



Scientific Integrity and Authorship Issues in Mentorship

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- How many of you are mentors?
- How many of you mentor mentors?
- How many of you have a mentor?

- Are you a manager?
- Do you run a lab?
- Do you run clinical investigative studies?
- Do you run a clinical service?

- Have you ever had an scientific integrity issue?
- Have you ever had an authorship issue?



- Do you know:
- Your Research Integrity Officer (RIO)
- Your Authorship Dispute Officer (ADO)
- Gretchen Brodnicki, JD
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- (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 Bringhurst
- 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
 - Each Harvard-affiliated institution also has a research integrity policy
 - Specific to human subjects: if you don't know them, read the full text of the federal regulations (OHRP/FDA/OCR) regarding the main protections for human subjects:
 - IRB approval, Informed consent, Privacy
- or:
- Ask your friendly and knowledgeable IRB administrator
 - Your IRB administrator will become, or is, your best friend.
 - Your other best friend is your RIO.

Research Integrity



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- Research misconduct
- Data integrity
- Conflict of interest
- Authorship
- Confidentiality



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.

vs Sloppiness or unintentional error

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.

Institutional Policy Provisions



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- 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.

So, what to do?



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

Policies and Procedures



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

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.

Data Management



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- Many institutions and laboratories establish standards for accurate collection and recording of data and for storing data.
 - If your institution or department has established standards, know what they are.
 - If your institution or department has not, consider establishing your own standards and expectations.
 - Communicate these standards.
 - Ensure consistency of application.
 - Establish some system of oversight.

Data Management



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- 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 no right way to manage data.

Critical Record Keeping Practices



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- Common language (usu 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

Data Management



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- Data: information, observations, experimental specimens, technologies, and products.
- Data ownership: control and rights over the data, data management, and use.
 - Data is not (usually) owned by the PI but by the sponsoring institution (and sometimes funding agency)
- Consistent, comprehensive, reliable and valid data collection and record keeping essential
- Necessary and sufficient data storage protects research; access should be limited and data retention expectations known.
- Data analysis appropriate and data sharing policies known.

Data security and integrity: Three important considerations



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- Physical security
 - Malicious hacker
 - Unauthorized individual and someone not part of research team
 - Part of research team but with no need to access data
- Logical integrity
 - Maintain content of file
 - Prevent data from being “scrambled”
 - Protect against loss of data
- Audit integrity
 - Verifiably know
 - Who entered data
 - When data were entered
 - Who changed data
 - When data were changed

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

- Courses: RCR (Responsible Conduct of Research)
- Seminars
- PI as educator
 - Be a role model
 - Do what you say
 - Be careful, considerate and respectful
 - Do not ridicule or belittle others
 - Use every opportunity to educate
 - Remember life is long (and science is small)

Substantial contribution to:

- Conception, design, data analysis or interpretation, and
- Drafting or revising of the article, and
- Final approval of manuscript

Generally:

provision of funding or of reagents not sufficient,
being the big boss not sufficient, etc.

Authorship issues



- Authorship is complicated:
 - Criteria for authorship unclear
 - Disagreements common
 - No established standard for order of authors (first, middle, 7 of 11, last, *co-authors)
- Many problems with authorship:
 - Guest authors (persons who have made trivial contributions to the paper)
 - In study: 21% of articles¹
 - Ghost authors (individuals who have made substantial contributions but are not listed as authors)
 - In study: 13% of articles¹
- The revised federal regulations include authorship disputes as research misconduct.

¹ Flanagin A et al. JAMA 1998; 280: 22-224.

- **Cases**

- Authorship disputes:

- 4th of 6th authors
- Failure to complete manuscript
- Redraft of published review chapter

Copyright Law differs from Principles of Authorship

HMS Authorship Guidelines



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- Everyone who is listed as an author should have made a substantial, direct, intellectual contribution to the work. For example (in the case of a research report) they should have contributed to the conception, design, analysis and/or interpretation of data. Honorary or guest authorship is not acceptable. Acquisition of funding and provision of technical services, patients, or materials, while they may be essential to the work, are not in themselves sufficient contributions to justify authorship.
- Everyone who has made substantial intellectual contributions to the work should be an author. Everyone who has made other substantial contributions should be acknowledged.
- When research is done by teams whose members are highly specialized, individual's contributions and responsibility may be limited to specific aspects of the work.
- All authors should participate in writing the manuscript by reviewing drafts and approving the final version.
- One author should take primary responsibility for the work as a whole even if he or she does not have an in-depth understanding of every part of the work.
- This primary author should assure that all authors meet basic standards for authorship and should prepare a concise, written description of their contributions to the work, which has been approved by all authors. This record should remain with the sponsoring department.

Copyright Law differs from Principles of Authorship

HMS Authorship Disputes



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- Research teams should discuss authorship issues frankly early in the course of their work together.
- Disputes over authorship are best settled at the local level by the authors themselves or the laboratory chief. If local efforts fail, the Faculty of Medicine can assist in resolving grievances through its Ombuds Office.
- Laboratories, departments, educational programs, and other organizations sponsoring scholarly work should post, and also include in their procedure manuals, both this statement and a description of their own customary ways of deciding who should be an author and the order in which they are listed. They should include authorship policies in their orientation of new members.
- Authorship should be a component of the research ethics course that is required for all research fellows at Harvard Medical School.
- These policies should be reviewed periodically because both scientific investigation and authorship practices are changing.



Case 1: Data Integrity

You arrive in the laboratory and are assigned to finish a project that was initiated by a very talented postdoc that just left the lab. The materials are prepared and methods have been well described.

Should you do it? Any upside? Any downside?

Do you discuss authorship before you start?

You decide to take on the project. The methods are familiar to you. It takes a few weeks to establish the system again, but the results do not replicate the initial results.

What do you do?



Case 1: Data Integrity

You continue to repeat the experiment, trying many variations of the protocol, generating all new reagents, calling the postdoc for advise and direction. While she is helpful, the results continue to be equivocal. The PI wants you to give lab meeting, presenting the earlier successful results.

What should you do?

What should you present?

The PI decides that he wishes to submit an abstract to a meeting that will be held in 5 months, convinced that by then you will have good results. He tells you to 'write it up.'

What do you do?

Authorship?

Cases: Research Integrity



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Case 1: Data Integrity

After 6 months of frustration, you want to move on to another project. Your PI doesn't want you to 'quit'.

What should you do?

What do you do with the now submitted abstract?

Has there been research misconduct?

Misconduct: fabrication, falsification, or plagiarism

Conclusions



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- No question is too stupid
- No manuscript is worth it
- Life is long (and science is small)

- A culture of compliance
- An environment of honesty, integrity, and openness

- Get help when you need it.

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