NIH’s Role in Research Misconduct Matters

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NIH Extramural Research Integrity Officer
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ARIO meeting
The National Institutes of Health

27 Institutes and Centers
Invests about $30 billion annually in medical research
80% of funds awarded to institutions in the U.S. and around the world
One goal is to “exemplify and promote the highest level of scientific integrity, public accountability, and social responsibility in the conduct of science.”
Everyone’s Responsibility

Integrity
Stewardship
Protection
Responsibilities of Recipient Organizations
Recipient Responsibilities (42 CFR 93)

• Hold active assurance of compliance with the HHS Office of Research Integrity (ORI)
  – Have written policies & procedures for addressing allegations of research misconduct
  – Foster environment promoting research integrity
  – Ensure confidentiality and protect whistle-blower
  – Cooperate with and make reports to ORI

• Submit annual report to ORI – January each year
Instruction in the Responsible Conduct of Research

• NOT-OD-10-019
  – Institutional training grants
  – Individual fellowships
  – Career development awards
  – Dissertation awards
  – Research education grants

• Requirements:
  – At least 8 contact hours
  – Minimum of once every four years,
  – Need training at each career stage (T, F, K)
Record Retention Policy for Recipients

- Retain relevant records for 3 years from the date of submission of annual Federal Financial Report (FFR)
- Applies to both paper and electronic information
- Exceptions to the 3-year retention requirement include litigation, audit, others (45 CFR 75.361)

NIH GPS 8.4.2
Research Misconduct Proceedings

- **Allegation**: Inquiry involves sequestration; prelim fact-finding
- **Assessment**: Inquiry determines whether investigation is warranted
- **Inquiry**: Investigation based on institution’s rules
- **Investigation**: ORI oversight

**60 days** **120 days**

**42 CFR § 93**
Institution’s Responsibilities During RM Proceedings

• Confidentiality
  – Maintain confidentiality for all respondents, complainants, and research subjects identifiable from the research records and evidence.
  – Disclosure limited to those who need to know.
  – Must disclose to ORI and administrative hearings are open to the public.

42 CFR § 93.108
Institution’s Responsibilities During RM Proceedings

• Protect human participants, live vertebrate animals and the environment
  – Report to NIH, OHRP, OLAW

NIH GPS 4.1.27
Institution’s Responsibilities During RM Proceedings

• Protect the scientific integrity of the project
  – Work with NIH Program Official to protect research
  – Report NIH-supported research affected by FFP to NIHResearchIntegrity@mail.NIH.gov

NIH GPS 4.1.27
(rev 10/2018)
Institution’s Responsibilities During RM Proceedings

• Ensure the proper expenditure of funds and, if appropriate, continuation of the project during the investigation
  – Change of PI senior/key personnel requires NIH approval
  – Change of scope requires NIH approval
  – Contact NIH to suspend award if necessary

NIH GPS 4.1.27
When to Contact NIH

- When there are concerns of
  - human safety, animal safety, environmental safety, misuse of funds, or research affected by FFP
- If there is a need to suspend or terminate award
- Change of PD/PI or other key personnel (Requires NIH approval prior to change!)
- Change of scope (Requires NIH approval!)

NIH GPS 8.1.2 & 8.5.2
NIH and Research Misconduct
HHS ORI oversees allegations of RM involving PHS-funded activities

Public Health Service includes these OpDivs:
NIH, CDC, FDA, HRSA, IHS, SAMHSA
National Institutes of Health

Agency Research Integrity Liaison Officer

Agency Intramural RIO

Agency Extramural RIO

Extramural RIOs

26 Extramural IC RIOs
Number of Allegations Received by OER-RI

<table>
<thead>
<tr>
<th>Calendar Year</th>
<th>Number of Allegations</th>
</tr>
</thead>
<tbody>
<tr>
<td>2013</td>
<td>80</td>
</tr>
<tr>
<td>2014</td>
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<td>2016</td>
<td>70</td>
</tr>
<tr>
<td>2017</td>
<td>110</td>
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</table>
Process for Handling Allegations

1. **Allegation**
   - Allegation from a reviewer, whistleblower, PI, colleague, etc.

2. **IC RIO**
   - Designated senior NIH Officials in ICs

3. **ERIO/ERILO & AERIO**
   - Dr. Lauer and designated staff

4. **HHS ORI**
   - Office of Research Integrity
Process for Handling Allegations

Allegation from a reviewer, whistleblower, PI, colleague, etc.

IC RIO
Designated senior NIH Officials in ICs

ERIO/ERILO & AERIO
Dr. Lauer and designated staff

HHS ORI

OHRP
Office of Human Research Protections

OMA
Office of Management Assessment

OLAW
Office of Laboratory Animal Welfare
Stewardship During RM Proceedings

Stewardship of awards and reporting must continue

- Allegation
- Assessment
- Inquiry
- Investigation
- ORI oversight
NIH Interim Actions

• To protect public and research participants, to promote integrity of research and research process, and to conserve public funds

• Interim actions include, but not limited to:
  – Special award conditions
    • Additional supervision
    • Certification of data
  – Request change of PI
  – Suspend or Terminate award
NIH Enforcement Actions

• Failure to comply with the terms and conditions of award
• NIH enforcement actions include, but not limited to:
  – Disallowance of costs
  – Withholding of further support
  – Suspension or termination of the grant
  – Recovery of funds
Recovery of Funds

• NIH ICs may recover funds at any time.
• Reasons for recovery of funds include, but are not limited to:
  – Cost disallowances
  – Unobligated balances
  – Findings of research misconduct
  – Failure to comply with terms & conditions of award
  – Other circumstances
NIH Contacts

• Human subjects concerns
  – NIH funding Institute or Center
• Animal Welfare concerns
  – OLAW: olawdco@mail.nih.gov
• Fraud, Waste, and Abuse of NIH Grant Funds
  – NIH CGMO
  – OPERA DGCO: GrantsCompliance@mail.nih.gov
  – OMA: NIHHotline@mail.nih.gov
• NIH-supported research affected by Falsification, Fabrication, or Plagiarism
  – NIH OER-RI: NIHResearchIntegrity@mail.nih.gov
Scenario 1

• An institution conducts an investigation into allegations of research misconduct across several NIH-funded papers by one PI over the past few years.
• The images appear to have been inappropriately manipulated, and the PI cannot locate any of the raw data for comparison.
• The journals decide to retract the papers since the underlying data are missing.
Scenario 1 (Questions)

• Will the institution be able to make a finding of research misconduct?
• Will ORI be able to make a finding of research misconduct?
• The PI serves on several active NIH awards. What actions can be taken?
• What can the institution do to help prevent future cases like this?
Scenario 2

• Institution A made a finding of research misconduct against an Investigator who serves as PI on an active NIH award. The investigation determined that falsified data were included in the original application and supported publications.

• The PI decides to resign from Institution A and requests that the active award be transferred to Institution B.

• Institution A contacts the NIH to relinquish the award to Institution B.
Scenario 2 (Questions)

- What actions did Institution A take to protect the integrity of the funded research?
- Could Institution A have done more? Examples?
- Must Institution A relinquish the award to Institution B?
Research Integrity

NIH Agency Goal

To exemplify and promote the highest level of scientific integrity, public accountability, social responsibility in the conduct of science.

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

Research Integrity

- 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

Research Misconduct

- Overview
- Definitions
- Requirements for Making a Finding of Research Misconduct
- NIH Process for Handling Research Misconduct Allegations
- What Happens if there is a Finding of Research Misconduct?
- What should you do if you Suspect Research Misconduct?
- PHS Administrative Action Bulletin Board
- PHS Research Misconduct Case Summaries
- Info for the Press

Policies & Regulations

- Public Health Service (PHS) Policies on Research Misconduct; 42 CFR Part 93
- NIH Requirement for Instruction in the Responsible Conduct of Research
- NIH Policies and Procedures for Promoting Scientific Integrity
THANK YOU!

NIHResearchIntegrity@mail.nih.gov