



# Case Studies: Research Integrity

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January 12, 2009



## **Rules of the day:**

- This is a discussion
- Silence is not golden
- No comment is too stupid
- There is no right answer
- All cases are made up
- If you know anyone that sounds like this, speak to me later.

# Federal regulations and guidance

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- We must follow Federal regulations. We can't make them up and we don't have a choice.
- You must (not should) also follow the Federal regulations.
  - Both ORI and NIH have regulations regarding integrity
- If you are doing clinical trials:
  - Your IRB administrator will become, or is, your best friend.
  - Your other best friend is your RIO.
- If you are not doing clinical trials:
  - Your best (but not only) friend is your RIO.



## Research Misconduct

- **Falsification** (making up results and reporting them)
- **Fabrication** (manipulating research materials, data, or processes; or manipulating data such that the research is not accurately represented in the record)
- **Plagiarism** (the appropriation of another person's ideas, results, or words without giving that person appropriate credit)

In proposing, performing, or reviewing research, or in reporting research results. The regulations require perpetrators to act intentionally.

## And Sloppiness

And it's the right thing to do.

# Federal regulations on research misconduct



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- First promulgated in 1990's – 42 CFR Parts 50 and 93
- Requires institutions that receive PHS research support to have policies and procedures for reporting and responding to allegations of research misconduct
- Have a number of definitive provisions and definitions:
  - Provisions:
    - Confidentiality
    - Protections
    - Stages of investigation
  - Definitions:
    - Complainant means a person who in good faith makes an allegation of research misconduct. (Emphasis on “good faith.”)
    - Respondent means the person against whom an allegation of research misconduct is directed or the person who is the subject of a research misconduct proceeding. There can be more than one respondent in any inquiry or investigation.
- Both complainant and respondent have rights that must be respected.
- The regulations are very general. The institutional policy is not.
- Any investigation must be timely and fair.

# Federal Regulations on Research integrity investigations



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Involvement of complainant and respondent in the (PHS) process:

- Inquiry stage:
  - Institution must provide respondent with opportunity to comment on report;
    - Not the complainant
- Investigation stage:
  - Institution must notify the respondent whether an investigation is warranted;  
Institution may inform the complainant
  - Institution must interview each complainant
  - Institution must provide respondent with copy of the draft report;  
Institution may provide complainant with a copy of the draft report.
- First step: contact the institutional research integrity officer (RIO)
- Our inquiries and investigations are performed in cooperation with Harvard Medical School.

- The first step: contact your friendly research integrity officer (RIO)
- Partners policy - reporting:
  - All individuals “should report observed or apparent research misconduct, or where there are reasonable grounds to suspect research misconduct, to RIO.”
  - If individual is unsure, can call upon RIO to discuss situation informally, get consult and “will be counseled about appropriate procedures for reporting allegations.”
- Confidentiality maintained and respected: Don't talk to anyone else.
- Fair process: Do maintain evidence if any such evidence exists.
- Protection against retaliation for complainant.
- Reputation, livelihood and professional life should be restored.

# Help

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Do you know:

- Your Research Integrity Officer (RIO)
- Your Authorship Dispute Officer (ADO)
- Gretchen Brodnicki, JD  
[Gretchen\\_Brodnicki@hms.harvard.edu](mailto:Gretchen_Brodnicki@hms.harvard.edu)  
(617) 432-2496

# Your RIO

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- BIDMC      Randy Mason
- BWH        Barbara E. Bierer
- CHB        Carleen Brunelli
- DFCI       Beverly Ginsburg Cooper
- HMS        Gretchen Brodnicki
- HSPH       Bernita Anderson
- Joslin      Dianne McCarthy
- McLean     Peter Paskevich
- MGH        Richard Bringham
- Spaulding   Roberta Nary

# Conclusions

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- A culture of compliance
- An environment of honesty, integrity, and openness
- No question is too stupid
- No manuscript is worth it
- Life is long (and science is small)
- Get help when you need it.

<http://ori.hhs.gov/education/>