Responsible Conduct of Research (RCR)

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Why RCR?

Clinical and Basic Science Researchers:
Students, Post-docs, Fellows, Faculty,
Coordinators, Administrators...

*We all share a commitment to a productive and ethical environment.*
Today’s Agenda

1. Intro to RCR
2. Data
   • The notebook
   • Authorship
   • Honesty
3. Guidelines & Policies

What are our objectives?

During today’s session, you will learn about:
• Professional, institutional, and government guidelines for RCR
• Common problems that you may encounter while conducting research
What is Research Misconduct?

- A continuing problem across all disciplines of research
- Office of Research Integrity investigation of research misconduct cases in public health services during 1994-2003
  - Falsification is the #1 misconduct issue (2/3 of all cases)
    - 40% falsification
    - 27% falsification plus fabrication
    - 22% fabrication
    - 6% plagiarism

Adapted from W. McCormack, U. of Florida

What is Plagiarism?

- You probably understand plagiarism as using someone else’s words as your own.
- Actually, there are many different kinds of plagiarism. The most common are:
  - Stealing
  - Misquoting
  - Insufficient paraphrasing
  - Duplicating publication

- For more details: Cite It Right! A Guide to Thesis Preparation
3 Types of Research Misconduct

**FFP**

- Three major types of research misconduct
  - Fabrication
  - Falsification
  - Plagiarism

**PHS definition:** practices that seriously deviate from those that are commonly accepted within the scientific community for proposing, conducting, or reporting research.

It *does not* include honest error or honest differences in interpretations or judgments of data.

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**Misconduct Issues Are Wider Than Just FFP...**

- A study in *Nature* asserts that researchers need to be aware of more than just **FFP**
  - the majority of problems include a much wider range of unethical behaviors ...

Misconduct Issues Are Wider Than Just FFP...

• 33% of researchers admitted to engaging in unethical behaviors such as changing the
  – design and/or
  – methodology and/or
  – results (!)
in a study in response to pressure from a funding source

Adapted from W. McCormack, U. of Florida

Misconduct Issues Are Wider Than Just FFP

• In addition, scientists admitted to:
  – overlooking others’ use of flawed data
  – circumventing aspects of human-subject requirements
  – failing to present data that contradicts one’s own research

Adapted from W. McCormack, U. of Florida
Consequences of Not Maintaining a High Level of Research Integrity

• So what, especially if it doesn’t harm people?
  – **Undermines** public confidence in results of scientific research
  – **Inhibits** open communication among scientists
  – Medical research is built on trust!

Adapted from W. McCormack, U. of Florida
Research Fraud
(some recent examples)

1. Childhood vaccines and autism

2. Large scale clinical study: where are the patient records?

(1) Childhood vaccines and autism

*British Medical Journal* Charges Fraud in Autism-Vaccine Paper
by Jennifer Couzin-Frankel on 6 January 2011

- A 1998 paper linking autism to vaccines was based on data falsification


- alleged alterations of medical records for the 12 children in the study: preexisting symptoms the children had were "played down" to build a case that they'd had a serious reaction to the measles-mumps-rubella vaccine.

- *BMJ* investigation by journalist Brian Deer
  — *editorial* that calls the paper "fraudulent,"
  — recommendation that other publications by the senior author, Andrew Wakefield, be scrutinized because "past experience tells us that research misconduct is rarely isolated behaviour."
Nature 439, 248-249 (19 January 2006) | doi:10.1038/439248b

(2) Doctor admits Lancet study is fiction
by Emma Marris

• Jon Sudbo, a Norwegian cancer researcher “dreamed up” the lives and lifestyles of some 900 people — and used them in a study on cancer. The results were published as a ground-breaking study in The Lancet (October 2005).

• Later, Sudbø admitted that the data had not come from the Norwegian patient database or any other database, but from thin air.

Questions:
How effective is peer review, even in top journals?
Does the reviewer of a clinical study need access to the patient records?
Who should be responsible for catching fraud?

Misconduct has “long legs…”

• Former MIT Researcher Convicted of Fraud
(Science Insider 4 March 2011)

• http://news.sciencemag.org/scienceinsider/2011/03/former-mit-researcher-convicted--html?etoc
Research Guidelines: What are they & why do we need them?

- Professional codes of conduct, rules, guidelines, and principles
  - are designed to protect participants and the accuracy of research
  - help us understand the research enterprise and standards that researchers must adhere to while conducting research

The primary safeguards against research misconduct

- You
- Your notebook and lab records
- Thoughtful and rational decision making
- All of us working together in a research community
Safeguards

- You and your notebook are the #1 safeguards

- The laboratory notebook ensures that there is proper documentation of a research study.

- From the laboratory notebook one should be able to reconstruct your work step-by-step because this is what a collaborator, reviewer, or auditor will do!!

- These records are the source documents for data analysis, reports, and publications related to the research study.

- These source documents can also be used to establish and defend intellectual property rights, authorship, and other compliance issues resolved by auditing records.

Data Management Guidelines (NIH)

Research data are the essential components of scientific progress
  - detailed experimental protocols
  - all primary data
  - procedures of reduction and analysis

The results of research should be carefully recorded in a form that will allow continuous access for analysis and review.
  *annotating and indexing notebooks and
  *documenting computerized information to facilitate detailed review of data
Data Management Guidelines (NIH)

All research data should be treated comparably, including
• observations and experiments not directly leading to publication

All research data should be available for immediate review
• scientific collaborators
• Supervisors

How are research records properly kept?

• Notebooks (bound)
• DATES
• Digital Records
• PRINT and SAVE key observations
• Read only e-files with DATES

Scientific integrity is inseparable from meticulous attention to the acquisition and maintenance of research data (NIH)

Adapted from Jack Lenz, Albert Einstein College of Medicine
Data Management Guidelines (NIH)

“My Data!”

Data Management Guidelines, cont.

Data management, including the decision to publish, is the responsibility of the principal investigator.

After publication, the research data and any unique reagents that form the basis of that communication should be made available promptly and completely to all responsible scientists seeking further information.

Exceptions
• confidentiality of clinical data
• unique materials were obtained under agreements that preclude their dissemination.

Adapted from Jack Lenz, Albert Einstein College of Medicine
Publication of Data

Scientific papers are our “currency”

• Credit for a discovery
• Professional reputation
• Obtaining a position
• Promotions
• Generating funding

Adapted from Jack Lenz, Albert Einstein College of Medicine

Style of research publications

• Abstract
• Introduction
• Materials & Methods
• Results
• Discussion
• Tables and Figures
• References
• Acknowledgements

Adapted from Barbara Brustein & Robbie Burk, Albert Einstein College of Medicine
Authorship

- First author
- Joint first author* (*must be justified*)
- Last author (senior?)
- Second author
- Communicating author
- Tables and Figures
- Acknowledgements

Authorship Guidelines: Council of Scientific Editors

Authors
- Have fairly and accurately reported the findings
- Have disclosed relationships

Editors
- Have exercised due diligence to insure accurate reporting and disclosures

Adapted from Barbara Birstein & Robbie Burk, Albert Einstein College of Medicine
Authorship Credit: Council of Scientific Editors

Authors have made substantial contributions

- Concept
- Design
- Acquisition of data
- Analysis and Interpretation

Adapted from Barbara Birshtein & Robbie Burk, Albert Einstein College of Medicine

Authorship Credit: Council of Scientific Editors

- Authors have drafted the manuscript or revised important intellectual content

- Authors have final approval on all content

Adapted from Barbara Birshtein & Robbie Burk, Albert Einstein College of Medicine
Authorship

Can authorship be an “honor”? What about “local customs”? Can authorship be a “gift?”

Undesirable Authorship: Council of Scientific Editors

- Guest authorship to “improve chances of publication”
- Honorary or gift authorship “head of the department”
- Ghost authorship undisclosed contribution of a medical writer

Adapted from Barbara Birshtein & Robbie Burk, Albert Einstein College of Medicine
Avoid Publishing Pitfalls

• Rushing to publish because of competition
• Appropriating another person's ideas
• Not giving credit or acknowledgment
• Paraphrasing or plagiarizing
• Intentionally withholding data (“salami slicing”)
• Resusing data or reformatting data

Recap

1. Intro to RCR
2. Data
   • The notebook
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3. Guidelines & Policies
Goal of today’s RCR session

To increase your awareness about some dilemmas you may face in the future
– and hopefully help prepare you for conducting responsible research throughout your career

Where to go for: Information, Concerns or Complaints

- PI, lab members, Departmental Chairs
- Human Resources
- Handbooks: Faculty, Graduate Division
  - Affirmative Action Officer
- Director, Animal Institute
- Directors of Programs
- The Dean
- Hospital administration
More information...

Office of Research Integrity [http://www.ori.dhhs.gov](http://www.ori.dhhs.gov)


Macrina, FL. *Scientific Integrity.* ASM Press, Washington DC, 2005

*When in doubt, ask questions!!*

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and all our colleagues…