Compliance Officer's Suick and Dirty Guide to Scientific Misconduct

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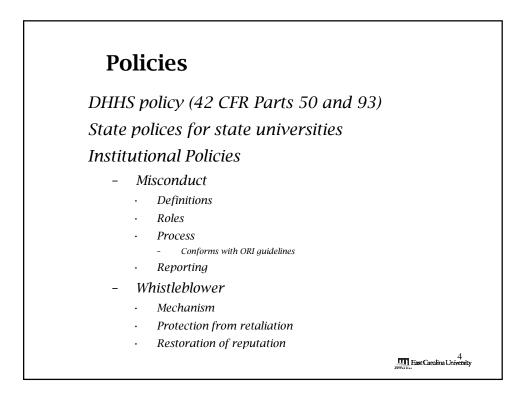
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Introduction Confession: I lied. No quick solutions Quick guide and Reference Materials This is a "scratch the surface" overview What is Scientific Misconduct? Plagiarism _ Fabrication _ Falsification _ Does not include honest error or differences in scientific interpretation No two cases are alike Know your Institutional polices and procedures Know the DHHS policy (42 CFR Parts 50 and 93) East Carolina University



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

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- 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 other there 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 mEase Canalina University

Notifications and Sequestrations

What and Who to Notify

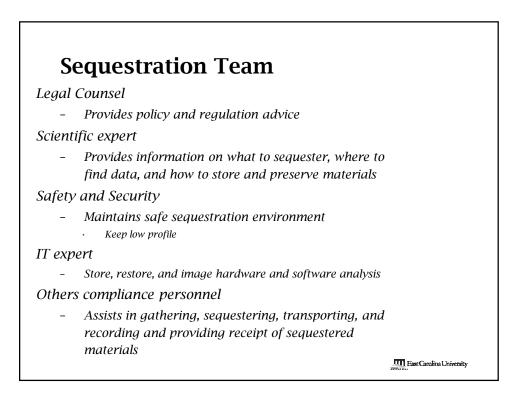
- Respondent of allegations made
- Respondent's rights
- Institutional policies and procedures
- Sequestration is in respondent's best interest
- ORI or sponsor of investigation as required

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?

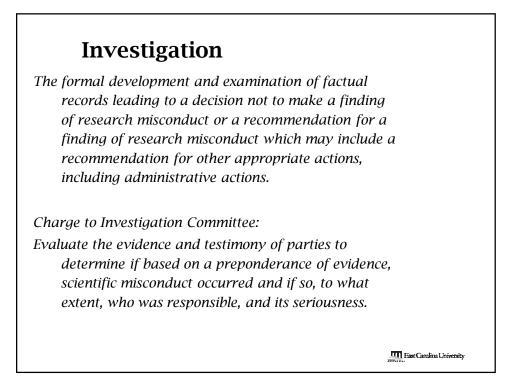
- Critical Data Digital and analogue
- Equipment Computers, Recorders,
- Specimens Chemical, biological, and physical



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 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

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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

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- Identify the person(s) responsible for the misconduct
- · List current and pending support for respondent
- Comments by respondent
- Listing of records and documentation

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

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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		
Person	nel	
-	RIO	
-	Committee members	
-	Witnesses	
-	Legal counsel and senior administrators	
-	Supporting personnel or departments	
-	Outside consultants or experts	
Suppli	es and other costs	
-	Document duplication and handling	
-	Records management	
-	Court Reporter	
-	Investigating and researching fees	
Restor	ation	
_	Restoring and protecting parties	
_	Notifying and retracting publication	
-	Restoring department's unity	
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