SRA INTERNATIONAL | SOCIETY OF RESEARCH ADMINISTRATORS INTERNATIONAL

Navigating Research Misconduct

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Introduction

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Agenda

1. Background & Regulatory Environment
2. Key Definitions
3. Institutional Responsibilities
4. Research Misconduct Process Overview
5. Challenges and Considerations

Background & Regulatory Environment

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- White House Office of Science and Technology Policy (OSTP) Federal Research Misconduct Policy, issued on December 6, 2000 (2000 OSTP Policy)
  - Applies to federally funded research and proposals submitted to Federal agencies for research funding and requires that all Federal agencies that conduct or support research implement the policy
  - Set forth the definition of research misconduct and criteria for findings of research misconduct
  - Set forth the three-phase process for misconduct proceeding
- Federal Agency Research Misconduct Policies (non-exhaustive list)
  - Public Health Service (PHS) Policies on Research Misconduct: 42 CR Part 93 – originally promulgated in 2005; revised September 17, 2024 (referred to throughout as the "Final Rule")
  - National Science Foundation (NSF): 45 C.F.R. part 689 and the NSF Proposals and Award Policies and Procedures Guide (PAPPG) Chapter XII (most recent version is 24-1)
  - U.S. Dept of Energy: 10 CFR Part 733 and 2 CFR 910.132
  - NASA: 14 CFR Part 1275
  - USDA: 2 CFR Part 422
  - Veterans Health Administration (VHA): VHA Handbook 1058.2 May 4, 2005
- Responsible Conduct of Research (RCR) Training
  - NIH, NSF and other federal agencies have established RCR training requirements for all trainees and other individuals conducting agency funded research
  - RCR is as a critical component of research integrity programs

Key Definitions & Concepts

What is Research Misconduct?

Research misconduct is **fabrication**, **falsification**, or **plagiarism** in proposing, performing, or reviewing research, or in reporting research results.

Key Definitions

Fabrication

Making up data or results and recording or reporting them.

Falsification

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.

Plagiarism

Appropriation of another person's ideas, processes, results, or words, without giving appropriate credit.

Newly added to the definition of plagiarism in the Final Rule:

- Includes the **unattributed verbatim or nearly verbatim copying** of sentences and paragraphs from **another's work** that **materially misleads** the reader regarding the contributions of the author. It does not include the limited use of identical or nearly identical phrases that describe a commonly used methodology.
- **Does not include self-plagiarism or authorship or credit disputes**, including disputes among former collaborators who participated jointly in the development or conduct of a research project.
- **Self-plagiarism and authorship disputes do not meet the definition of research misconduct**.

Key Definitions

Complainant

An individual who in good faith makes an allegation of research misconduct.

Respondent

An individual against whom an allegation of research misconduct is directed or who is the subject of a research misconduct proceeding.

Research Integrity Officer (RIO)

The institutional official responsible for administering the institution's written policies and procedures for addressing allegations of research misconduct.

Institutional Deciding Official

The institutional official who makes final determinations on allegations of research misconduct and any institutional actions.

Institutional Responsibilities

Institutional Responsibilities

1. Establish written policies and procedures for addressing research misconduct.
2. Respond to allegations thoroughly, competently, objectively, and fairly, avoiding conflicts of interest.
3. Promote research integrity and promptly address misconduct allegations.
4. Protect the positions and reputations of good faith complainants, witnesses, and committee members from retaliation.
5. Ensure confidentiality for all parties involved in the misconduct proceeding.
6. Ensure cooperation from respondents and other institutional members in providing information and evidence.
7. Cooperate with HHS during misconduct proceedings or compliance reviews.
8. Assist in enforcing HHS administrative actions.
9. Maintain active research integrity assurance.

Research Misconduct Process Overview

Process Overview

1 Assessment

Review of readily accessible information to consider whether an allegation:

- appears to fall within the definition of research misconduct;
- appears to involve PHS-support; and
- is sufficiently credible and specific.

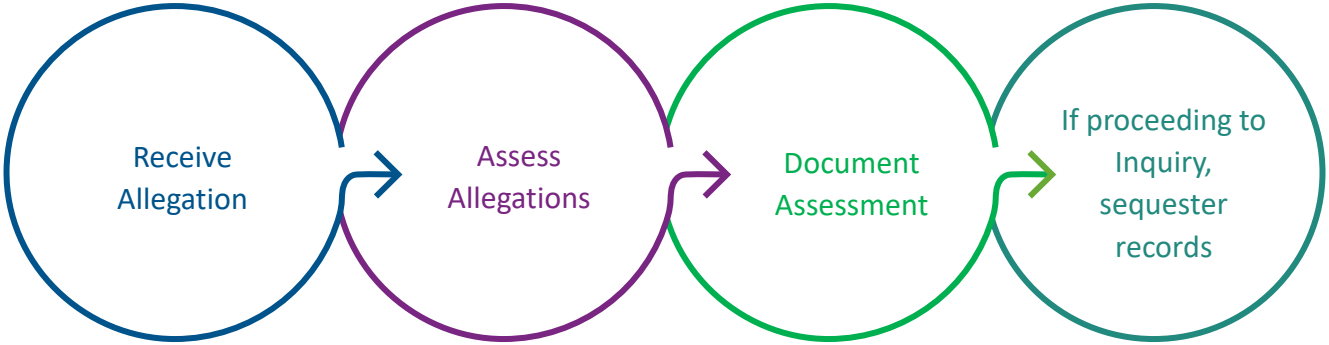
2 Inquiry

Preliminary information-gathering and preliminary fact-finding (i.e., collecting and reviewing evidence) to determine whether an allegation warrants investigation. It is not a full review of the evidence.

3 Investigation

Formal development of a factual record and the examination of that record to make a determination of whether misconduct occurred. This is a full review of all relevant evidence.

Process Overview: Assessment



- Allegations can arise from many sources
- Any concerns about research misconduct should be reported to the institution's RIO

- RIO or another designated institutional official evaluates 3 questions:
  1. Does it fall within the definition of FFP?
  2. Within the jurisdiction of 42 CFR 93?
  3. Specific and credible?

- Document the answers to each of the three questions for each allegation

- Promptly sequester all research records and other evidence
- Electronic notebooks, emails, etc.

Process Overview: Sequestration

1. Take all reasonable and practical steps to obtain all research records or other evidence before or at the time the institution notifies the Respondent of the allegation(s) and whenever additional items become known or relevant.

2. Final Rule clarifies that research records "may include copies of the data or other evidence so long as those copies are substantially equivalent in evidentiary value." 42 CFR § 93.305(a)

3. Institution must provide the Respondent copies of the records, or reasonable supervised access to the sequestered records.

4. An institution must maintain the sequestered research records and other evidence in a secure manner for seven years after completion of the institutional proceeding or the HHS proceedings, whichever is longer.

Process Overview: Inquiry

Purpose
Preliminary review to determine if there is a reasonable basis for believing the allegation(s): 1) meets the definition, 2) is within PHS jurisdiction, and 3) may have substance

Respondent Notification
Must be notified in writing before or on initiation of the Inquiry

Who Conducts Inquiry
RIO, another designated institutional official or committee of experts

Interviews
May be conducted but not required, and no requirement to record or transcribe

Time Limit
Final Rule extended to timeframe for Inquiry to 90 days (was previously 60)

Inquiry Results and Report
Inquiry report must be provided to the Respondent for review and comment, and the report, including Respondent comments, must be submitted to ORI

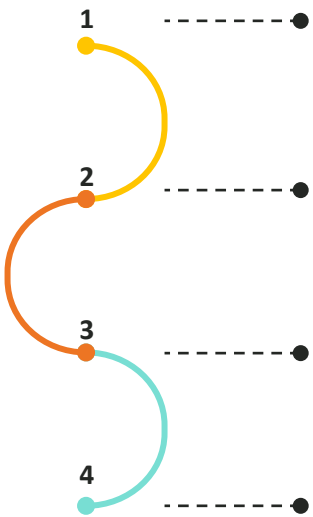
Process Overview: Inquiry

Required Inquiry report components*

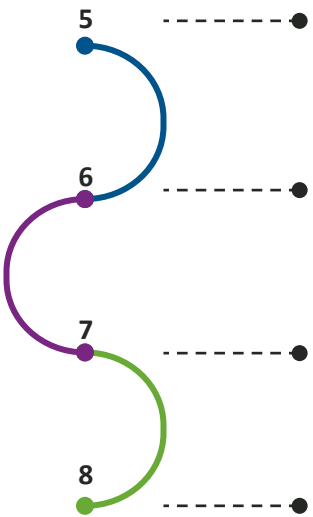
1. Identities and roles of the respondent and complainant
2. Description of the allegations
3. Details of PHS support (grants, contracts, publications)
4. Inquiry committee information (names, roles, expertise)
5. Inventory sequestered research records and evidence and description of sequestration process
6. Transcripts of any interviews, if conducted
7. Timeline and procedural history
8. Scientific or forensic analyses
9. Basis for recommending the allegation(s) warrant an investigation
10. Basis for determining the allegation(s) does not warrant an investigation
11. Respondent's comments on the Inquiry report
12. Institutional actions taken, including communications with journals or funding agencies.

* 42 CFR § 93.309; new items added per the Final Rule are listed in green

Process Overview: Investigation



1. Notify ORI and initiate within 30 days of determination
2. Notify Respondent in writing before start and upon identification of new allegations
3. Full review of all evidence and thorough documentation
4. Interviews of Respondent and witnesses required, with recording and transcriptions of interviews



5. Ensure fair, impartial and unbiased investigation with appropriate expertise
6. Time Limit is 180 days (Final Rule extended from previous 120)
7. Respondent must have opportunity to review and comment on draft Investigation Report
8. Institutional Deciding Official makes final determination of research misconduct findings

Process Overview: Investigation

Criteria for Research Misconduct Finding

A finding of research misconduct requires that (42 § 93.104):

- There be a significant departure from accepted practices of the relevant research community;
- The misconduct be committed intentionally, knowingly, or recklessly; and
- The allegation be proven by a preponderance of the evidence.

Mental States (i.e. form of intent)

The Final Rule added definitions for the forms of "intent":

- **Intentionally** - to act with the aim of carrying out the act (42 CFR § 93.221)
- **Knowingly** - to act with awareness of the act (42 CFR § 93.223)
- **Recklessly** - to propose, perform, or review research, or report research results, with indifference to a known risk of fabrication, falsification, or plagiarism (42 CFR § 93.231)

Burden of Proof

- **Preponderance of the evidence** means proof by evidence that, compared with evidence opposing it, leads to the conclusion that the fact at issue is more likely true than not. (42 CFR § 93.228)
- Applies to all conclusions made throughout the proceeding

Process Overview: Investigation

The Final Rule expanded the required Investigation report* components, including:

- Composition of the investigation committee (names, positions, and subject matter expertise)
- Inventory of sequestered research records and other evidence, except records the institution did not consider or rely on; and a description of how any sequestration was conducted during the investigation
- Transcripts of all interviews
- Identification of the specific published papers, manuscripts submitted but not accepted for publication (including online publication), PHS funding applications, progress reports, presentations, posters, or other research records that allegedly contained the falsified, fabricated, or plagiarized material
- Any scientific or forensic analyses conducted

* 42 CFR § 93.313

Challenges and Considerations

Challenges and Considerations

- Coordination across institutional offices
- Compliance with both federal regulation and institutional policy
- Sequestration processes
- Documentation and evidence management
- Multiple institutions
- Stressful nature of proceedings

Thank you!
Questions?