Scenario 1

You are collecting data at a preschool and the preschool director has been extremely helpful in facilitating your research. She provided space, distributed fliers, and personally encouraged parents to participate. One day, the director says to you, "I see Sammy did your project. I'm glad he did because I'm a little worried about him. How'd he do?" What should you do?

Scenario 2

You are testing a college student who signed up for our study. He reported that he does not have a prior diagnosis involving language or learning difficulties. According to the standardized tests you give for the study, the student shows clear signs of a learning disability. In addition, he has told you about his plans to apply to grad school. If he were informed of his learning problems, he could get help through the University's Disability Resource Center and would most likely have a better chance of getting into grad school. Should you tell him that he has a learning disability?

Scenario 3

A college student has signed up to participate in your study because he will receive class credit in Psych 101 for volunteering a s a research subject. The faculty member who oversees the Psych 101 study participation system has been complaining about labs not providing enough research opportunities for all the students that want them. When your student arrives, you read over the his information sheet and you see that he is not yet 18 years of age. What should you do?

Establishing a Lab Environment for the Responsible Conduct of Research: Research Participants

Elena Plante

Lisa Goffman

Mario Svirsky

Establishing a Responsible Environment

The reputation of a thousand years may be determined by the conduct of one hour.

--Japanese Proverb

The reputation and integrity of your lab is a function of the environment you create and the actions you take over time to maintain it.

--Lessons for Success Staff

Infamous Human Subject Breaches

- Nazi "medical experiments" on concentration camp prisoners (1946)
- Intentional infection of children with Down Syndrome with Hepatitus (1963-1966)
- Failure to treat men with syphilis (1932-1972)

Not Really an Issue for Your Lab

Actual Issues That Do Occur

- Scenario 1: You are collecting data at a preschool and the preschool director...
- Scenario 2: You are testing a college student who signed up for our study...clear signs of a learning disability...
- Scenario 3: A college student has signed up to participate in your study because he will receive class credit ...

Real-Life Vulnerabilities

- Scenario 1: Potential for violation of confidentiality of research findings
- Scenario 2: Increased risk of psychological harm from participating in the research
- Scenario 3: Potential for violation of informed consent procedures

Identify Points of Vulnerability

Examples from my lab:

- ✓ Work with language-impaired populations
- ✓ Encouragement vs. coercion of child participants
- ✓ Communication with parents
- ✓ Safety concerns for MRI research
- ✓ Periodic incidental health findings
- ✓ 20 student lab members a year
- ✓ Student assumptions concerning my expectations (e.g., hypothesis guessing, willingness to bring problems to my attention)
- ✓ Changes in undergraduate student staffing every semester
- ✓ Data collection in the department clinic
- ✓ Off-site data collection
- ✓ Short term and long term data storage
- ✓ Reliance on others for data collection and analysis
- ✓ The limited memory of human beings for verbatim information
- ✓ The fact that Americans don't read manuals (including lab manuals)

What are the potential sources of vulnerability in YOUR lab?

What are YOU doing to reduce your vulnerability?

Discuss

Points of Vulnerability

Managing Vulnerability

Establishing a Lab Environment for the Responsible Conduct of Research: Scientific Integrity & Replicability

Elena Plante
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Mario Svirsky

Scientific Conduct in the Lab

- Replication of findings is a current (and ongoing) emphasis at NIH; relates closely to scientific conduct

- Requirement of every investigator to safeguard against misconduct and, more commonly, to build a laboratory in which scientific integrity and reproducibility of data are central

Themes

- Factors leading to findings that are not replicable
- Closely related to scientific integrity and conduct

Misconduct - Falsification, Fabrication, or Plagiarism

- Engaged in scientific misconduct by falsifying and fabricating certain figures and research results supported by Public Health Service (PHS) grants P01 NS13274 and P30 HD03352 and reported in ``Orofacial motor control impairment in Parkinson's disease''
- “Although I have fundamental differences with some of the findings,” Hauser wrote, “I acknowledge that I made mistakes. ... I let important details get away from my control, and as head of the lab, I take responsibility for all errors made within the lab, whether or not I was directly involved.”
- Whistle blowers tend to be students or post docs in the lab

What do we need to guard against?

- Extreme commitment to a particular theory or result
  - Leads to bias in how data obtained and/or are interpreted
  - Bias is rampant
  - Difficulty in publishing negative findings contributes to problem; big rewards in exciting findings

Experimental Issues

- Poor experimental design also contributes
- Lack of blinding or randomization
- Lack of appropriate controls
- Cherry picking (participants; results)
- Incomplete description of analyses, statistics, sample size; lack of inclusion of details

What are granting agencies and journals doing about replication problems?

- Increasing systematicity of review process
- Rewarding replication studies and negative results
- Encouraging journal editors to include more detailed methods sections

What can we do to Establish a Responsible Scientific Environment in the Lab

Replicability begins in each lab

Creating an environment that is conducive to maintaining the highest standards of scientific integrity is the job of the principal investigator.

Thanks to Julie Washington

Building a Responsible Environment: Entry into the Lab

Entry into the Lab

- Orientations for new members of the lab
  - RCR training
  - Explicit instruction in data analysis and documentation
  - Systematic manuals and notebooks that are used for training and for consistency; revisit at least annually as an entire lab group
  - Pairing with experienced research assistant/lead doctoral student; shared accountability

Building a Responsible Environment: Ongoing Management of Data Acquisition and Analysis

Ongoing Management of Data Acquisition and Analysis

- Regular lab meetings that include reporting; establishes accountability
- Bring difficult and detailed data to the entire lab group
- Develop lab manuals that include rules for managing details of data analysis

Ongoing Management of Data Acquisition and Analysis

- Keep records and lab notebooks indicating decisions made and why
- Maintain records including subjects collected but not included or participating
- Maintain well labeled files with data (and manuscripts) for a number of years (10).

Ongoing Management of Data Acquisition and Analysis

- Document processes in research
  - Steps used to arrive at outcomes
    - Helps those who follow
    - Clarifies procedures where there might be questions
    - Stands up to an audit

Building a Responsible Environment: Theoretical Framing of Findings

Theoretical Framing of Findings

- Discuss and guard against bias and adherence to a theory
- Teams dedicated to and responsible for a given component of the project and lab meetings provide opportunity to discuss findings openly and including a range of individuals (undergrads; research associates; colleagues); ideally include individuals with different theoretical perspectives
- Openly discuss that the data need to tell the story; that the most interesting results are often counter to predictions; and that the truth is what we are seeking.

Establishing a Responsible Environment

- Above all else, model the behavior you expect from students in your lab.

- Stay close to the data and to the processes in your lab
  - You are responsible, even if you are absent

Establishing a Lab Environment for the Responsible Conduct of Research: Authorship

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Mario Svirsky

AUTHORSHIP MATTERS

Authorship is crucial to your success as an academic

Who Is an Author?

The ICMJE recommends that authorship be based on the following 4 criteria: scholarship, drafting or revising, approval, and accountability

- Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND
- Drafting the work or revising it critically for important intellectual content; AND
- Final approval of the version to be published; AND
- Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

From ICMJE recommendations

Some clarifications

- All authors should meet all four criteria
- All who meet the four criteria should be identified as authors.
- Those who do not meet all four criteria should be acknowledged.
- These authorship criteria are intended to reserve the status of authorship for those who deserve credit and can take responsibility for the work.
- The criteria are not intended for use as a means to disqualify colleagues from authorship who otherwise meet authorship criteria by denying them the opportunity to meet criterion #s 2 or 3.

From ICMJE recommendations

Who should not be an author (unless they meet the four conditions)

- Your supervisor.
- The Principal Investigator of the grant that funded the work.
- The people who collected the data.
- Those who analyzed the data.
- Those who provided writing or editorial assistance
- The supervisor of the whole research group.

…unless they made substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work

Lead author

- Assumes overall responsibility for the manuscript.
- Often serves as the managerial and corresponding author, as well as
- Providing a significant contribution to the research effort.
- A lead author is not necessarily the principal investigator or project leader.
- The lead author is responsible for:
  - Authorship: Including as co-authors all and only those who meet the authorship criteria
  - Approval: Providing the draft of the manuscript to each individual contributing author for review and consent for authorship. Obtain from all coauthors their agreement to be designated as such.
  - Integrity: The lead author is responsible for the integrity of the work as a whole, and ensuring that reasonable care and effort has been taken to determine that all the data are complete, accurate, and reasonably interpreted

Based on “Policy for Authorship on Scientific and Scholarly Publications”, Washington University

Co-authors

- All co-authors of a publication are responsible for:

- Authorship: co-authors acknowledge that they meet authorship criteria. A coauthor should have participated sufficiently in the work to take responsibility for appropriate portions of the content.
- Approval: By providing consent to authorship to the lead author, co-authors are acknowledging that they have reviewed and approved the manuscript.
- Integrity: Each co-author is responsible for the content of all appropriate portions of the manuscript, including the integrity of any applicable research.

- An individual retains the right to refuse co-authorship of a manuscript

Based on “Policy for Authorship on Scientific and Scholarly Publications”, Washington University

Unacceptable Authorship

- Guest, gift, and ghost authorship are all inconsistent with the definition of authorship, and are unacceptable and a violation of this policy.
- Guest (honorary, courtesy, or prestige) authorship is defined as granting authorship out of appreciation or respect for an individual, or in the belief that expert standing of the guest will increase the likelihood of publication, credibility, or status of the work.
- Gift authorship is credit, offered from a sense of obligation, tribute, or dependence, within the context of an anticipated benefit, to an individual who has not contributed to the work.
- Ghost authorship is the failure to identify as an author, someone who made substantial contributions to the research or writing of a manuscript that merited authorship, or an unnamed individual who participated in writing the manuscript. Ghost authorship may range from authors for hire with the understanding that they will not be credited, to major contributors not named as an author.

Based on “Policy for Authorship on Scientific and Scholarly Publications”, Washington University

Authorship Order

- The order of authors is a collective decision of the authors or study group.
- In conjunction with the lead author, co-authors should discuss authorship order at the onset of the project…
- … and revise their decision as needed.
- All authors must work together to make these informed judgments.

Based on “Policy for Authorship on Scientific and Scholarly Publications”, Washington University