Responsible Conduct of Research

Carol D. Frost
Office of Research and Economic Development
October 16, 2008
Responsible Conduct

We are all faced throughout our lives with agonizing decisions, moral choices. Some are on a grand scale; most of these choices are on lesser points.


- High crimes
- Misdemeanors
High Crimes = Federal definition of research misconduct

- **Falsification: altering data**
  - “manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record.”

- **Fabrication: publishing data not collected**
  - “making up data or results and recording or reporting them.”

- **Plagiarism: stealing the work of others**
  - “the appropriation of another person’s ideas, processes, results or words without giving appropriate credit.”

(Definitions from 42 CFR Section 93.103)
High Crimes: Dire consequences

- Federal Register: January 23, 2008 (Volume 73, Number 15)
- Scott E. Monte, Huntington Memorial Hospital, Pasadena, CA: Based on the findings of an investigation conducted by Huntington Memorial Hospital (HMH) and information obtained by the Office of Research Integrity (ORI) during its oversight review, the U.S. Public Health Service (PHS) found that Scott E. Monte, L.V.N., former Clinical Research Associate, HMH, engaged in scientific misconduct by knowingly and intentionally falsifying and fabricating clinical research records in HMH cancer prevention and treatment protocols supported by National Cancer Institute (NCI), National Institutes of Health (NIH), awards U10 CA69651, U10 CA12027, U10 CA32012, and U10 CA86004.

- ORI has implemented the following administrative actions for a period of three (3) years, beginning on January 7, 2008:
  1. Mr. Monte is debarred from any contracting or subcontracting with any agency of the United States Government and from eligibility or involvement in nonprocurement programs of the United States Government pursuant to HHS' implementation of the OMB Guidelines to Agencies on Governmentwide Debarment and Suspension at 2 CFR Part 376; and
  2. Mr. Monte is prohibited from serving in any advisory capacity to PHS, including but not limited to service on any PHS advisory committee, board, and/or peer review committee, or as a consultant.
UW policy on Research Misconduct

- Applies to all individuals at UW engaged in research
  - faculty, students, technicians, guest researchers, affiliated collaborators
- Observed or suspected misconduct must be reported to VP for Research
- Process: assessment, inquiry, investigation
- Policy: confidentiality, protection of complainant, respondent, witnesses, committee members
Misdemeanors

- Failure to complete reporting
- Failure to disclose funding sources
- Failure to disclose conflicts of interest
- Publishing incomplete methods section
- Providing honorary authorship
Reporting requirements

- Financial
  - Sponsored Programs Office
- Technical
  - PI
- Audits on both financial and technical
Misdemeanors in publication practices¹

- **Obligation to publish**
  - Publication is implicit in accepting grants
  - Much of US research is taxpayer supported
  - Ethical obligation
    - To publish important results
    - Not to shingle in order to pad CV

¹Zigmond and Fischer (2002) Science and Engineering Ethics, v 8 (2), 1-6
Misdemeanors in publication practices

- Citation practices
  - Obligation to cite the first observation of a phenomenon
    - Not the latest substantiation
    - Not a review article
  - Obligation to read the articles we cite
    - Copying citations from other papers may perpetuate errors
  - Obligation to cite papers that do not support our hypotheses along with those that do
Misdemeanors in publication practices

- Methods section
  - Enables readers to evaluate work presented
  - Facilitates replication of work by others
  - Must be adequate to allow this
Misdemeanors in publication practices

- Presentation of results
  - Avoid “data not shown”
  - Avoid “unpublished data”
  - What about statistical summaries of data?
- Are graphs presenting data honestly?
  - Baselines changed to exaggerate differences
  - Curves imposed on data to show trends that aren’t there
  - Scales that are irregular and misleading
Misdemeanors in publication practices

- Clarity of writing
  - Poor writing can be misleading
  - It wastes time, patience and space in journals
  - Responsibility for communication lies with the author, not the reader
Misdemeanors in authorship

- (group exercise)
Misdemeanors in authorship

- Authors should provide
  - Data collection
  - Intellectual contributions
  - Writing

- Authors should
  - Be able to defend the paper
  - Approve the final version
Conflict of interest

- When UW employee or trustee is in a position to affect the business transactions of UW with an organization in which the employee or trustee has an interest (UW Reg. 4-2)
- Not all COI can be avoided, therefore
- We must **disclose** any conflict or **appearance** of conflict of interest, and
- We must **manage** COI
Conflict of Financial Interest

- 42 CFR 50 and 45 CFR 64
- Must follow if accepting federal funds
- Must report and manage any Significant Financial Interest that could be affected by the federally funded research at the time the grant is submitted
  - Anything of monetary value over $10,000
    - salary, consulting fees, honoraria,
    - equity such as stocks,
    - Intellectual property rights
- Also applies to spouse and dependent children
Conflict of commitment

- When consultation or other outside activities interfere with the paramount obligations of the UW employee to students, colleagues and primary missions and policies of UW (UW Reg 4-2).
- COC typically involve questions of obligation and effort but they may be tied to financial remuneration and therefore also be COI.
- Conflicts of commitment must be disclosed to the Provost’s office ("yellow sheet").
Conflict of commitment

- Example: It is a conflict of commitment for a full-time UW faculty member or lecturer to teach at another institution without explicit approval from Academic Affairs.
- However, it is permitted to teach under cooperative agreements between UW and other institutions. The Outreach School handles these arrangements.
Why worry about research ethics?

- We are held to higher standard of conduct
  - We have freedom in the questions we study and the approaches we use
  - We may be supported by public money
  - Some of us seek to cure disease and reduce suffering
  - We teach others

- With privilege comes obligation to uphold high standard of conduct