



Office of Biotechnology Activities
National Institutes of Health
U.S. Department of Health and Human Services

Safety Considerations in Recombinant DNA Research with Pathogenic Viruses

NIH Recombinant DNA Advisory Committee Meeting



September 21-22, 2004

*Bethesda Marriott
Bethesda, Maryland*



AGENDA

Tuesday, September 21, 2004

- 8:30 a.m. - 8:40 a.m. **Opening Remarks**
Elias Zerhouni, M.D., Director, NIH
- 8:40 a.m. - 8:45 a.m. **Welcoming Remarks**
Amy P. Patterson, M.D., Director, Office of Biotechnology Activities, NIH
- 8:45 a.m. - 9:05 a.m. **Welcome and Introduction**
Moderators: *Neal DeLuca, Ph.D., University of Pittsburgh*
Kathryn Holmes, Ph.D., University of Colorado
- 9:05 a.m. - 9:20 a.m. **Roundtable Introductions**
- Session I: Recombinant Influenza Virus Research**
- 9:20 a.m. - 9:50 a.m. **Reverse Genetics Techniques to Generate Recombinant Viruses**
Yoshihiro Kawaoka, D.V.M., Ph.D., University of Wisconsin, Madison
- 9:50 a.m. - 10:20 a.m. **Characterization of the 1918 Influenza Virus**
Adolfo García-Sastre, Ph.D., Mount Sinai School of Medicine
- 10:20 a.m. - 10:50 a.m. **Highly Pathogenic Avian Influenza Virus Research**
Robert Webster, Ph.D., St. Jude Children's Research Hospital
- 10:50 a.m. - 11:20 a.m. **Vaccine Applications**
Kanta Subbarao, M.D., M.P.H., National Institute of Allergy and Infectious Diseases, NIH
- 11:20 a.m. - 11:35 a.m. **Break**
- Session II: SARS-Corona Virus**
- 11:35 a.m. - 12:05 p.m. **Recombinant SARS-CoV Research**
Ralph Baric, Ph.D., University of North Carolina, Chapel Hill

Tuesday, September 21, 2004 (continued)

12:05 p.m. - 1:05 p.m.

Lunch

Session III: Lessons from Research with Infectious Viruses

1:05 p.m. - 1:20 p.m.

Early Research with HIV

Larry Arthur, Ph.D., National Cancer Institute at Frederick, NIH

1:20 p.m. - 1:35 p.m.

Newcastle Disease Virus Research

Siba Samal, Ph.D., M.V.Sc., University of Maryland, College Park

Session IV: Guidance Provided by the NIH Guidelines for Research Involving Recombinant DNA Molecules and Biosafety in Microbiological and Biomedical Laboratories (4th edition) and U.S. Department of Agriculture (USDA) Regulations

1:35 p.m. - 2:05 p.m.

Risk Assessment and Containment

Emmett Barkley, Ph.D., Howard Hughes Medical Institute

2:05 p.m. - 2:20 p.m.

Update on the Revision to the Influenza Section of Biosafety in Microbiological and Biomedical Laboratories (4th edition)

Deborah Wilson, Dr.P.H., CBSP, Office of Research Services, NIH

2:20 p.m. - 2:35 p.m.

USDA Guidance

Lee Ann Thomas, D.V.M., M.S., Animal and Plant Health Inspection Service, USDA

2:35 p.m. - 3:05 p.m.

Public Questions and Comments

3:05 p.m. - 3:20 p.m.

Break

3:20 p.m. - 5:05 p.m.

Discussion of Points to Consider to Assist Institutional Biosafety Committee Reviews

5:05 p.m.

Adjournment

Wednesday, September 22, 2004

9:00 a.m. - 12:00 noon

Discussion of Points to Consider to Assist Institutional Biosafety Committee Reviews

12:00 noon

Adjournment

PANELISTS

RAC Members

Emmett Barkley
Director of Laboratory Safety
Howard Hughes Medical Institute

Neal DeLuca
Professor
Department of Molecular Genetics and
Biochemistry
School of Medicine
University of Pittsburgh

Larry Johnson
Associate Professor of Medicine
Division of Pulmonary Diseases and Critical
Care Medicine
Cystic Fibrosis/Pulmonary Research and
Treatment Center
University of North Carolina, Chapel Hill

Philip Johnson
Professor of Pediatrics
President
Children's Research Institute
Columbus Children's Hospital

Terry Kwan
Independent Collaborator
TK Associates

Glen Nemerow
Associate Professor
Department of Immunology
The Scripps Research Institute

Madison Powers
Director
Kennedy Institute of Ethics
Georgetown University

Naomi Rosenberg
Professor
Department of Pathology
School of Medicine
Tufts University

***Ad Hoc* Members**

Rafi Ahmed
Director
Emory Vaccine Center
Department of Microbiology and Immunology
School of Medicine
Emory University

Larry Arthur
Associate Director
National Cancer Institute at Frederick
National Institutes of Health
U.S. Department of Health and Human Services

Ralph Baric
Professor
Program in Infectious Diseases
Department of Epidemiology
School of Public Health
University of North Carolina, Chapel Hill

Cristina Cassetti
Program Officer, Basic and Preclinical Influenza
Research
Respiratory Diseases Branch
Division of Microbiology and Infectious Diseases
National Institute of Allergy and Infectious
Diseases
National Institutes of Health
U.S. Department of Health and Human Services

Adolfo García-Sastre
Professor of Microbiology
Department of Microbiology
Mount Sinai School of Medicine

Robert Heckert
National Program Leader, Animal Health
Agricultural Research Service
U.S. Department of Agriculture

Kathryn Holmes
Professor
Department of Microbiology
University of Colorado Health Sciences Center

Ad Hoc Members (continued)

Jacqueline Katz

Senior Service Fellow
Immunology and Viral Pathogenesis Section
Division of Viral and Rickettsial Diseases
National Center for Infectious Diseases
Centers for Disease Control and Prevention
U.S. Department of Health and Human Services

Yoshihiro Kawaoka

Professor
Department of Pathobiological Sciences
School of Veterinary Medicine
University of Wisconsin, Madison

Robert Krug

Professor of Molecular Genetics and Microbiology
Institute for Cellular and Molecular Biology
University of Texas, Austin

Robert Lamb

John Evans Professor of Molecular and Cellular
Biology
Investigator
Howard Hughes Medical Institute
Department of Biochemistry, Molecular Biology
and Cell Biology
Northwestern University

Sam Lipson

Director of Environmental Health
Cambridge Public Health Department

Randall Morin

Director
Environment, Health and Safety Program
National Cancer Institute at Frederick
National Institutes of Health
U.S. Department of Health and Human Services

Brian Murphy

Co-Lab Chief
Respiratory Viruses Section
Laboratory of Infectious Diseases
Division of Intramural Research
National Institute of Allergy and Infectious
Diseases
National Institutes of Health
U.S. Department of Health and Human Services

Janet Peterson

Assistant Director and Biosafety Officer
Department of Environmental Safety
University of Maryland, College Park

Siba Samal

Professor of Virology
Associate Dean and Department Chair
Virginia-Maryland Regional College of
Veterinary Medicine
University of Maryland, College Park

James Schmitt

Medical Director
Occupational Medical Service
Division of Safety
Office of Research Services
Office of the Director
National Institutes of Health
U.S. Department of Health and Human Services

Kanta Subbarao

Senior Investigator
Laboratory of Infectious Diseases
Division of Intramural Research
National Institute of Allergy and Infectious
Diseases
National Institutes of Health
U.S. Department of Health and Human Services

Lee Ann Thomas

Director
Animals, Organisms and Vectors, and Select
Agents
National Center for Import and Export
Veterinary Services
Animal and Plant Health Inspection Service
U.S. Department of Agriculture

Robert Webster

Professor
Department of Infectious Diseases
Division of Virology
St. Jude Children's Research Hospital

Deborah Wilson

Chief
Occupational Safety and Health Branch
NIH Biosafety Officer
Division of Safety
Office of Research Services
Office of the Director
National Institutes of Health
U.S. Department of Health and Human Services