NIH Guidelines: Honoring the Past, Charting the Future

National Institutes of Health
5635 Fishers Lane
Rockville, Maryland 20892
Conference Rooms 508/509

DAY 1 - Tuesday 18th July 2017

8:00 am – 8:30 am **Registration**

8:30 am – 9:00 am **Welcoming Remarks**

Carrie D. Wolinetz, Ph.D.
Associate Director for Science Policy, NIH

9:00 am – 9:15 am **Introduction**

Francis S. Collins, M.D., Ph.D.
Director, NIH

9:15 am – 10:00 am **SESSION I – Keynote Presentation**

The keynote will provide insights into the historical significance of Asilomar, the 40 year history of the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules, and the Recombinant DNA Advisory Committee (RAC); and explore the future of biosafety oversight in the life sciences in light of the emergence of new biotechnologies.

David Baltimore, Ph.D.
President Emeritus; Robert Andrews Millikan Professor of Biology, California Institute of Technology

10:00 am – 10:15 am **BREAK**

10:15 am – 11:30 am **SESSION II – The Current NIH Framework for the Oversight of Research with Recombinant or Synthetic Nucleic Acid Molecules**

This session will explore the current framework established by the NIH Guidelines, including the roles of Institutional Biosafety Committees (IBCs) and the RAC.

Panelists:

Jessica Tucker, Ph.D.
Director, Biosafety, Biosecurity and Emerging Biotechnology Policy Division, Office of Science Policy, NIH

Stephen J. Libby, Ph.D.
IBC Chair, Research Associate Professor, University of Washington

Hans-Peter Kiem, M.D., Ph.D.
Director, Cell and Gene Therapy Program, Fred Hutchinson Cancer Research Center

11:30 am – 12:45 pm **Lunch Break**

12:45 pm – 2:15 pm **SESSION III – Role of the *NIH Guidelines*: Intersection with Other Biosafety Regulations and Guidance**

The panel will examine the essential elements of the system of oversight established in the NIH Guidelines, and how the NIH Guidelines intersect or complement other biosafety guidance.

Panelists:

Federal Representatives

2:15 pm – 2:30 pm **BREAK**

2:30 pm – 4:15 pm **SESSION IV – Emerging Biotechnologies: Issues Raised for the Current System of Biosafety Oversight**

If Asilomar were today, what emerging biotechnologies would be captured in the biosafety oversight system? An overview of various emerging biotechnologies will be presented, along with a discussion of whether there are distinct biosafety issues posed by these technologies. Can these potential challenges be managed by the current framework for risk assessment and biosafety oversight?

Panelists:

Feng Zhang, Ph.D.
Professor in Neuroscience, MIT

Drew Endy, Ph.D.
Associate Professor, Bioengineering, Stanford University

Zach Adelman, Ph.D.
Associate Professor, Department of Entomology, Texas A&M University

Kenneth Oye, Ph.D.
Professor of Political Science, and Data Systems and Society, MIT

4:15 pm – 4:30 pm **Wrap-up of Day 1**

4:30 pm **ADJOURN**

DAY 2 – Wednesday 19th July 2017

8:00 am – 8:15 am **Introduction**

8:15 am – 10:15 am **SESSION V – Roundtable Discussion - Future Role of the RAC**

This roundtable will include a discussion of the benefits of having a public forum for biosafety discussions, and the types of engagement that would best meet the needs of the scientific community and the public. Questions explored will include, how can the RAC be best used to help ensure the safe advancement of life sciences research? Are there emerging biotechnologies that would benefit from the public engagement provided by RAC discussions? What role should the RAC have in providing biosafety guidance?

Moderator:

Howard Federoff, M.D., Ph.D.
Vice Chancellor for Health Affairs and CEO UC Irvine Health System, University of California, Irvine

Lead Discussants:

Marie-Louise Hammarskjöld, M.D., Ph.D.
Professor, Microbiology, Immunology, and Cancer Biology, University of Virginia

Margaret Foster Riley, J.D.
Professor of Law, University of Virginia

Joseph Kanabrocki, Ph.D, CBSP
Associate Vice President for Research Safety, University of Chicago

Nancy King, J.D.
Professor, Social Sciences and Health Policy, Wake Forest School of Medicine

10:15 am – 10:30 am **BREAK**

10:30 am – 12:30 pm **SESSION VI – Roundtable Discussion - Future Face of Biosafety Oversight**

This roundtable will include a discussion of what the ideal Federal and local oversight systems for helping to ensure the safe conduct of life sciences research might look like. Questions explored will include, what should be the scope of the biosafety oversight system? What are the pros and cons of a biosafety oversight framework that focuses on research with recombinant or synthetic nucleic acid molecules? Are there additional types of research that pose biosafety concerns that warrant oversight, which are not captured in the current system; are there types of research that are part of the current system that no longer require such oversight? How can we help ensure adequate biosafety oversight without unduly burdening the research enterprise?

Moderator:

Joseph Kanabrocki, Ph.D, CBSP
Associate Vice President for Research Safety, University of Chicago

Lead Discussants:

Elizabeth Gilman Duane, M.S., RBP, CBSP
Biosafety/Laboratory Safety Service Leader, Environmental Health and Engineering, Inc.

Lydia Sohn, Ph.D
IBC Chair, Professor of Mechanical Engineering, University of California, Berkeley

Ara Tahmassian, Ph.D.
Chief Research Compliance Officer, Harvard University

Maureen O'Leary Ph.D., CBSP
President, American Biological Safety Association (ABSA) International

12:30 pm – 12:45 pm	**SESSION VII - Open Forum for Stakeholder Input**
12:45 pm – 1:00 pm	**Closing Remarks** ***Carrie D. Wolinetz, Ph.D.*** **Associate Director for Science Policy, NIH**
1:00 pm	**ADJOURN**