

# LEGAL ISSUES IN RESEARCH MISCONDUCT CASES

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# HANDLING EVIDENCE

- Prompt and complete sequestration of evidence through institutional evidence management process
- Data and products generated under PHS grants or cooperative agreements belong to the institution, not the principal investigator
- Identifiable chain of custody

# BURDEN OF PROOF

- ORI bears burden under Preponderance of Evidence Standard that:
  - ✓ Respondent committed scientific misconduct
  - ✓ Cause for debarment exists
  - ✓ Proposed administrative actions are reasonable

# LEVEL OF INTENT

- Intentional conduct
- Knowing conduct
- Reckless conduct
- Not honest error or difference of opinion

# MATERIALITY

- Significance of the alleged misconduct to the research project, PHS grant application and/or funding process, or scientific paper
- Not a required element to establish a finding of research misconduct
- Useful concept in establishing requisite intent or knowledge

# MOTIVE

- Why was the misconduct committed?
- Not required to be proved
- Lack of motive may negate intent

# APPEAL OF ORI ADJUDICATIONS

- De novo hearing before a Research Integrity Adjudication Panel of the Departmental Appeals Board of the Department of Health and Human Services
- Panel may include scientists and attorneys
- Hearings are open to the public

# USE OF THE FALSE CLAIMS ACT

- Submitting false records or statements to the government to get false claims paid
- In research misconduct cases, submitting grant applications and progress reports to NIH that contain false information
- Generally filed against both institution and individual, see Thomas Jefferson Univ. 2000
- PHS administrative procedures need not be exhausted prior to filing

# WHISTLEBLOWER PROTECTION

- Current regulatory language 45 CFR 50.103(d)(13)
- November 2000, HHS Notice of Proposed Rulemaking on Whistleblower Protection, 65 Fed Reg 70830
  - ✓ Preventing and responding to retaliation against whistleblowers
  - ✓ Applies to entities who have a Research Misconduct Assurance filed
- ORI Guidelines for Institutions and Whistleblowers: <http://ori.hhs.gov>

# DUE PROCESS FOR THE ACCUSED

- Provision of written charges
- Access to counsel
- Opportunity to present evidence
- Opportunity to appeal ORI decision

# BACKLASH AGAINST UNIVERSITIES

- Accused researchers sue universities who accuse them
- Immunity needed?