



ROUNDTABLE ON ENVIRONMENTAL HEALTH SCIENCES, RESEARCH, AND MEDICINE  
with the COMMITTEE ON SCIENCE, TECHNOLOGY, AND LAW, NATIONAL RESEARCH COUNCIL

## **PRINCIPLES AND BEST PRACTICES FOR SHARING DATA FROM ENVIRONMENTAL HEALTH RESEARCH**

### **AGENDA**

**March 19, 2014**

Lecture Room

National Academy of Sciences Building  
2100 Constitution Avenue, NW  
Washington, DC

**March 19, 2014**

8:30 a.m.

#### **Welcome**

Frank Loy, LL.B.  
Roundtable Chair

8:40 a.m.

#### **Workshop Overview**

Lynn Goldman, M.D., M.P.H.  
Roundtable Vice-Chair  
Dean, School of Public Health and Health Services  
George Washington University

#### **Session 1: Brief History and Current Legal and Executive Branch Framework for Data-Sharing**

Objectives:

Federal rulemaking routinely involves the use of studies in which there are questions raised about how they were prepared and the reliability of the data and the conclusions drawn. Through the Administrative Procedure Act and the process of judicial review, there is now a reasonably well-developed understanding how agencies handle those problems and what information must be made available to the public, to OIRA, and to the courts (if judicial review is sought as it is for most significant rules).

The goal of this session is to inform workshop attendees on the basic ground rules of agency decision making in this area and to set the stage for the panels that follow.

Moderator: **Alan Morrison, LL.B.**, Lerner Family Associate Dean for Public Interest and Public Service Law, George Washington University

8:50 a.m. **Paul R. Verkuil, J.S.D.**  
Chairman, Administrative Conference of the United States

9:10 a.m. **George Gray, Ph.D.**  
Professor  
Department of Environmental and Occupational Health  
Director of the Center for Risk Science and Public Health  
School of Public Health and Health Services  
George Washington University

9:30 a.m. **Discussion** (20 minutes)

### **Session 2: Benefits and Importance of Data-Sharing**

Objectives:

Most researchers and policy makers in environmental health agree that, as in other fields, research data—especially when underpinning regulations—should be shared as freely as necessary. Most also recognize that there need be some limits on when and how data should be shared.

The goal of this session is to clarify when, why, and how data-sharing is beneficial for the researcher, the regulatory agency, the participants, and the public. The session should distinguish between sharing data for reanalysis and for facilitating replication.

Moderator: **Gwen Collman, Ph.D.**, Director, Division of Extramural Research and Training, National Institute of Environmental Health Sciences

9:50 a.m. **Panelist Presentations** (30 minutes)

**Bernard Lo, M.D.**  
President and CEO  
The Greenwall Foundation

**Francesca Dominici, Ph.D.**  
Professor of Biostatistics and Senior Associate Dean for Research  
Harvard University School of Public Health

**Julia Brody, Ph.D.**  
Executive Director  
Silent Spring Institute

**Louis Anthony (Tony) Cox, Jr., Ph.D.**  
Chief Sciences Officer, NextHealth Technologies

10:20 a.m.

**Panel Discussion (60 minutes)**

**Session 3: Challenges Associated with Data-Sharing**

Objectives:

While data-sharing is quickly becoming the norm, especially for federally-funded research, challenges exist for the investigator and her institution, the person or entity requesting the data, and the research participants, whose identity can be compromised. Concerns of the investigator are ensuring right to publication and to quality control over re-analyses.

The goal of the session is to articulate the potential administrative, ethical, financial, and public health drawbacks to data-sharing.

Moderator: **Glenn Paulson, Ph.D.**, Science Advisor, Office of the Administrator, U.S. Environmental Protection Agency

11:20 a.m.

**Panelist Presentations (30 minutes)**

**Daniel Barth-Jones, Ph.D., M.P.H.**  
Assistant Professor of Clinical Epidemiology  
Mailman School of Public Health  
Columbia University

**John Howard, M.D., M.P.H., J.D., LL.M.**  
Director, National Institute for Occupational Safety and Health

**Greg Bond, Ph.D.**  
Dow Masters Fellowship Program  
University of Michigan

**Kevin Casey, J.D.**  
Associate Vice President for Public Affairs and Communications  
Harvard University

11:50 a.m.

**Panel Discussion (60 minutes)**

12:50 p.m.

**Lunch Break (60 minutes)**

## **Session 4: Ways Forward—Practices, Technologies, and Tools for Data-Sharing**

Objectives:

As data-sharing becomes more common and an accepted practice, tools and best practices need to be identified to ensure the benefits of sharing data and avoid the challenges, as discussed earlier in the program. The goal of this session is the identify principles, practices, and programs that could be used more widely for maximizing data-sharing.

Moderator: **Lynn Goldman, M.D., M.P.H.**, Roundtable Vice-Chair

1:50 p.m. **Panelist Presentations** (30 minutes)

**Edward Sondik, Ph.D.**

Former Director,  
National Center for Health Statistics  
Centers for Disease Control and Prevention

**Daniel Greenbaum, M.S.**

President  
Health Effects Institute

**Kristina Thayer, Ph.D.**

Director  
Office of Health Assessment and Translation  
National Toxicology Program

**George Daston, Ph.D.**

Victor Mills Society Research Fellow  
Proctor & Gamble

2:20 p.m. **Panel Discussion** (60 minutes)

3:20 p.m. **Break** (20 minutes)

## **Session 5: Reflections on the Workshop and Concluding Remarks**

Objectives:

The objective of this session is to have reflections on the day, including next steps, from experts with different perspectives.

Moderator: **Frank Loy, LL.B.**, Roundtable Chair

3:40 p.m. **Linda S. Birnbaum, Ph.D., DABT, ATS**  
Director  
National Institute of Environmental Health Sciences  
National Institutes of Health

3:50 p.m. **Jerry Blancato, Ph.D.**  
Director  
Office of Science and Information Management  
Office of Research and Development  
U.S. Environmental Protection Agency

4:00 p.m. **Joseph Rodricks, Ph.D., DABT**  
Principal, ENVIRON

4:10 p.m. **Ellen Silbergeld, Ph.D.**  
Editor-in-Chief, Environmental Research  
Professor, Johns Hopkins Bloomberg School of Public Health

4:20 p.m. **Discussion (40 minutes)**

5:00 p.m. **Closing Remarks and Adjourn**

