Research Misconduct: The ORI and Institutional Perspectives

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PHS Research Misconduct Regulation

- Public Health Service Policies on Research Misconduct
  - 42 C.F.R. Part 93, effective June 16, 2005
- Purpose of the regulation is to protect the public health and safety, to protect the integrity of scientific research and to conserve public funds.
Definition of Research Misconduct

- Research misconduct is defined as “fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.”
  - Research misconduct does not include honest error or differences of opinion.

Findings of research misconduct

- Require a “significant departure from accepted practices to the relevant research community”; and
- That the misconduct be committed intentionally, knowingly, or recklessly; and
- That it be proven by the preponderance of the evidence.
Protecting PHS funds

- General policy states that grantee institutions have affirmative duty to protect PHS funds from misuse by ensuring the integrity of PHS-supported research.
  - Each grantee institution must submit an annual assurance to ORI that it will comply with the research misconduct regulation.

Institutional Responsibilities

- Institutions retain responsibility for:
  - Responding to allegations
  - Conducting an inquiry
  - Conducting an investigation and reporting it to ORI
  - Institutional appeal (if institution’s procedures provide for one)
Institutional Responsibilities (continued)

- Must have written policies and procedures for addressing allegations.
- Respond to each allegation in a thorough, competent, objective and fair manner.
- Must deal promptly with the allegations.
- Foster a research environment that promotes responsible research conduct.

Institutional Responsibilities (continued)

- Must protect the positions and reputations of “good faith” complainants, witnesses, and committee members.
- This includes protecting them from retaliation by respondents or other institutional members.
- Provide confidentiality.
Institutional Assurances
(applies to institutions receiving PHS support)

- Must provide HHS with an assurance of compliance to the responsibilities delineated in the regulation.

- Compliance means:
  - Having written policies and procedures
  - Fostering research integrity
  - Filing an annual report with ORI

Assurances for Small Institutions

- If the institution is too small to handle research misconduct proceedings, it can file a “Small Organization Statement” with ORI.

- In so doing, institution agrees to report all allegations of research misconduct to ORI.
Responding to Allegations

Major Players:
Complainant – a person who in good faith makes an allegation of research misconduct.
Respondent – A person against whom an allegation of research misconduct is directed or who is the subject of the misconduct proceeding.
Witnesses – those with direct information relevant to the allegation.

Responding to Allegations, cont.

Additional Major Player:
Research Integrity Officer or Institutional Official-
The person responsible for protecting the following:
Complainant(s)
Respondent(s)
Witnesses
Committee Members
Confidentiality
Sponsor's resources
Integrity of the Process
Allegation Received. Now What?

Determine if allegation:
1. falls within definition of research misconduct and
2. is credible and specific so that evidence can be identified.

Allegation – written or oral?
If allegation meets requirements above, prepare for Inquiry.

Preparing for Inquiry

Know your internal policy and follow it to the letter.

Record-keeping
- Obtain custody of the records - sequestration
- Inform Respondent
- Inventory the records
- Appoint Inquiry Committee members
  - Statement of No Bias or Conflict of Interest
- Convene Inquiry Committee
- Open file –
  - Maintain “activity log” of all activities
  - Maintain statements of witnesses
  - Inventory - ongoing
Institutional Inquiry
(continued)

- Purpose of inquiry is to review the evidence to determine whether an investigation is warranted.
- Not required to fully review evidence.
- Must prepare written report following inquiry and provide it to the Respondent and ORI.

Institutional Inquiry
(continued)

- Must make good faith effort to notify Respondent in writing of the allegation.

- Must take practical steps to obtain custody of all research records and evidence.

- Have 60 calendar days to complete inquiry after its initiation. If it takes longer, inquiry report must reflect the reasons for exceeding the 60-day period.

- Request for Extension of Time – request to Institutional Official.
Skeleton of Inquiry Report

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Research Misconduct Inquiry
Report Date: Inquiry Report

I. Background
II. Relevant Policy
III. Scope of the Inquiry
IV. Allegations
V. Inquiry
VI. Inquiry Committee Analysis
VII. Conclusions and Recommendation
VIII. Federal Support
IX. Interviews Conducted by Inquiry Committee
X. Inquiry Report Exhibits

What Criteria Warrants an Investigation?

- After inquiry, must have a reasonable basis to conclude that the allegation falls within the definition of research misconduct under HHS’s regulation.
Institutional Investigation

- Must begin investigation within 30 days of determining that the investigation is warranted.
- Notify ORI of decision to begin an investigation.
- Notify Respondent.
- Obtain or maintain custody or research record, if not done so at inquiry stage.

Investigation

Who should be on your Investigation Committee?

Same members from Inquiry Committee or a new set of members?
Institutional Investigation (continued)

- Must conduct an impartial and unbiased investigation.

- Must interview Respondent, Complainant, or any other persons who might have information relevant to the allegation.

- Must record or transcribe these interviews in order to avoid any ambiguity in the record.

Institutional Investigation (continued)

- Should conclude investigation within 120 days from its initiation.

- Can request an extension from ORI (must be in writing).

- Must provide Respondent with an opportunity to comment after investigation report is completed.

- Institution makes its final determination.
What Happens Next?

**ORI’s Responsibilities**

- After ORI receives the final investigation report, it conducts an oversight review of the institutional findings.
- ORI may make findings of research misconduct and propose corresponding administrative actions, e.g.
  - Debarment (Debarring Official must concur)
  - Supervision/certification
  - Retraction/correction

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What if ORI has a different outcome?

Institution and ORI come up with different findings.

a) Institution finds research misconduct; ORI does not.

b) Institution finds no evidence of research misconduct; ORI finds research misconduct.
Federal Case

  - Involved cross claims of research misconduct
  - Court discussed the “co-extensive procedures”- fed regulations and faculty handbook
  - ORI declined to pursue

Chao case cont’d

- Plaintiff argued lack of ORI finding proved malice
- Court stated:
  - “This argument fails because ORI’s determination does not amount to a finding that no research misconduct occurred, and ORI’s determination did not in any way diminish [institution’s] authority to make its own findings of misconduct pursuant to its own process, as expressed by ORI itself. The ORI determination does not vindicate [the respondent].” (Emphasis added).
Another Federal Case-Defamation

- Chandok v. Klessig, 632 F.3d 803 (2nd Cir. 2011)
  - Respondent sued PI for defamation
  - PI contacted Respondent on numerous occasions to replicate the work
  - Court acknowledged that PI “was required to inform the pertinent agencies of suspicious scientific misconduct.” PI “was complying with the reporting requirement.”

OGC’s Role in ORI Research Misconduct Cases

- Draft charging documents and other legal memoranda.
- Negotiate settlements
- Represent ORI in HHS administrative hearings
Respondent’s Choices

- If ORI makes findings and proposes administrative actions, Respondent
  - May agree to settle the case

-OR-

Respondent’s Choices (continued)

- If ORI makes findings and proposes administrative actions, Respondent
  - May contest the findings by requesting an administrative hearing before an administrative law judge (ALJ) within HHS Departmental Appeals Board (DAB).
    --requiring additional institutional involvement
    institutional officials may serve as witnesses
    involved employees may be called as witnesses
HHS Administrative Hearing

- Regulation outlines the process of the administrative litigation. 42 C.F.R. Part 93, Subpart E.
- At the conclusion of the hearing process, ALJ issues a written decision.
- The ALJ sends a copy of the ruling to parties and the Assistant Secretary for Health (ASH)

ASH’s Decision

- ALJ's ruling is a recommended decision to the ASH.
- Within 30 days of service of the ALJ’s recommended ruling, ASH must notify parties of if he/she intends to review.
  - If ASH does not provide notification of review, ALJ's recommended decision becomes final HHS action, unless debarment/suspension is involved.
ASH’s Decision (2)

- If ASH decides to review the ALJ’s recommended decision, ASH may
  - Accept the ALJ’s recommended decision
  - Modify it or reject it in whole or in part
    - after determining that the modified or rejected part is arbitrary and capricious or clearly erroneous.
- ASH’s acceptance, modification or rejection becomes final HHS action, unless debarment/suspension is involved.

Final HHS action

- If the ALJ or ASH decision recommends debarment/suspension, ASH serves copy of decision to debarring official.
  - Debarring official accepts decision as findings of fact
  - Debarring official’s decision is the final HHS action re: administrative actions against the Respondent.
Discussion of recent ORI cases

- Chandok v. Klessig, 632 F.3d 803 (2nd Cir. 2011)
- Matter of Vipul Bhrigu, Ph.D.

Does Tampering = Research Misconduct?

- Graduate student complains something is going awry with experiments
- Multiple accusations-
  - possible self-sabotage
- Campus police set up cameras
- Camera show lab member tampering with cultures
- No doubt this was destruction of property, but was it research misconduct?
Falsification Defined

- 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

Analysis

- Who was respondent?
- Who was victim?
- What was tampered/manipulated?
- Any effect on the research record?

- Requirements of finding must be met.
“Most people say that it is the intellect which makes a great scientist. They are wrong; it is character.”

Albert Einstein