NIH Guidelines:
Honoring the Past, Charting the Future

Bethesda North Marriott Hotel & Conference Center
Salon F – H
5701 Marinelli Rd
Rockville, MD 20852

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.
Acting Chief of Staff &
Associate Director for Science Policy,
NIH

9:00 am – 9:15 am **Introduction of Keynote Speaker**

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 panel 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. (Moderator)
Director, Division of Biosafety, Biosecurity and Emerging Biotechnology Policy, Office of Science Policy, NIH

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

Hans-Peter Kiem, M.D., Ph.D.
Endowed Chair for Cell and Gene Therapy, 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**

This panel will examine how the NIH Guidelines intersect or complement other biosafety regulations and guidance documents.

Panelists:

Paul Meechan, Ph.D., MPH, RBP, CBSP, SM(NRCM) (Moderator)
Senior Advisor for Laboratory Safety, CDC

Deborah E. Wilson, RADM, DrPH, CBSP
Director, Division of Occupational Health and Safety, NIH

Samuel Edwin, Ph.D.
Director, Division of Select Agents and Toxins, CDC

Freeda E. Isaac, DVM
Director, Agriculture Select Agent Services, USDA

Thomas Nerad, MPH, Ph.D.
Director, Office of Biological Hazards, OSHA

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 aspects of emerging biotechnologies would raise unique risks or challenges for 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?

Panelists:

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

Feng Zhang, Ph.D.
James and Patricia Poitras Professor of Neuroscience, MIT

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

Drew Endy, Ph.D.
President, BioBricks Foundation
Associate Professor, Bioengineering, Stanford University

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

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:

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

Lead Discussants:

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

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

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

***Hans-Peter Kiem, M.D., Ph.D*.**
Endowed Chair for Cell and Gene Therapy, Fred Hutchinson Cancer Research Center

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, and where should NIH's oversight fit in? 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 NIH system; are there types of research that are part of the current NIH 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 and Professor of Microbiology, University of Chicago

Lead Discussants:

Elizabeth Gilman Duane, M.S., RBP, CBSP
Director, Environment, Health, Safety, and Sustainability, *Amgen Inc.*

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

Maureen O'Leary Ph.D., MBA, CBSP
President, American Biological Safety Association (ABSA) International
Director, Environmental Health and Safety, Dartmouth College

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

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.*** **Acting Chief of Staff &** **Associate Director for Science Policy,** **NIH**
1:00 pm	**ADJOURN**