RESPONSIBLE CONDUCT OF RESEARCH

SCIENTIFIC MISCONDUCT & WHISTLE BLOWING

Susan Frey, Esq.
Assistant Provost for Research Compliance and Health Information Privacy, Boston University
617-414-4736

Kaley Klanica, Esq., Health Law and Bioethics Fellow (SPH), assisted with the preparation of an earlier version of this PowerPoint presentation.
1995 (and after)

- Government, as Sponsor of Research, Requires Institutions to Investigate Misconduct
- Government requires Reporting of Allegations of Research Misconduct
- Attempts to Protect Whistle Blowers
Scientific professional societies

• Commented on federal regulations as they were developed

• But, were not the original source of these requirements
Federal Government Policy on Scientific Misconduct

- Federal Policy on Research Misconduct [1]
  - Establishes definitions of misconduct
  - Requires institutions receiving federal funds to have procedures for reporting and investigating misconduct
  - Provides protection for whistleblowers and persons accused of misconduct

[1] 42 CFR Part 50
Federal definition of scientific misconduct

- Defines research misconduct as *fabrication*, *falsification*, or *plagiarism* in proposing, performing, or reviewing research, or in reporting research results.

- Actions must:
  - Represent a significant departure from accepted practice
  - Have been committed *intentionally, or knowingly, or recklessly*
  - Be proven by a preponderance of the evidence
What is not scientific misconduct?

- Honest error
- Honest differences in the interpretation of data
Examples of unprofessional conduct by researchers that would not meet the current federal definition of research misconduct

- Unintentionally misrepresenting the results of a study by using inappropriate statistical methods
- Maintaining incomplete research records because of a poorly planned research protocol
- Releasing accurate research results without providing sufficient explanation of methods to allow peers to reproduce the results
- Refusing to give authorship credit to a colleague who provided limited advice on a research project
What is at stake in cases of “scientific misconduct”?

- Federal funding of science in the U.S.
- Reputations (if not kept confidential)
  - Accused individuals
  - Accusers
  - Institutions
  - Colleagues
Reporting suspected scientific misconduct—“Whistle blowing”

- Retaliation against whistle blowers is illegal, but...

- Whistle blowers often claim that they suffer some adverse consequences
Responsible Whistle blowing

- Ask questions first; have some evidence before making allegations

- Maintain your credibility by stating evidence carefully
  - Facts you know from observation
  - Hearsay – what someone else said
Boston University Policy

- BU Policies and Procedures Concerning Allegations of Misconduct in Scholarship & Research, Boston University Faculty Handbook
  www.bu.edu/facultyhandbook/policies

Boston Medical Center has a comparable policy applied to cases arising in BMC research.
Duty to report allegations of scientific misconduct at Boston University

- Contact the Chairman of the Department in which the conduct took place, or the Dean of the School or College

  - To report indirectly to the Chairman, contact the Whistleblower hotline – [http://www.bu.edu/ethics/](http://www.bu.edu/ethics/)

  - For preliminary guidance on an anonymous basis, contact:
    - Assistant Provost, Susan Frey (617-414-4736, sfrey@bu.edu)
    - Ombudsperson, Francine Montemurro (617-358-5960)

  - For legal guidance, if you think you may be a witness to scientific misconduct, contact:
    - Boston University Office of the General Counsel
Boston University Uses EthicsPoint to Receive and Forward Anonymous Complaints

**Reporting Hotline**

Boston University has established a hotline to provide a way to anonymously and confidentially report activities that may involve improper conduct or violations of University policies. The University has selected EthicsPoint to provide this service for the University community.

If you would like to make a report through EthicsPoint, you may do so on the web by going to [www.ethicspoint.com](http://www.ethicspoint.com), selecting "File a New Report or Follow-up on a Report," entering "Boston University" under "File a New Report," and then clicking the "Submit" button. Alternatively, dial toll-free 1-866-294-8451 or submit a report in writing to the following address: Boston University, C/O EthicsPoint, PO Box 230369, Portland, OR 97223.
What happens after the report is made?

- Chairman gathers facts within a few days and reports to Dean
- Dean recommends to the Provost whether an Inquiry (not to exceed 60 days) should be commenced to further review the allegation
- Inquiry Committee recommends either dismissal of case or commencement of a formal Investigation
- Investigation Committee recommends either exoneration or finding that misconduct has been committed; and may recommend sanctions.
Possible Sanctions

- Retraining
- Subjected to supervision
- Retract publications
- Reprimand
- Suspension/fired/demoted
- Can’t sit on peer review board (agency)
- Suspension of grants (agency)
- Blacklisted for federal funds (agency)
How can you prevent scientific misconduct in your lab?

- Laboratories and projects that go astray generally lack adequate supervision and instruction
- Office of Research Integrity finds common elements to misconduct cases, in order of importance [1]:
  - Poor supervision
  - Too much work
  - Lack of training
  - Lack of interest
  - Incentives for enrollment of human subjects

To sum up:

- Since 1995 American scientists funded by the government have been subject to federal policies on scientific misconduct.
- Allegations of scientific misconduct must be reported by scientists and investigated by institutions.
- Questions remain as to effectiveness of federal policy to:
  - Prevent or correct scientific misconduct.
  - Protect the innocent and the whistleblowers.