



Case Studies: Research Integrity and Ethics

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So, what to do?



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- Approach
- Policies and Procedures
- A few 'Best Practices' re:data
- Educational Directives
- Culture of Compliance

Resources Available

- Your most friendly compliance officer:
Allison Moriarty
APMoriarty@partners.org
(617) 732-8335
- Partners Compliance Hot line (anonymous):
(800) 856-1983
www.partners.org/complianceline

Policies and Procedures



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- Clear
- Complete
- Readable and understandable
- Transparent
- Communicated
- Monitored

This is the updated HMS website/policy:

<http://hms.harvard.edu/public/coi/policy/integritypolicy.html>

But, some policies aren't written.

If policies are written, some can't be found.

If policies are written, individuals rarely (if ever) read them.

And, if read, individuals rarely remember.

HMS Integrity in Science website



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The screenshot shows the Harvard Medical School website. At the top, there is a navigation bar with links for Home, Research, Departments / Admin, Consumer Info, and Harvard University. Below this is a red banner with the Harvard crest on the left and the text 'HARVARD MEDICAL SCHOOL' in white. A large image of a building facade is visible in the background. On the left side, there is a vertical menu with buttons for Home, HMS Policy, Office of Research Issues, The Facts, HMS Review Committee, Harvard University Information, Dean's Corner, Newsroom, Events, and Your Comments Are Invited. The main content area is titled 'Faculty Policies on Integrity in Science' and includes a 'Table of Contents' with the following links: Guidelines for Investigators in Scientific Research, Guidelines for Investigators in Clinical Research, Principles and Procedures for Dealing With Allegations of Faculty Misconduct, Faculty of Medicine Statement on Research Sponsored by Industry, Policy on Conflicts of Interest and Commitment, Guidelines for Editors and Authors of Medical Textbooks, Authorship Guidelines, Guidelines for Attribution of Credit and Disposition of Research Products, and Letters of Reference. At the bottom of the page, the contact information for the Office for Research Issues is provided: Office for Research Issues, Harvard Medical School, 25 Shattuck Street, Boston, MA 02115. (617) 432-3191.

<http://hms.harvard.edu/public/coi/policy/integritypolicy.html>

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
(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

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

- 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.

- Data records:
 - Methodology notebook
 - Written
 - Web (Intranet/Internet) application
 - Privacy
 - Experimental notebook
- Some laboratories keep a laboratory master log annotating individual research projects.
- Some laboratories maintain a data selection file containing data selected for publication and documents for each publication and paper resulting from a study.
- Many institutions and laboratories establish standards for accurate collection and recording of data and for storing data.

There are lots of ways to manage data, and these are not prescriptive.

Critical Record Keeping Practices



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- Common language (use English unless discussed)
- An accurate reflection of process:
 - Ideally in ink, no skipped pages, no deletions
 - Deleted or crossed out information initialed
 - Not six months later: “I think I can. I think I can”
- Legible and understandable by others
- All experiments recorded, not just those that work
- Primary data kept in or adjacent to the notebook
- Mice breeding and housing, and reagent sources recorded
- Reagent location recorded, especially for items that aren't commercially available.
- Each notebook with front index and dates
- Life is long

PI Responsibility



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- Ensuring data validity
 - Maintaining and reviewing notebooks and, if they exist, laboratory master logs
 - Ensuring that notebooks are clear, interpretable, and maintained
 - Meeting with the research and staff associates to review progress and data at some frequency and periodicity
- PIs should establish clear practices for maintaining laboratory notebooks
 - Some PIs initial and date laboratory (experimental) notebooks

Look at the data
Look at the notebook
Question what you see

And, if you don't have time...
Assign the responsibility to someone who does

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/>