

## How to study research ethics?

*A dialogue between different (research) perspectives*

**May 6<sup>th</sup> 2011 / 12 – 4:30 pm**

Fainsod Room (John F. Kennedy School of Government, 79 John F. Kennedy Street, Littauer Building, Room 324)

### WORKSHOP OBJECTIVE

Research ethics (as widely understood) is often dealt with along the way by various strands of science studies (e.g., history and sociology of medicine, intellectual property law, comparative policy studies), but rarely studied in its own right. Moreover, the various strands have been working very much in parallel, from different perspectives, with different methods, and on different framings of the overall picture.

We are thus inviting you to an explorative discussion about the particular value of some of these disciplinary or field-specific perspectives, in order to assess synergies, perhaps meaningful differences, and potential avenues for future research.

### PRELIMINARY PROGRAM

**12:00 – 12:15**    **Getting settled** (*lunch and beverages will be provided*)

**12:15 – 12:30**    **Welcome and Introduction**

Sheila Jasanoff (Harvard Kennedy School, Director, STS Program)

Diana Schmidt-Pfister (University of Konstanz, Germany / STS Program, HKS)

**12:30 – 1:30**    **I    Disciplinary Perspectives on Norms and Practices in Science**

*Chair: Chris Jones (HKS, STS Program)*

What Counts? A Historian reflects on the Problems in Reconstituting Past Norms in Medicine and Science

*Charles E. Rosenberg (Harvard University)*

Creating and using history to broaden ethical perceptions of scientists

*Charles Weiner (MIT)*

Rotten Apples or a Rotting Barrel: Challenging the Orthodoxy of Methodological Individualism

*Susan Silbey (MIT)*

Ethics and Ontologies. A Co-Productionist View

*Sheila Jasanoff (HKS)*

**1:30 – 1:45**    *Coffee break*

**1:45 – 2:45      II Disciplinary Perspectives on Research Ethics and Governance**

*Chair: Margo Liptsin (HKS, STS Program)*

Empirical Investigations on Research Misconduct: Assumptions and Strategies

*Melissa S. Anderson (University of Minnesota)*

Reclaiming empirical ethics

*Laura Stark (Wesleyan University)*

Does Financial Conflicts of Interest Bias Research? An Inquiry into the “Funding Effect” Hypothesis

*Sheldon Krinsky (Tufts University)*

Research Ethics: From Headlines and Hotlines to Influences and Incentives

*Jonathan Marks (Pennsylvania State University / Edmond Safra Center for Ethics, Harvard University)*

2:45 – 3:00      *Coffee break*

**3:00 – 4:00      III – Enacting Ethics: Conflicts of interest in practice**

*Chair: Ellen Bales (HKS, STS Program)*

*David Korn (Harvard University, Vice Provost for Research)*

*Patrick Taylor (Children's Hospital Boston / Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics at Harvard Law School)*

*David Lewis (National Whistleblowers Center)*

**4:00 – 4:30      Wrap up and final discussion: Where to go from here?**

*Sheila Jasanoff (HKS, STS Program)*

*Diana Schmidt-Pfister (University of Konstanz, Germany / HKS, STS Program)*

## **Short abstracts**

### **What Counts? A Historian reflects on the Problems in Reconstituting Past Norms in Medicine and Science**

*Charles E. Rosenberg (Harvard University)*

I will discuss some problems and findings in research conducted on applied scientists (in medicine and agriculture) in late-nineteenth and early-twentieth century America. It will conclude with some reflections on continuities and discontinuities over time.

### **Creating and using history to broaden ethical perceptions of scientists**

*Charles Weiner (MIT)*

Historical case studies provide knowledge of patterns, contexts, and changing notions of research ethics and integrity and their relation to the human, social, and political consequences of science and technology. Examples include historical documentation of continuing conflicts related to commercialization and patenting of academic biomedical research, past and current efforts to anticipate the consequences of genetic technologies, university involvement in weapons development, and ongoing public controversies on the health and environmental effects of nuclear radiation.

### **Rotten Apples or a Rotting Barrel: Challenging the Orthodoxy of Methodological Individualism**

*Susan Silbey (MIT)*

Most people recognize two forms of causality: physical forces or atomic structure and human will or intention. When asked to interpret or explain social phenomena, common accounts conventionally rely on individual agency, choice and personality. Unable to recognize or describe forms of social organization, ordinary citizens as well as well trained scientists adopt a rationalist, often reductionist model of social action, producing an unreflexive orthodoxy. In my remarks, I will challenge the orthodoxy of what, in social science, is called methodological individualism -- the explanation that social life, including ethical behavior, is the result of individual choices and personality. Rather than address the orthodoxy head on, I will focus on issues of ethical misconduct to illustrate what is missing from conventional professional and scientific cultures.

### **Empirical Investigations on Research Misconduct: Assumptions and Strategies**

*Melissa S. Anderson (University of Minnesota)*

This presentation will consider assumptions that inform choices made in the course of collecting and analyzing empirical data on scientific misconduct. Studies grounded in scientists' experiences must be based on the best solutions available -- which are never perfect -- to methodological problems. Investigators must then control the interpretation of the findings, subject to unavoidable limitations.

### **Reclaiming empirical ethics**

*Laura Stark (Wesleyan University)*

The field of clinical bioethics evaluates the effectiveness of ethical and regulatory protections for the people who participate in research. Yet clinical bioethicists rarely explore the histories, assumptions, and implications of the ethical practices that they evaluate, such as consent practices. Scholars in STS are well

positioned to use the tools of knowledge-production to inquire about ethics-production by asking how “ethics work” is defined, by whom, and how demarcation is carried out. I will describe exemplary work by scholars such as Don Brenneis and Ray DeVries. This talk will also be based on my own ethnographic and historical research on ethics review for *Behind Closed Doors: IRBs and the Making of Ethical Research* (Chicago, in press).

### **Research Ethics: From Headlines and Hotlines to Influences and Incentives**

*Jonathan Marks (Pennsylvania State University / Edmond Safra Center for Ethics, Harvard University)*

A few high-profile disputes between physician-researchers and industry sponsors of clinical trials have attracted considerable attention, and (at some academic medical centers) have triggered significant institutional reforms, such as the creation of research ethics consultation services with telephone hotlines. Although these reforms are commendable, they do not address other important concerns—not least, the more subtle effects of sponsor influence and reciprocity on the design and interpretation of clinical trials and, more fundamentally, the role that research funding and other structural incentives play in determining which research questions are explored and which are neglected. Research ethics should speak to the institutional (as well as individual) actors who may be responsible for addressing these concerns, and explore potential procedural and substantive measures that might alleviate them.

### **Does Financial Conflicts of Interest Bias Research? An Inquiry into the “Funding Effect” Hypothesis**

*Sheldon Krimsky (Tufts University)*

The concept of a “funding effect” was coined when it was discovered that study outcomes could be statistically correlated with funding sources, largely in drug safety and efficacy studies. The “funding effect” was first found in the mid-1980s when drug studies were divided up by those funded by private companies versus those funded by non-profit organizations or government agencies. It has also been identified in tobacco research and chemical toxicity studies. This paper examines the strongest evidence for the “funding effect” and explores alternative explanations that can account for it. Systematic bias is one of several explanations. The paper draws on multiple product assessment (drugs) and single product assessment (tobacco and bisphenol A) to illustrate the complexities of concluding that the “funding effect” is a definitive indicator or research bias. Additional analyses of the methodology of the studies, interpretation of the data, and comparison of the products studied can resolve whether the existence of a “funding effect” is driven by scientific bias.