LEGAL ISSUES AND STRATEGIES
FOR RESPONDING TO
RESEARCH MISCONDUCT
ALLEGATIONS

May 30-31, 2001
Washington, DC

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AGENDA

Legal Issues and Strategies for Responding to Research Misconduct Allegations
May 30-31, 2001
Sheraton Four Points Hotel
Washington, DC

MAY 30, 2001

7:30am Registration

8:45 - 9:00am Welcome
Mark S. Frankel, AAAS, and Chris Pascal, Esq., ORI

SESSION I
The Regulatory Framework and Interactive Relationship Between Government and Institutional Policies

9:00-9:30am From Self-Regulation to Government Regulation: The Evolution of Responses to Research Misconduct
Paul Friedman, University of California, San Diego
Moderator: Alicia Dustira, ORI

9:30-10:30am Overview of Federal Policies and Procedures: Regulatory Framework for Responding to Allegations of Research Misconduct
Caroline Elmendorf, Esq., ORI, Anita Eisenstadt, Esq., NSF
Moderator: Kendra Dimond, Esq., Arent Fox Kintner Plotkin & Kahn

10:30-10:45am Break

10:45-11:30am Navigating the Regulatory Terrain: The Institutional Perspective
Sheila Zimmet, Esq., Georgetown University Medical Center
Moderator: Gregory Glover, Esq., Ropes & Gray

11:30-12:30pm Handling Research Misconduct Involving Violations of Other Federal Rules Governing Research (e.g., human & animal subjects, conflict of interest)
Dawn Crumel, Esq., Howard University, Susan Sherman, Esq., Office of Human Subjects Protection, DHHS, Barbara Mishkin, Esq., Hogan & Hartson
Moderator: Gary Ellis, U.S. Office of Science and Technology Policy

12:30-1:30pm Lunch
SESSION II

Legal Issues Embedded in Inquiry, Investigation and Appeals Processes

1:30-2:00pm

Jurisdictional and Definitional Issues
Julie Gottlieb, The Johns Hopkins University
Moderator: Mark S. Frankel, AAAS

2:00-3:00pm

Rights and Responsibilities of Parties: Respondent, Whistleblower, Witnesses, and Institutional Officials
Peter Poon, Esq., Veterans Administration, C.K. Gunsalus, Esq., University of Illinois, Urbana
Moderator: Dawn R. Crumel, Esq., Howard University

3:00-3:15pm

Break

3:15-4:00pm

Evidentiary Matters: Sequestration of Lab Records and Other Relevant Materials
David Gleason, Esq., University of Maryland, Baltimore County, Gail Gibbons, Esq., ORI
Moderator: Julie Gottlieb, The Johns Hopkins University

4:00-5:00pm

Assessing Culpability and Proving Intent and Materiality
Stephen Godek, Esq., ORI, C.K. Gunsalus, Esq., University of Illinois, Urbana
Moderator: Michael J. Brown, Esq., The Institute for Genomic Research

5:00pm

Recess

5:00-6:00pm

Reception

May 31, 2001

8:00-8:45am

Preparing the Investigation Report and Disclosure Responsibilities
Margaret Dale, Esq., Harvard Medical School, Stephen Godek, Esq., ORI
Moderator: Leanne Cusumano, Esq., National Science Foundation

8:45-9:15am

Settlement Issues
Gail Gibbons, Esq., ORI
Moderator: Irma Robins, Esq., University of Maryland - Baltimore
9:15-10:00am  Administrative Actions (Institutional and Federal)  
*Judith Leonard, Esq., University of Arizona, Timothy Morris, Esq., ORI*  
*Moderator: Rachel Gray, AAAS*

10:00-10:15am  Break

**SESSION III**  
**Litigation Issues**

10:15-11:15am  Administrative Hearings (Institutional and Federal)  
*Robert Terrell, Esq., University of Pennsylvania, Caroline Elmendorf, Esq., ORI*  
*Moderator: Robin Alexander, Esq., University of District of Columbia*

11:15-11:45am  Lawsuits Arising from Research Misconduct  
*David Hoffman, Esq., Assistant U.S. Attorney, Eastern District of Pennsylvania*  
*Moderator: Marcel LaFollette, Independent Scholar and Consultant*

11:45-12:45pm  Lawsuits Arising from the Conduct of Misconduct Investigations and from Findings of No Misconduct  
*Gerard Pecht, Esq., Fulbright & Jaworski, Barbara Mishkin, Esq., Hogan & Hartson*  
*Moderator: Nancy Morrison O'Connor, Esq., Bracewell & Patterson*

12:45-1:00pm  Closing Remarks

1:00pm  Adjourn
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2. SPEAKER/MODERATOR INFORMATION
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3. SPEAKERS SUMMARY REMARKS

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• Caroline Elmendorf
• Anita Eisenstadt
• Sheila Zimmet
• Susan Sherman
• Barbara Mishkin

Session II
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Session III
• Caroline Elmendorf
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• Barbara Mishkin
4. **HHS AND ORI MATERIALS**

- Public Health Service Act, Office of Research Integrity, 42 U.S.C. § 289b.


- HHS Debarment Regulation, "Governmentwide Debarment and Suspension (Nonprocurement) and Governmentwide Requirements for Drug-Free Workplace (Grants)," 45 C.F.R. Part 76 (1995).


- List of Available ORI Materials.

- ORI Website Homepage.


- Selected ORI Newsletter Policy Articles:
  - "PHS Funding Jurisdiction in Scientific Misconduct Cases Explained," Vol. 8, No. 3: 3 (June 2000).
  - "OIG Investigations Viewed as Last Resort," Vol.8, No.1 at 7 (December 1999).
  - "Policy Clarifies Complainant Role As Witness in Misconduct Cases," Vol. 8, No. 1:8 (December 1999).

- Conflict of Interest

- Human Research Subjects
• Animal Research
  • National Institutes of Health, Office of Laboratory Animal Welfare, "Public Health Service Policy on Humane Care and Use of Laboratory Animals," (September 1986; Reprinted 2000).

5. INSTITUTIONAL POLICIES

• Baylor College of Medicine
• Georgetown University Faculty Handbook
• Harvard Medical School, Faculty Policies on Integrity in Science
• Howard University
  • Code of Ethics and Conduct
  • "Certification of Conflict of Interest Disclosure Statement for Research and Educational Activities," Howard University Form, CO-1.
  • "Financial Interest Worksheet," Howard University, Form CI-3.
  • "Directive on Conflict of Interest in Research Funded by Public Health Service, US Department of Health and Human Services, or by the National Science Foundation, "Memorandum to Interim Dean," Howard University, February 9, 2001.
• The Johns Hopkins School of Medicine
  • Procedures for Dealing with Issues of Research Misconduct
  • Procedures for Dealing with Issues of Professional Misconduct
• University of California, San Diego, Integrity of Research
• University of Maryland, Policy on Misconduct in Scholarly Work

6. OTHER FEDERAL POLICIES AND MATERIALS

• Office of Science and Technology Policy

• National Science Foundation
  • NSF Grant Policy Manual, Chapter 930.

7. SAMPLE INQUIRY AND INVESTIGATION REPORTS

• Sample Inquiry Report, BCM/Angelides, ORI 93-15
• Sample Investigation Report Section, BCM/Angelides, ORI 93-15
• Sample Investigation Report Attachment, BCM/Angelides, ORI 93-15
8. LEGAL CASES AND DECISIONS

- Summaries of Some Civil and DAB Decisions

- ORI No. 94-15 (Kimon J. Angelides, Ph.D.) and Angelides v. Baylor.
  - ORI Summary of Angelides Decision, DAB No. 1677 (February 5, 1999) and Related Civil Suit.
  - 64 Federal Register 48 (1999).
  - 117 F.3d 833 (5th Circuit, 1997).

  - No. 91-867, slip op. (W.D. Penn. August 4, 1994).

- ORI No. 99-27 (Evan B. Dreyer, M.D., Ph.D.) and U.S. ex rel. Dreyer v. Massachusetts Eye & Ear Infirmary.

- ORI No. 97-07 (Lingxun Duan, M.D.) and U.S. Yong Wu v. Jefferson Medical College.

- U. S. ex rel. Berge v. The Board of Trustees of the University of Alabama, et al.
  - 104 F.3d 1453 (4th Circuit, 1997).


- Vermont Agency of Natural Resources v. U.S. ex rel. Stevens.
  - 120 S. Ct. 1858 (2000).
• **Fisher v. National Institutes of Health**

• **Abbs v. Sullivan**
  - 756 F. Supplemental 1172 (W.D. Wis. 1990).

• **McCutchen v. United States Department of Health and Human Services**
  - 30 F. 3d 183 (D.C. Circuit, 1994).

• **Popovic v. The United States of America**

9. **OTHER MATERIALS**


- Paul J. Friedman, "Advice to Individuals Involved in Misconduct Accusations," *Academic Medicine, Vol.11: 716 (July 1996).*


- Table of Contents from *Science and Engineering Ethics, Vol. 5, No. 2, (April 1999).*

10. **BIBLIOGRAPHY**