



INSTITUTE OF MEDICINE

OF THE NATIONAL ACADEMIES

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 to 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**

