Research Misconduct and Integrity

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NIH Virtual Seminar

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Everyone’s Responsibility

Integrity
Stewardship
Protection

UNIVERSITY

National Institutes of Health

NIH

INTEGRITY

THE OFFICE OF

Research

JOURNAL

NIH

National Institutes of Health

Office of Extramural Research
Overview of NIH Allegation Review Process

- Research Misconduct
- Harassment
- Grant Fraud
- Foreign Interference
- Peer Review Integrity

ALLEGATION ENTRY

INITIAL ASSESSMENT

ACTIONS TO CONSIDER, DEPENDING ON OUTCOME OF ASSESSMENT
- Contact institution
- Remove individual from peer review service
- Refer to agency/office with oversight responsibility
- Administrative actions
- Regulatory actions
Research Misconduct and Integrity

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Office of Research Integrity (ORI)
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Most of the scientists conduct research with a high degree of integrity contributing to advancement in science.

A Slippery Slope?

Research Laboratories

Lab 1
Lab 2
Lab 3

Research Misconduct
Questionable Research Practices/Sloppy Science
High Degree of Integrity

Small lapses in judgment could lead to a slippery slope ending in research misconduct.

1. TAKING SHORTCUTS
   Lack of care in experimentation that might impact reproducibility

2. CHEATING
   Such as puffery, which is inflating your resume, can establish dangerous behavior patterns

3. “BEAUTIFICATION” OF IMAGES
   Removing an unwanted feature, even if unrelated to the result, could be scientifically significant

4. LACK OF APPROPRIATE CONTROLS
   Failure to perform a control with the experimental sample could affect result interpretation

5. COMPOSITE IMAGES
   Assemblies of images that are not clearly labeled, such as a montage of cell images from the same experiment but not labeled as such.

6. OUTLIERS
   Omitting outlier data without appropriate pre-experiment justification which alters the overall conclusion of the analysis

7. IMAGE MANIPULATION
   Splicing, cutting, or cropping images; without properly documenting changes, that alters the results or falsely claims a result which was not obtained.

Questionable or Detrimental Research Practices may be considered research misconduct in some cases, but the facts of each case differ and must be individually evaluated.
Research misconduct - 42 CFR § 93.103

Fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.

(a) Fabrication is making up data or results and recording or reporting them.

(b) Falsification is manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record.

(c) Plagiarism is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit.
Scenario 1 - Are you liable?

You submit an NIH grant application not aware that the data and/or text included by others were falsified/fabricated and plagiarized.

Yes!

Decisions by an ALJ on two of the recent ORI cases established that a PI and/or corresponding author, can be liable for research misconduct even if he/she was completely unaware of any falsification or plagiarism.
Research Misconduct Findings are made when

- The allegation is proven by a preponderance of the evidence
- The misconduct is committed intentionally, knowingly, or recklessly.
- There is a significant departure from accepted practices of the relevant research community.
Steps in Research Misconduct Proceedings

1. **Allegation**
   - Colleagues
   - Peer reviewers
   - Coauthors
   - Journal editors
   - Institutional officials
   - Funding agency
   - Journal
   - ORI

2. **Assessment**
   - Research Integrity Officer (RIO)
     - Initial assessment
     - Organizes the remaining institutional processes

3. **Inquiry**
   - 60 days

4. **Investigation**
   - 120 days

5. **ORI oversight**
   - Agree
   - Insufficient evidence for ORI finding

   **Recommend Administrative Actions:**
   - Fix research record
   - Require special certification(s)
   - Suspend/terminate PHS-funding
   - Supervise offender(s)
   - Prohibit PHS-advisory role
   - Debar from future funding

**All ORI Findings are published in The Federal Register, the ORI website and newsletter, and the NIH website**
Your Role in Preventing Research Misconduct

Perceived Pressure
Rationalization
Opportunity

INSTITUTIONS
Foster a culture of research integrity through mentoring, education, and policies

RESEARCHERS
Reproduce, expand on, and openly debate research results

WHISTLEBLOWERS
Draw attention to questionable research

GOVERNMENT REGULATORY AGENCIES
Protect humans, animals, and tax dollars in research and handle research misconduct allegations

FUNDING AGENCIES
Ensure funding of quality research through rigorous grant review

JOURNALS & PEER REVIEWERS
Scrutinize submissions to disseminate accurate research
Statements From Case Interviews

COMPETITIVE PRESSURES
"I felt it was necessary to get a paper in a high-profile journal in order to get a faculty position."

PERSONAL CIRCUMSTANCES
"I had been applying for a green card and felt pressured to make a good paper and get good publications."

INDIVIDUAL PSYCHOLOGY
"Half of me wanted to make [my PI] proud. The other half was terrified of failing... so I fabricated a piece of data."

POOR SUPERVISION
"I was scared to go to [my PI]. He used to scream & yell at me when things did not work as planned."

INADEQUATE TRAINING
"After two years of a postdoctoral fellowship... I still don’t know how to properly publish Western blot data."
Same Cell Images to Represent Different Results

Figure 3c in *Nature Medicine*

Figure C.2.5 in NIH grant application
Same cell images representing “2h LPS” and “12h LPS”

Same cell images representing “no LPS” and “24h LPS”

Intensity Enhanced and size adjusted
Figure 4D = Figure 6 in R21 CA120017-01 + Figure 6C in R21 CA120017-02 + Figure 10D R01 CA130897 01 A1

Pancreatic tumor

Rectangular section from Figure 6C in R21 CA120017-02 was rotated 90 degrees counter clockwise

Figure 6 in R21 CA120017-01
submitted 2/05
hepatic tumor 2 days post iv Cp/plc-

Figure 6C in R21 CA120017-02
pancreatic tumors, 5 days post injection with bacterial strain Cp/sod-

Figure 10D R01 CA130897 01 A1
submitted 10/07
2 days pancreatic tumor 2 days post cp/sod-in mice treated with control liposomes
Follow up Visits For Patient 10: dated “01-18-88” and “11-29-88”

<table>
<thead>
<tr>
<th>Follow up Date</th>
<th>Patient Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>01-18-88</td>
<td>Patient is fine.</td>
</tr>
<tr>
<td>11-29-88</td>
<td>Patient is fine.</td>
</tr>
</tbody>
</table>
Follow up Visits For Patient 10: dated “03-21-89” and “02-02-90”

<table>
<thead>
<tr>
<th>INSTITUTION</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>DATE PATIENT LAST SEEN OR CONTACTED</td>
<td>02-02-90</td>
</tr>
</tbody>
</table>

**Patient's Last Name**: [Redacted]

**Method of Patient Contact**: Arm

**Parameter Nodules**: N/A

**Other Physical Findings**: Patient is doing well.
Patient 10: Death Certificate “September 29, 1987”
28 months prior to last reported follow-up (2-2-90)
4 months prior to first shown (1-18-88) follow up

- FFP in clinical research involve
  - Interviews
  - Entry criteria
  - Screening logs
  - Approval forms
  - Follow-up visits, exams/data
  - Consent forms
  - Test scores
  - Laboratory results
  - Patient data
  - Number of subjects
  - Dates of procedures
  - Study results
When to Contact NIH: Changes in Project and Budget

• Notify NIH of developments that have a significant impact on the award-supported activities

• Notify NIH of problems, delays, or adverse conditions which materially impair the ability to meet the objectives of the award

• Notification shall include a statement of the action taken or contemplated, and any assistance needed to resolve the situation

When to Contact NIH:
Fraud, Waste & Abuse of NIH Grant Funds

- Report false statements related to research misconduct to NIH or HHS OIG.
- NIH may administratively recover misspent grant funds.
- The Federal government may pursue administrative, civil, or criminal action under a variety of statutes relating to fraud and making false statement or claims.

https://grants.nih.gov/grants/policy/nihgps/HTML5/section_2/2.3.10_fraud__waste_and_abuse_of_nih_grant_funds.htm
Short Case Study

• Months into a research misconduct investigation, it’s becoming clear that data in an NIH application were reused and relabeled as different experiments. The actual experiments were never conducted.

• The PI of the grant notifies university officials that he has a tentative job offer at a new university out of state. The job offer requires that he bring the NIH grant with him, so he asks his current university to relinquish the active NIH grant to his new university.

• The PI’s current institution has reservations about transferring the grant, especially since the data in the application may be unreliable.

• What should the institution do?
The integrity of research is based on adherence to core values—objectivity, honesty, openness, fairness, accountability, and stewardship. - NASEM report on Fostering Integrity in Research (2017)

To report research misconduct, and for any questions or comments on research integrity, contact OER-RI.

- What is Research Integrity?
- Why does Research Integrity Matter?
- What can be done to Promote Research Integrity?
- Promoting Research Integrity - NIH Initiatives
- Integrity and Confidentiality in NIH Peer Review
- Glossary: Professional Codes, Norms, Ethics Training
Got Questions? Ask ORI.

**HOW DO I MAKE AN ALLEGATION OF RESEARCH MISCONDUCT?**
I’m the RIO, and I’m not sure what to do about...?

**Is it okay to use ORI’s educational materials in my RCR course?**
I reported misconduct; then my contract wasn’t renewed. Is this retaliation?

**How do I use ORI’s forensic image tools?**
I think someone plagiarized my work.

**I REPORTED MISCONDUCT BUT HAVEN’T HEARD ANYTHING... WHAT’S HAPPENING?**
What do I do?

If we can’t answer your question, we can refer you to the people who can.

Email us at AskORI@hhs.gov if you have questions about research integrity.