER
OI Pharma Partners

10:20 a.m. Discussion with speakers and participants:

- How can the 3Rs be best used effectively to deliver advancements in neuroscience?
- For what areas of neuroscience research is replacement a realistic long-term goal? How can this objective be most effectively pursued?
- Are current regulations causing neuroscientists to move away from animal work or to use less strictly regulated models?

- Are new regulations impeding the progress of neuroscience, or leading to neuroscience advancements?
- Is collaboration between sectors (industry/academia) effective and what is the impact of greater globalization of research?
- Critical analysis of systematic reviews – do they play a role? If so, should there be a new approach to experimental design so as to facilitate such reviews?

11:00 a.m. BREAK

SESSION V: ENGAGING AND INFORMING THE PUBLIC

Session Objective: Provide an opportunity for international dialog around communication strategies regarding animal use in research. Examine successes and failures in the engagement of the public, politicians and the media in productive discussions of the use of animals in research. Identify opportunities to educate non-researchers in the animal use regulatory system.

11:15 a.m. Overview and Session Objectives

FRANKIE TRULL, *Session Chair*

11:25 a.m. Panelists:

Neuroscientist

RANDALL NELSON
Professor
The University of Tennessee Health Science Center

Popular Press Journalist

PALLAB GHOSH
Science News Correspondent
BBC

Science Writer

MARK HENDERSON
Science Correspondent
The Times

Patient group administrator

TIM COETZEE
Chief Research Officer
National Multiple Sclerosis Society

12:25 p.m. Discussion with speakers and participants

- What is the responsibility of individual scientists, patient groups and organizations to engage the public in dialog about animal research?

- Are there teachable examples of successful engagement and dialog by animal researchers with the public?

1:00 p.m. LUNCH

SESSION VI: CORE PRINCIPLES FOR ANIMAL RESEARCH REGULATION

Panel Objective: Provide an opportunity for international dialog around the development of core principles and outcomes for regulating animal research. Identify areas of research where such adoption would be beneficial. Discuss next steps in development of core principles and outcomes, including analysis of the role of the 3Rs (replacement, reduction, and refinement). Identify key stakeholders important for the success of this endeavor.

2:00 p.m. Overview and Session Objectives

RICHARD NAKAMURA, *Session Chair*

2:10 p.m. Panelists:

European Government Regulator

JUDY MACARTHUR CLARK
Chief Inspector
UK Home Office

US Government Regulator

PATRICIA BROWN
Director
Office of Laboratory Animal Welfare

Industry Representative

MARGARET LANDI
Vice President, Global Laboratory Animal Science;
Chief of Animal Welfare and Veterinary Medicine
GSK Pharmaceuticals

ILAR Council member

TIMO NEVALAINEN
Professor
University of Eastern Finland

3:30 p.m. Discussion with speakers and participants:

- Are there core principles and outcomes specific to regulations for animal use in neuroscience research?

4:15 p.m. MEETING WRAP-UP WITH SESSION CHAIRS

Panelists:

Session I: JUDY MACARTHUR CLARK

Session II: ARTHUR SUSSMAN

Session III: ROBERTO CAMINITI

Session IV: COLIN BLAKEMORE

Session V: FRANKIE TRULL

Session VI: RICHARD NAKAMURA

5:00 p.m. FINAL REMARKS

COLIN BLAKEMORE, *Co-Chair*
ARTHUR SUSSMAN, *Co-Chair*

5:30 p.m. ADJOURN
