



Compliance Officer's Quick and Dirty Guide to Scientific Misconduct

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Agenda

- *Introduction*
- *Policies*
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- *Reporting*
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- *Video - The Role of the RIO*



Introduction

Confession: I lied. No quick solutions

Quick guide and Reference Materials

This is a “scratch the surface” overview

What is Scientific Misconduct?

- *Plagiarism*
- *Fabrication*
- *Falsification*

Does not include honest error or differences in scientific interpretation

No two cases are alike

Know your Institutional polices and procedures

Know the DHHS policy (42 CFR Parts 50 and 93)

Policies

DHHS policy (42 CFR Parts 50 and 93)

State polices for state universities

Institutional Policies

- *Misconduct*
 - *Definitions*
 - *Roles*
 - *Process*
 - *Conforms with ORI guidelines*
 - *Reporting*
- *Whistleblower*
 - *Mechanism*
 - *Protection from retaliation*
 - *Restoration of reputation*

Receipt of Allegation

How are allegations received?

- *Any means of communications*
 - *Office visit*
 - *Hotline*
 - *Email*
 - *Phone call*
 - *Anonymously*

Often unexpected

From faculty, staff, students, or sponsor, or ORI

Request face to face meeting

- *Listen*
- *Document*
- *Explain policies*
- *Explain procedures*
- *Ask questions*
- *Review*

Preliminary Assessment

Ask these questions:

- *Does it fit definition of misconduct?*
- *What funding source is involved?*
- *Are the evidence presented sufficient and creditable?*
- *Who is the claimant?*
- *Who is the respondent?*
- *Who are other involved parties?*
- *What needs to be sequestered?*
- *Are there other regulatory issues (IRB, etc)?*
- *What are the priorities and approach to next step?*

Notify

- *Institutional officials*
- *Other regulatory committees*
- *University legal counsel*
- *Others (internal and external) with a need to know*

Notifications and Sequestrations

What and Who to Notify

- Respondent of allegations made
- Respondent's rights
- Institutional policies and procedures
- Sequestration is in respondent's best interest
- ORI or sponsor of investigation as required

When and how to sequester

- On or before notification of respondent
- Depends upon what is sequestered - get professional advice on how, what, and how to store
- Accommodate respondent when possible

What needs to be sequestered?

- Critical Data - Digital and analogue
- Equipment - Computers, Recorders,
- Specimens - Chemical, biological, and physical

Sequestration Team

Legal Counsel

- Provides policy and regulation advice

Scientific expert

- Provides information on what to sequester, where to find data, and how to store and preserve materials

Safety and Security

- Maintains safe sequestration environment
 - Keep low profile

IT expert

- Store, restore, and image hardware and software analysis

Others compliance personnel

- Assists in gathering, sequestering, transporting, and recording and providing receipt of sequestered materials

Inquiry

Inquiry Committee

- *Charge: conduct an initial review to determine if there is sufficient evidence to conduct an investigation.*

Investigation is warranted if:

- *Allegations falls within definition of misconduct*
- *Preliminary review shows allegation may have merit*
- *Reviews sequestered evidence, preliminary assessment report, and interviews parties if needed*
- *Respondent and Claimant must be notified of inquiry*
- *Inquiry must be completed within 60 days from initiation, RIO may grant extension with documentation of reason*
- *Inquiry committee's report must be provided to Respondent, Claimant and Institutional Official.*

Investigation

The formal development and examination of factual records leading to a decision not to make a finding of research misconduct or a recommendation for a finding of research misconduct which may include a recommendation for other appropriate actions, including administrative actions.

Charge to Investigation Committee:

Evaluate the evidence and testimony of parties to determine if based on a preponderance of evidence, scientific misconduct occurred and if so, to what extent, who was responsible, and its seriousness.

Investigation Committee

- *Must begin within 30 days from determination that an investigation is warranted*
- *All parties must be notified, including ORI*
- *Records must be sequestered*
- *Investigation must be well documented*
- *Can be members (all or part) of Inquiry committee*
- *Steps taken to insure a fair and honest investigation*
- *Parties should be interviewed*
- *Leads must be pursued*
- *Must complete its investigation within 120 days of initiation. Extensions requires approval*
- *Respondent must and Complainant may be able to comment on investigation committee's report within 30 days*

Investigation Committee

Investigation Committee should answer:

1. *Does the preponderance of evidence prove that respondent committed misconduct as defined in the policy?*
2. *If so, does a preponderance of evidence prove that the misconduct constitute a significant departure from accepted practices of the research community?*
3. *If so, does a preponderance of evidence prove that scientific misconduct was committed knowingly or recklessly and not merely carelessly?*

Reporting

Investigation Report contents:

- *Allegations*
- *PHS Support*
- *Institutional Charge*
- *Policies and Procedures*
- *Research Records and Evidence*
- *Statement of Findings*
 - *Type of misconduct*
 - *Summarized facts and analysis that support conclusion*
 - *Identify PHS support*
 - *Identify any publications needing corrections or redaction*
 - *Identify the person(s) responsible for the misconduct*
 - *List current and pending support for respondent*
 - *Comments by respondent*
 - *Listing of records and documentation*

Reporting

Reporting Requirements:

- *Respondent must have opportunity to respond and comment on Inquiry and Investigation reports*
- *Whistle Blower may receive copy of Inquiry and Investigation report*
- *Institution's Deciding Officers receives copy of Inquiry and Investigation reports and makes decision to accept or not accept recommendations of reports*
- *ORI and federal sponsors must receive copy of Inquiry and Investigation report.*
- *Records maintained for 7 years*

Outcomes

Inquiry

- *Not sufficient evidence for an investigation*
- *Investigation warranted*

Investigation

- *No evidence of scientific misconduct found*
- *Sanctions*
- *Corrections and/or redaction in publications*
- *Dismissal*
- *Return of sponsored funds*
- *ORI - Debarment*
- *Civil action*

Closing the Loop The 3 R's

Reputation

- *Respondent*
- *Whistleblower*

Retaliation

- *Whistleblower*
- *Respondent*
- *Witnesses*
- *Committee members*

Restoration

- *Research laboratory*
- *Scientific community*

RCR Training

Federal Requirements

- *NSF funded personnel*
- *NIH training grants*
- *OHRP*

Training Resources

- *ORI*
- *Universities' websites*
- *Professional Organizations*

Target Audience

- *Faculty, Post docs, students, staff*
- *RIO and Institutional Official*

Costs

Personnel

- *RIO*
- *Committee members*
- *Witnesses*
- *Legal counsel and senior administrators*
- *Supporting personnel or departments*
- *Outside consultants or experts*

Supplies and other costs

- *Document duplication and handling*
- *Records management*
- *Court Reporter*
- *Investigating and researching fees*

Restoration

- *Restoring and protecting parties*
- *Notifying and retracting publication*
- *Restoring department's unity*

Case Studies

- ❖ *Fabrication*
- ❖ *Falsification*
- ❖ *Fabrication*
- ❖ *Plagiarism*

There is a lot to know and much to do when addressing allegations of scientific misconduct. Get advice, help, and support from others

Contact Information

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Any Questions?



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Video

The Role of the RIO

*A broad overview from the Office of
Research Integrity on the role of the
Research Integrity Officer in
addressing allegations of scientific
misconduct*

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