Department of Health and Human Services (HHS), Office of Research Integrity (ORI):

Institutional Research Misconduct Proceedings and ORI's Oversight Processes in Basic Science, Human Research Subjects, and Translational Research

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Learning Objectives for this Session

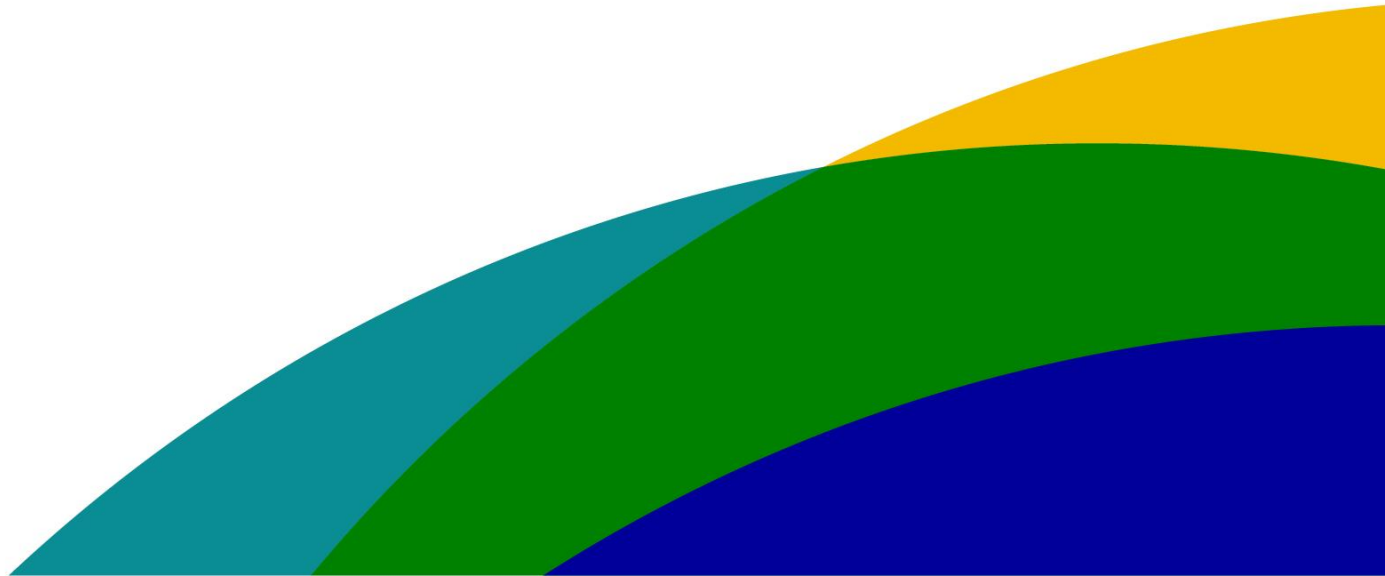
Learning Objective #1: *By the end of this session workshop, participants will be able to …*

- Evaluate allegations of research misconduct to determine whether allegations are specific, credible, and have substance and describe subsequent institutional research misconduct proceedings.

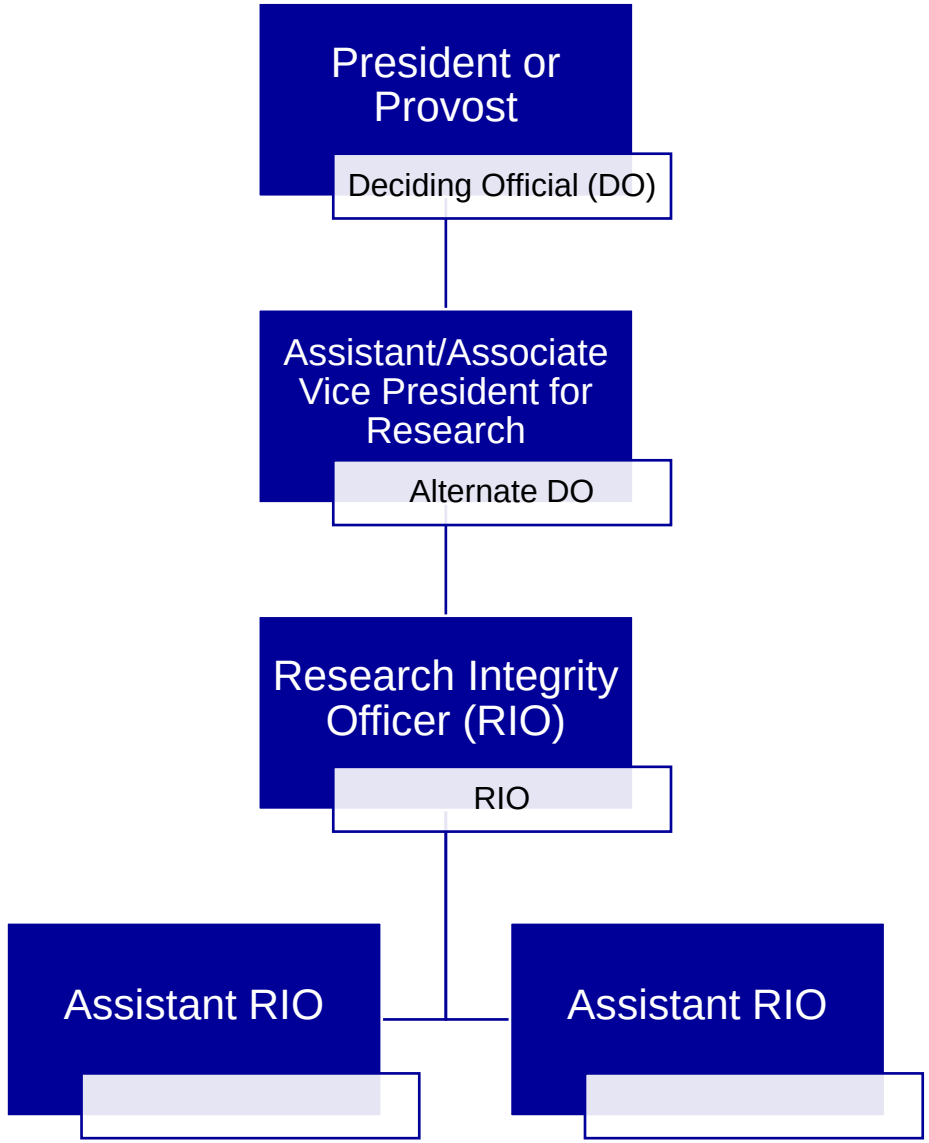
Learning Objective #2: *By the end of this session workshop, participants will be able to …*

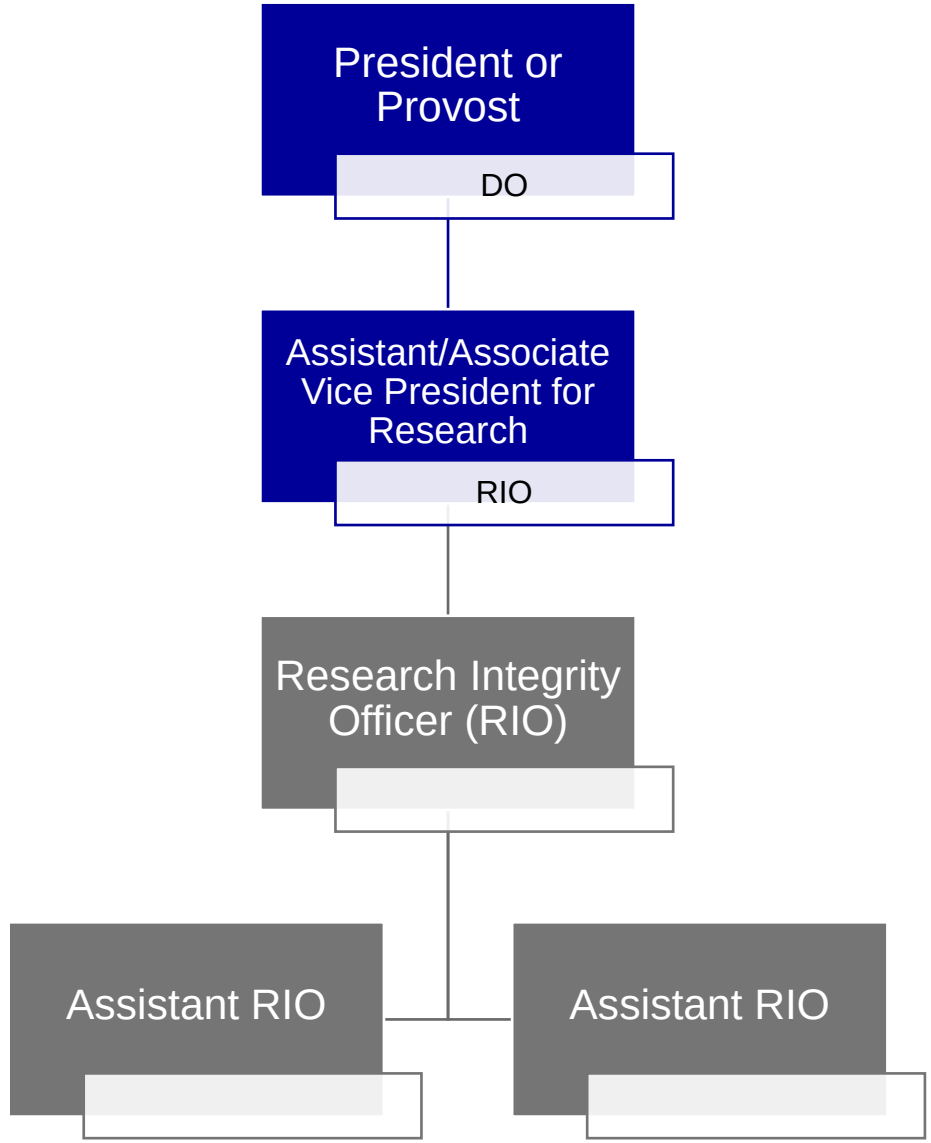
- Better identify differences between research misconduct and protocol deviations, refer to the proper channels, and communicate and cooperate among different institutional offices to address research misconduct allegations in clinical and translational research that involve protocol deviations, noncompliance, and animal welfare.

1. Research Misconduct Proceedings and Basic Science Research Walkthrough



Who are some of the relevant administrators at my institution?





Which institutions need these officials (42 C.F.R. § 93.301)?

§ 93.301 Institutional assurances.

- (a) ***General policy.*** An institution with **PHS supported biomedical or behavioral research, research training or activities related to that research or research training** must provide PHS with an assurance of compliance with this part, satisfactory to the Secretary. PHS funding components may authorize funds for biomedical and behavioral research, research training, or activities related to that research or research training only to institutions that have approved assurances and required renewals on file with ORI.

- (b) ***Institutional Assurance.*** The responsible institutional official {institutional certifying official} must assure on behalf of the institution that the institution—
  - (1) **Has written policies and procedures in compliance** with this part for inquiring into and investigating allegations of research misconduct; and
  - (2) Complies with its own policies and procedures and the requirements of this part.

Public Health Service (Jurisdiction)

The U.S. Public Health Service (PHS) comprises all Agency Divisions of Health and Human Services including:

-Administration for Children and Families (ACF);
-Administration on Aging (AoA);
-Agency for Healthcare Research and Quality (AHRQ);
-Agency for Toxic Substances and Disease Registry (ATSDR);
-**Centers for Disease Control and Prevention** (CDC);
-Centers for Medicare & Medicaid Services (CMS);
-Federal Occupational Health (FOH);
-**Food and Drug Administration*** (FDA);
-Health Resources and Services Administration (HRSA);
-Indian Health Service (IHS);
-**National Institutes of Health** (NIH: 27 ICs: NIGMS, …);
-Substance Abuse and Mental Health Services Administration (SAMHSA); and
-Public Health Service Commissioned Corps.

*Allegations of misconduct in *regulatory* research monitored by the FDA (testing/evaluating human/animal drugs, food/feed additives, human biological products & medical devices) are generally investigated by the FDA Office of Regulatory Affairs, except for research that is supported by PHS grants (§93.100(b), §93.209).

Why do we care about research misconduct (§ 93.101(e))?

§ 93.101 Purpose.

- Protect the health and safety of the public
- Promote the integrity of PHS supported research and the research process
- Conserve public funds

What is research misconduct (§ 93.103)?

§ 93.103 Research misconduct.

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

  - (a) **Fabrication** is making up data or results and recording or reporting them.

  - (b) **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.

  - (c) **Plagiarism** is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit.

  - (d) Research misconduct does not include honest error or differences of opinion.

Steps in Research Misconduct Proceedings

Allegation ➡ **Assessment**

- Colleagues
- Peer reviewers
- Coauthors
- Journal editors

Research Integrity Officer (RIO)
- Initial assessment
- Organizes the remaining institutional processes

- Institutional officials
- Funding agency
- Journal
- ORI

Steps in Research Misconduct Proceedings

Allegation → **Assessment** → **Inquiry** → **Investigation**

60 days — 120 days

- Colleagues
- Peer reviewers
- Coauthors
- Journal editors

Research Integrity Officer (RIO)
- Initial assessment
- Organizes the remaining institutional processes

- Institutional officials
- Funding agency
- Journal
- ORI

Steps in Research Misconduct Proceedings

Allegation → **Assessment** → **Inquiry** → **Investigation** → **ORI oversight**

60 days 120 days

- Colleagues
- Peer reviewers
- Coauthors
- Journal editors

Research Integrity Officer (RIO)
- Initial assessment
- Organizes the remaining institutional processes

- Agree – RM w/ AA, DTP, NM
- Disagree – RIO repeats investigation (scope)

- Institutional officials
- Funding agency
- Journal
- ORI

All ORI Findings are published in The Federal Register, the ORI website and newsletter, and the NIH website

Recommend Administrative Actions:
- Fix research record
- Require special certification(s)
- Suspend/terminate PHS-funding
- Supervision
- Prohibit PHS-advisory role
- Debar from future funding

Basic Science Case Study:
Research Misconduct Proceedings in Practice

Allegation and Assessment Stages

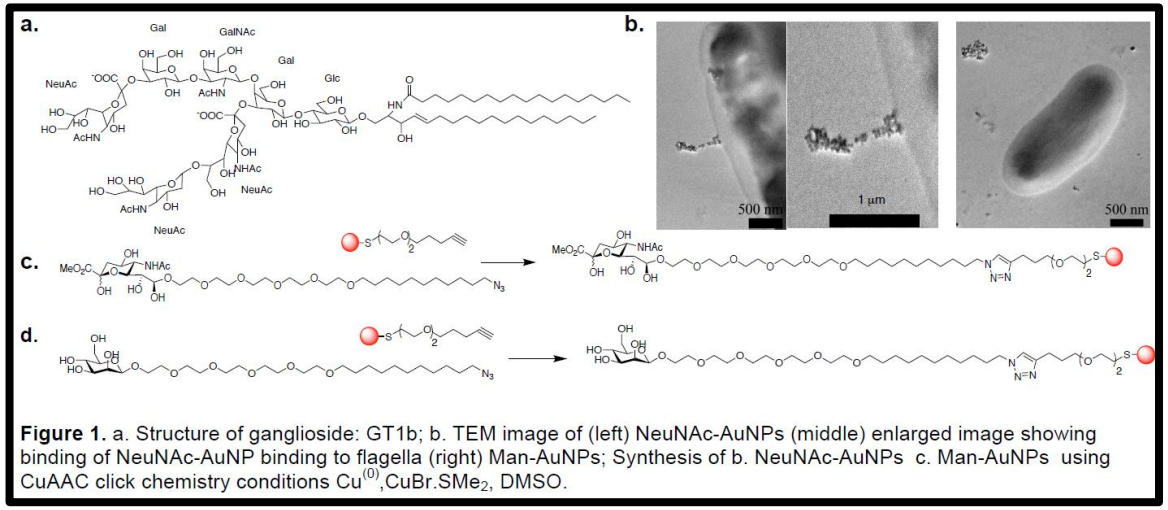


Figure 1. a. Structure of ganglioside: GT1b; b. TEM image of (left) NeuNAc-AuNPs (middle) enlarged image showing binding of NeuNAc-AuNP binding to flagella (right) Man-AuNPs; Synthesis of b. NeuNAc-AuNPs c. Man-AuNPs using CuAAC click chemistry conditions $Cu^{(0)}$,CuBr.SMe_2, DMSO.

NIH Grant #1

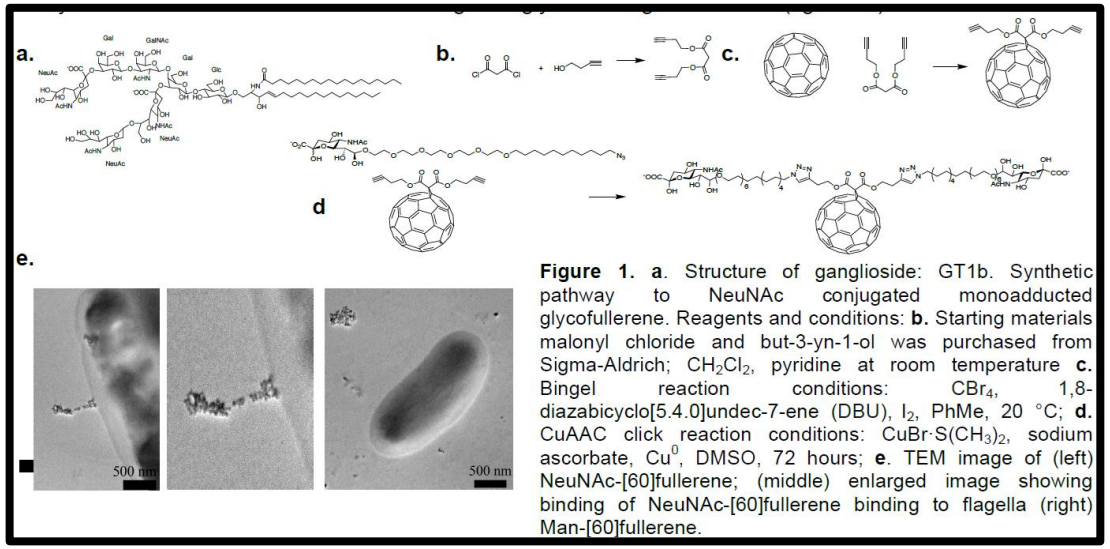
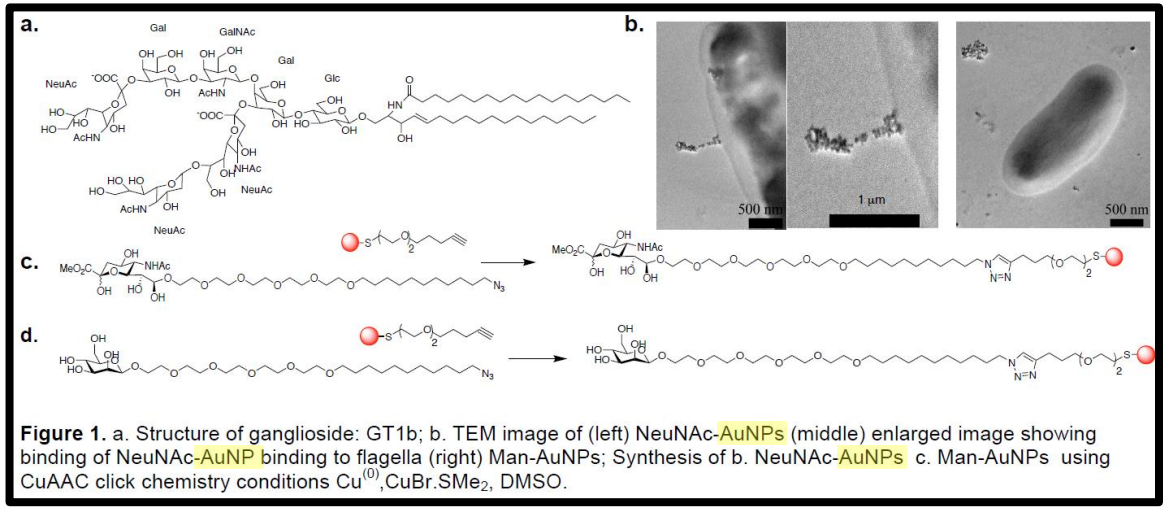


Figure 1. a. Structure of ganglioside: GT1b. Synthetic pathway to NeuNAc conjugated monoadducted glycofullerene. Reagents and conditions: **b.** Starting materials malonyl chloride and but-3-yn-1-ol was purchased from Sigma-Aldrich; CH_2Cl_2, pyridine at room temperature **c.** Bingel reaction conditions: CBr_4, 1,8-diazabicyclo[5.4.0]undec-7-ene (DBU), I_2, PhMe, 20 °C; **d.** CuAAC click reaction conditions: CuBr·$S(CH_3)_2$, sodium ascorbate, Cu^0, DMSO, 72 hours; **e**. TEM image of (left) NeuNAc-[60]fullerene; (middle) enlarged image showing binding of NeuNAc-[60]fullerene binding to flagella (right) Man-[60]fullerene.

NIH Grant #2

1. If this comes across your desk, what is your next step? Should you notify the respondent (author)?
2. What, if anything, is the allegation?

Allegation and Assessment Stages



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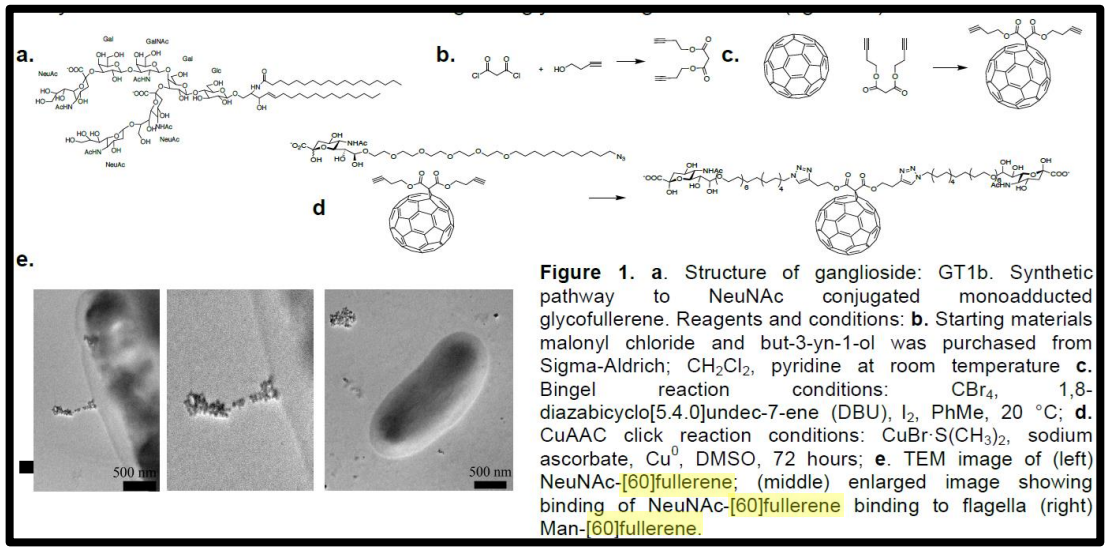

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NIH Grant #2

1. If this comes across your desk, what is your next step? Should you notify the respondent (author)?
2. What, if anything, is the allegation?
3. If present, does the allegation (§ 93.307(a))
   a. Fall within the definition of research misconduct?
   b. Appear to be funded by the Public Health Service or is an application for such funds? (if not, you can still pursue your own institutional policies)
   c. Appear to be credible and specific?
4. Is this research misconduct?

Inquiry Stage and More Allegations

1. RIO notifies respondent in writing and sequesters evidence (§ 93.307(b)).
2. Review of evidence can produce new allegations as below (§ 93.307(c)):

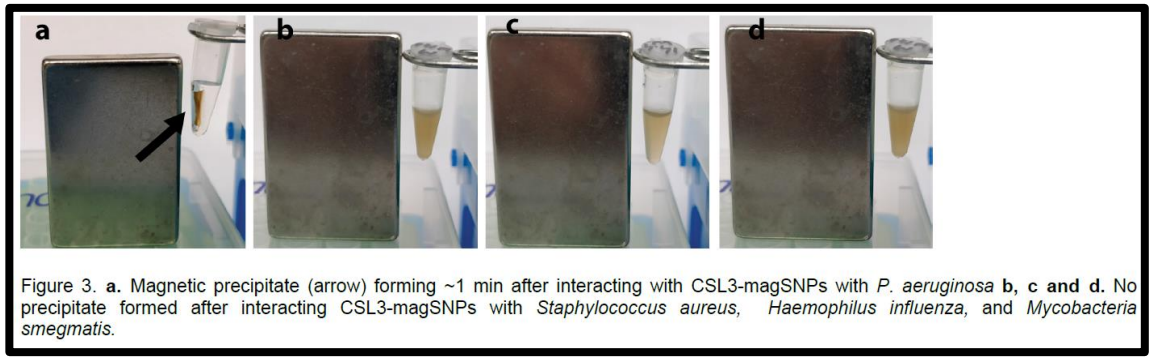

Figure 3. **a.** Magnetic precipitate (arrow) forming ~1 min after interacting with CSL3-magSNPs with *P. aeruginosa* **b, c and d.** No precipitate formed after interacting CSL3-magSNPs with *Staphylococcus aureus, Haemophilus influenza,* and *Mycobacteria smegmatis.*

NIH Grant #3

3. Does preliminary information-gathering and preliminary fact-finding from the inquiry indicate that the allegation(s) may have substance (§ 93.307(d))?

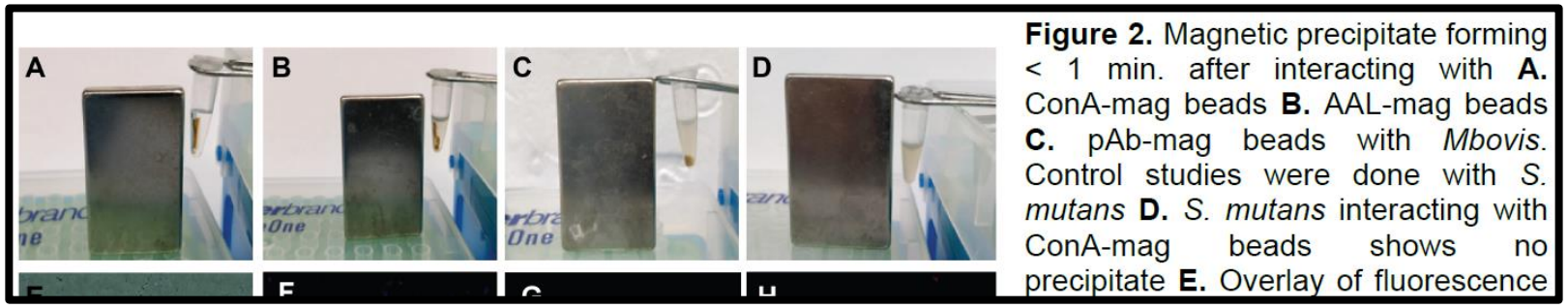

Figure 2. Magnetic precipitate forming < 1 min. after interacting with **A.** ConA-mag beads **B.** AAL-mag beads **C.** pAb-mag beads with *Mbovis*. Control studies were done with *S. mutans* **D.** *S. mutans* interacting with ConA-mag beads shows no precipitate **E.** Overlay of fluorescence

NIH Grant #4

Inquiry Stage and More Allegations

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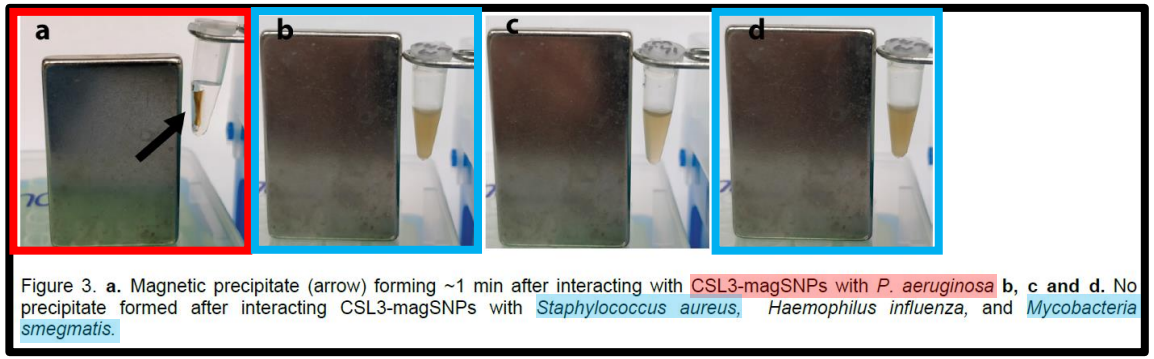

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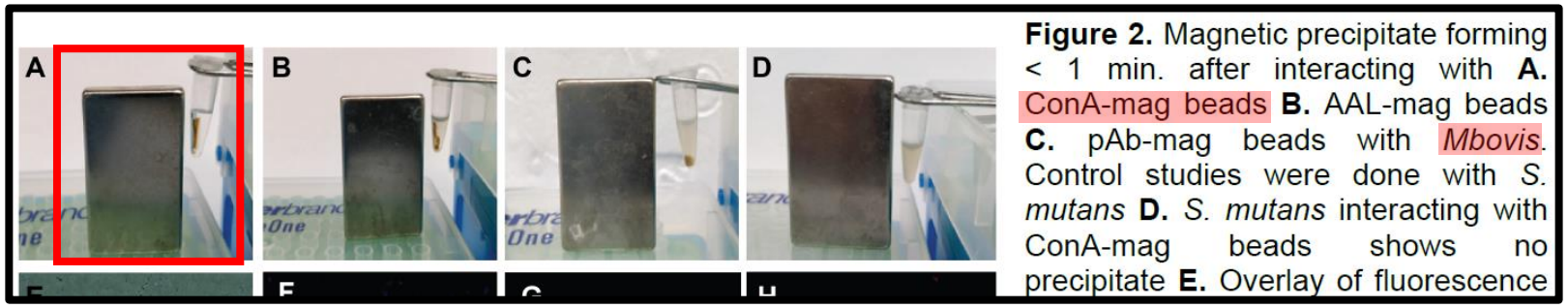

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NIH Grant #4

Investigation Stage and More Allegations

1. RIO notifies respondent and ORI in writing and continue to sequester (§ 93.310(b)- § 93.310(d)).
2. RIO conducts interviews of respondent and witnesses (§ 93.310(g)).
3. Review of full scope of evidence can produce new allegations as below (§ 93.310(h)):

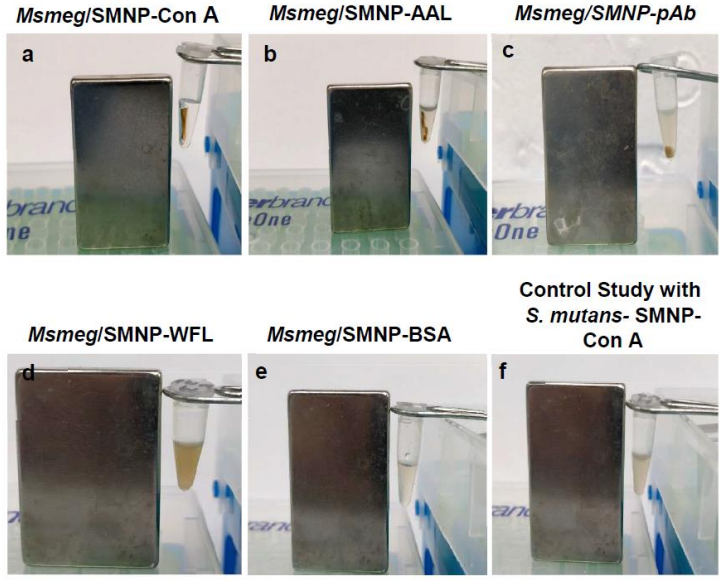
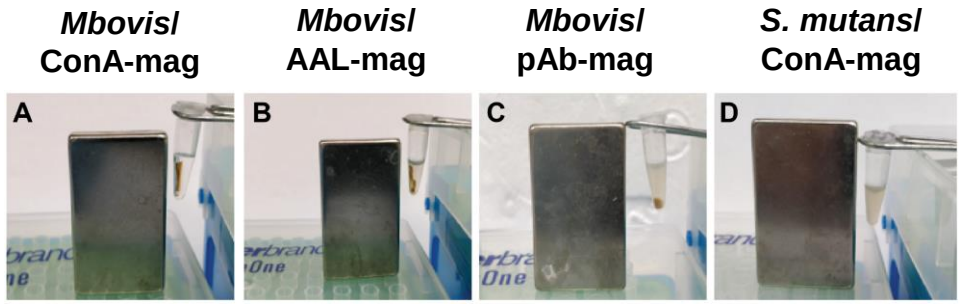


Figure 5.3.Photographs of magnetic precipitation assay.

Student A Dissertation



NIH Grant #4

Filenames for Figure 5.3a and Figure 5.3b contain “m smeg … .jpg” on Google Drive.

Investigation Stage and More Allegations

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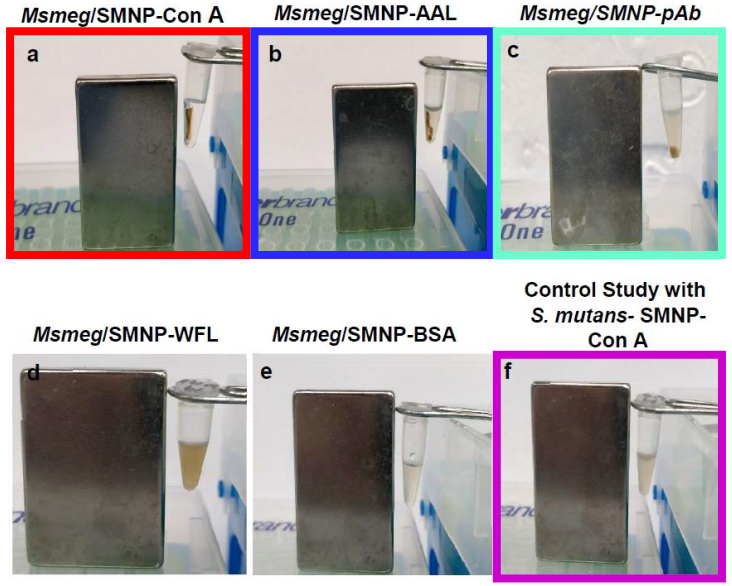

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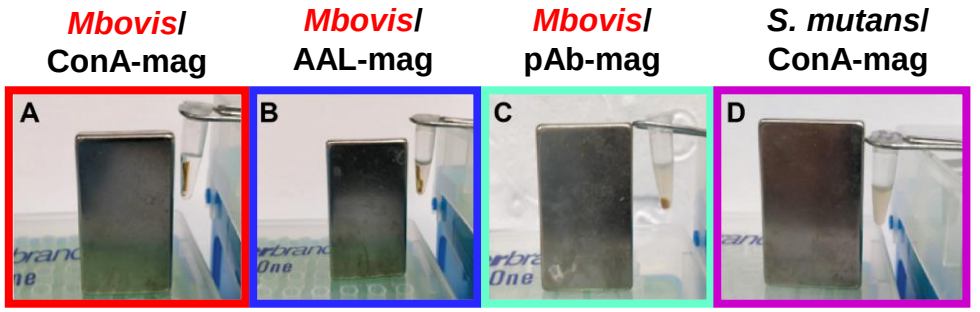

NIH Grant #4

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4. Investigation committee deliberates, writes investigation report with recommended administrative actions, respondent reviews and comments, some institutions allow for an appeals process, DO may concur with committee, report and appendices are sent to ORI (§ 93.312-§ 93.316).

Investigation Stage and Findings of Research Misconduct (§ 93.104)

§ 93.104 Requirements for findings of research misconduct.

- A finding of research misconduct made under this part requires that—

  a) There be a significant departure from accepted practices of the relevant research community; and

  b) The misconduct be committed intentionally, knowingly, or recklessly; and

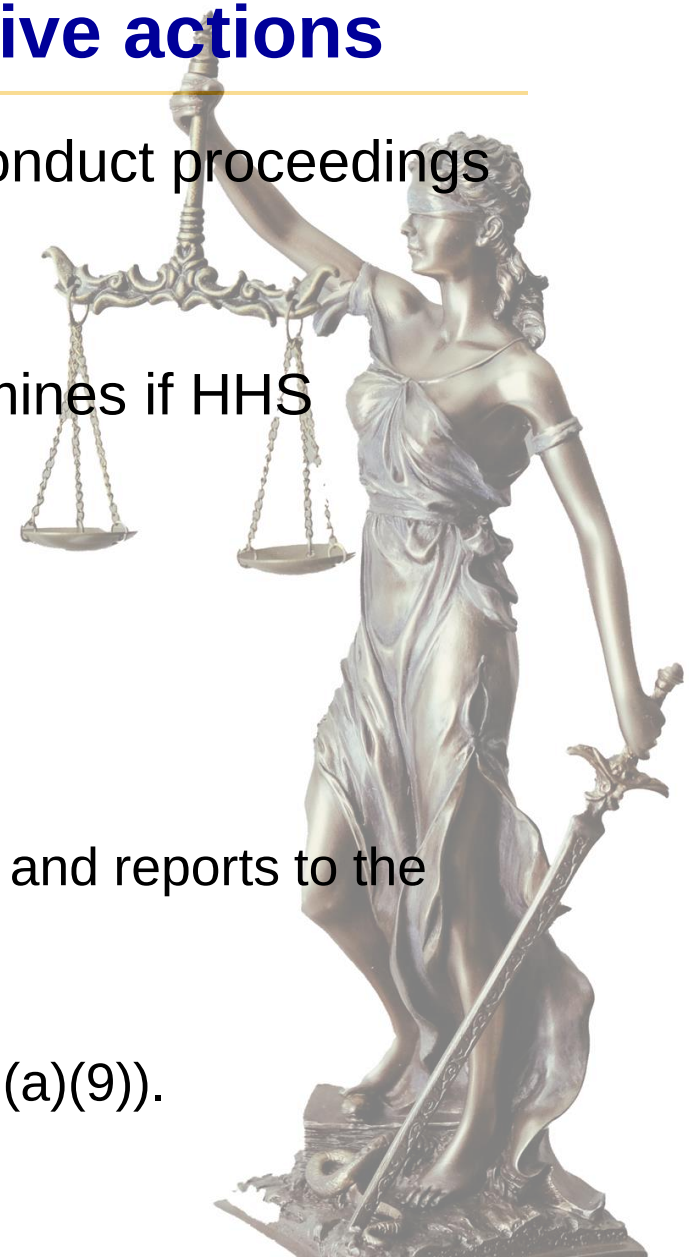
  c) The allegation be proven by a preponderance of the evidence.

ORI Oversight Review and HHS administrative actions

- ORI interacts with institutions **throughout** the research misconduct proceedings to ensure compliance with federal regulations.

- ORI reviews the investigation report and evidence and determines if HHS administrative actions are necessary (§ 93.403-§ 93.406).

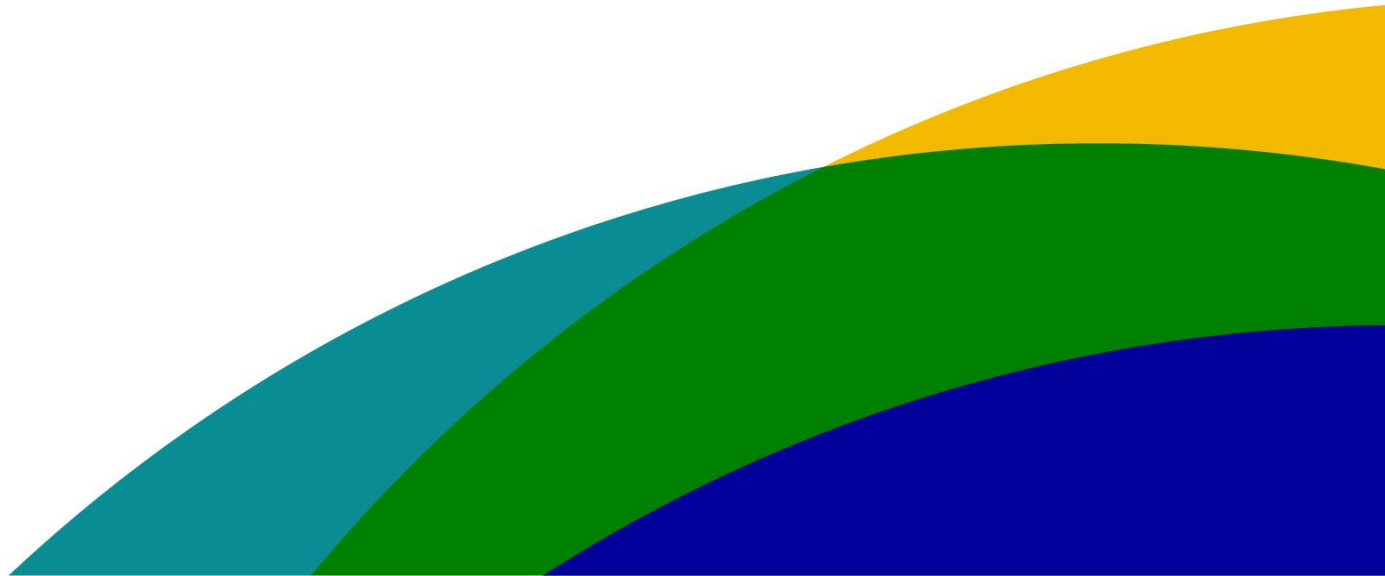
- For this case:
  - Supervision plan required for four (4) years (§ 93.407(a)(6-7)).
  - Certification of attribution or authenticity in all requests for support and reports to the PHS for four (4) years (§ 93.407(a)(8)).
  - Prohibition from PHS Advisory Service for four (4) years (§ 93.407(a)(9)).



ORI administrative actions FY2023

Debarment	Prohibition from PHS Advisory Service	Supervision Plan Required	Certification Required	Publication Retractions/ Corrections Requested
				
6	11	5	5	8

2. Research Misconduct Proceedings and Clinical and Translational Research Walkthroughs



Research Misconduct: 42 C.F.R. § 93.103

- **Research misconduct** means **fabrication, falsification, or plagiarism** in **proposing**, **performing**, or **reviewing** research, or in **reporting** research results.
  - ✓ **Fabrication** is making up data or results and recording and reporting them
  - ✓ **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
  - ✓ **Plagiarism*** is the appropriation of another person's ideas, processes, results, or words, without giving appropriate credit

    * ORI does not consider authorship, collaborator, or credit disputes as plagiarism, and refer to the extramural institution for resolution (ORI Policy on Plagiarism | ORI - The Office of Research Integrity (hhs.gov))

- **Research misconduct does not include honest error or differences of opinion**

Issues Not within ORI's Jurisdiction

- × Honest error or differences in scientific interpretations or judgements of data
- × Collaboration agreements or research-related disputes among collaborators
- × Intellectual property/patents
- × Financial Fraud in research
- × Authorship or credit disputes
- × Self-Plagiarism
- × Hostile Work Environments Outside of allegations of research misconduct
- × Unauthorized protocol deviations and non-compliance
  - × Backdating informed consent forms
  - × Failing to obtain informed consent
  - × Forging physician's signature on orders/prescriptions
  - × Failing to report an adverse event to IRB or sponsor

Case 1

Upon reviewing a manuscript submitted for publication, a journal editor identified the pediatric traumatic brain injury data as having been reported by the same research group, in a manuscript previously submitted for publication in a related journal. The corresponding author informed the journal editor that he was not aware of any wrongdoing, as he did not read the journals' instructions for authors, or the COPE guidelines. In addition, the corresponding author was unable to provide the raw data.

- **Does this action meet the definition of research misconduct?**
  - ✓ Yes
  - ✓ No
  - ✓ Need more information

Quick Considerations

- What are COPE Guidelines?

Case 1 Cont'd

After reviewing three (3) additional manuscripts submitted by the author and identifying the data reuse and data falsifications across the manuscripts, the journal editor notified the corresponding author's supervisor and the institution's research integrity officer (RIO) of his concerns about the reuse of the figures in multiple papers, and the author's inability to provide the raw data.

- **What next steps do you think the RIO should take?**
  - ✓ Request and review the raw data
  - ✓ Assess the allegation/perform an inquiry
  - ✓ Contact ORI
  - ✓ All of the above

Quick Considerations

- Does it meet the definition of Research Misconduct in PHS Supported research? §93.102; §93.103; §93.105.
- Is it sufficiently credible and specific so that potential evidence of research misconduct may be identified? §93.307.
- What institutional policies and procedures apply? e.g. Policies for Responding to Allegations of Research Misconduct, Data Management Policies and Procedures?

Case 1 Cont'd

The institution performed an inquiry and investigation. In addition to reporting the same data in multiple papers, the author: 1) represented animals who underwent a failed craniotomy + TBI as "sham" animals; and 2) reused and relabeled source data to represent TBI animals treated with NE, EPI, or DA, and to represent both male and female animals.

- **Is this research misconduct?**
  - ✓ Yes
  - ✓ No

- **Who should the institution notify?**
  - ✓ NIH
  - ✓ ORI
  - ✓ OLAW
  - ✓ All of the above

Quick Considerations

- Does it meet the requirements for finding Research Misconduct in PHS Supported research? §93.104
  - ✓ A significant departure from accepted practices of the relevant research community.
  - ✓ Committed intentionally, knowingly, recklessly.
  - ✓ Proven by a preponderance of evidence.
- What are the institution's reporting requirements? §93.318,§93.316;§93.313
- ORI may forward allegations that do not fall within its jurisdiction to the appropriate HHS component, Federal or State agency, institution of other appropriate entity. §93.401(e).

Case 1: Institution's Determination + ORI's oversight

Institution

- **Research misconduct-knowing and intentional**
  - ✓ Reuse of sham condition animals to represent different experiments
  - ✓ Reuse of data in multiple manuscripts submitted for publication
  - ✓ Failure to maintain raw data (research record)
  - ✓ Submission of the same data for multiple publications-unethical; against COPE guidelines

- **Institutional Administrative Action(s)**
  - ✓ Debarment, withdrawal of papers, retraction of papers, termination of employment

ORI

- **Research misconduct-knowing and intentional**
  - ✓ Falsification and fabrication of fifty-one (51) figures and the methods, data, results, and conclusions reporting on the effects of various vasoactive agents (NE, EPI, PHE, DOPA) on the neurologic response to TBI in piglets of different ages and genders
  - ✓ Five (5) published papers, one (1) unpublished manuscript, one (1) review article, three (3) posters, three (3) grant applications submitted for PHS funds, and four (4) NIH grant progress reports
  - ✓ Failure to maintain the raw data-aggravating factor

- **HHS (ORI) Administrative Action(s)**
  - ✓ Federal Register Publication of Findings
  - ✓ Publication on ORI's website
  - ✓ Referral to OLAW-mistreatment of animals
  - ✓ 7-year Government-wide debarment

Case 2

The clinical staff administering a clinical study evaluating the longitudinal effects of aging in women, identify blood glucose, total cholesterol, resting metabolic rates, body composition, TGs, LDL, HDL, T4, TSH, and muscle biopsy data recorded on the study's Excel spreadsheet that are inconsistent with the laboratory values recorded in the subjects' clinical record. The data and results were reported in published papers and grant applications submitted to the NIH.

- **Is the Excel spreadsheet part of the research record?**
  - ✓ Yes
  - ✓ No
  - ✓ Unsure

Quick Considerations

Research record means the record of data or results that embody the facts resulting from scientific inquiry, including but not limited to, research proposals, laboratory records, both physical and electronic, progress reports, abstracts, theses, oral presentations, internal reports, journal articles, and any documents and materials provided to HHS or an institutional official by a respondent in the course of the research misconduct proceeding. §93.224.

Case 2 Cont'd

- **What should the clinical staff do?**

  - ✓ Correct the data inconsistences on the Excel spreadsheet
  - ✓ Notify institution's compliance officer and/or IRB
  - ✓ Notify the institution's research integrity officer (RIO)
  - ✓ Notify OHRP, ORI, and/or NIH
  - ✓ More than one of the above

Quick Considerations

- What policies and procedures apply? (e.g., IRB, Research Misconduct, Research Protocol)
- What regulations may be applicable? (42 CFR Part 93; 45 CFR Part 46, etc.)
- What are the institution's reporting requirements? (OHRP, Funding Agency, ORI, FDA, etc.)

Case 2: Institution's Determination + ORI's oversight

Institution

- **Research misconduct Findings**
  - ✓ Knowing and intentional data falsification
  - ✓ Knowing and intentional data fabrication
- **Institutional Administrative Action(s)**
  - ✓ Termination of employment
  - ✓ Retraction of papers
  - ✓ Return unused PHS funds to NIH

ORI

- **Research misconduct**
  - ✓ Knowing and intentional falsification and fabrication of human research subjects' data in the clinical research record (Excel spreadsheet)
  - ✓ Knowing and intentional falsification of the reported statistics
  - ✓ Knowing and intentional falsification and fabrication and statistics of human research subjects' data reported in PHS grant applications and published papers
  - ✓ Referral to OHRP
- **HHS (ORI) Administrative Action(s)**
  - ✓ Federal Register Publication of Findings
  - ✓ Publication on ORI's website
  - ✓ Lifetime Government-wide debarment

Case 3

The P.I. administering a PHS-supported clinical trial is informed by one of the human research subjects that he did not receive his stipend for participating in the study. Upon initial evaluation, the PI informs the subject that he did not receive the stipend on his study debit card because he did not complete the weekly tasks, per the EMR. When provided evidence of completion of the weekly tasks, the PI reviews and identifies data inconsistencies between the hard copy clinical study record and the electronic medical record. He also notices that the records for the stipend funds indicate that the study subject received the stipend.

- **Who do you think the PI should report the data inconsistencies and financial concerns to?**
  - ✓ IRB
  - ✓ RIO
  - ✓ OHRP
  - ✓ ORI
  - ✓ Any of the above

Quick Considerations

- What policies and procedures apply? (e.g., IRB, Research Misconduct, Research Protocol)
- What regulations may be applicable? (42 CFR Part 93; 45 CFR Part 46 etc.)
- What are the institution's reporting requirements? (OHRP, Funding Agency, ORI, FDA, etc.)

Case 3 cont.

The P.I. notified the subcontractor who was awarded the PHS funds. The subcontractor instructed the PI to interview the study staff, review the study records, and report the outcome to them. The PI identified that the employee responsible for entering the clinical and demographic data into the EMR, did so with omissions, data duplications, and backdating some studies and results. In addition, the study staff manipulated the study subject's demographic data, such that the stipend funds were redirected to his study debit card.

- **Was the subcontractor correct in instructing the PI to perform the interview and investigation?**
  - ✓ Yes
  - ✓ No
  - ✓ Unsure

Case 3 cont.

- **Who should address the P.I.'s concerns?**
  - ✓ Subcontractor
  - ✓ Independent entity
  - ✓ Unsure
- **Who should be notified of the P.I.'s concerns?**
  - ✓ OHRP
  - ✓ ORI
  - ✓ OIG
  - ✓ More than one of the above

Quick Considerations

- The institution applying for or receiving PHS funding for any activities or programs that involves biomedical or behavioral research, biomedical or behavioral research training or activities related to that training is responsible for responding to each allegation of research misconduct in a thorough, competent, objective and fair manner, including ensuring that individuals responsible for carrying out any part of the research misconduct proceeding do not have unresolved personal, professional, or financial conflicts of interest with the complainant, respondent, or witnesses. § 93.300(b).

- What resources are available if the P.I. is unsatisfied with the institution's response to allegations of research misconduct?
  - ✓ Allegations of research misconduct can be made directly to ORI.
  - ✓ When ORI receives an allegation of research misconduct directly or becomes aware of an allegation or apparent instance of research misconduct, it may conduct an initial assessment and refer the matter to the relevant institution for appropriate actions. §93.402

Case 3: Institution's Determination + ORI's oversight

Institution

- **Research misconduct Findings**
  - ✓ Knowing falsification of human research subjects' clinical data
- **Institutional Administrative Actions**
  - ✓ Termination of employment
  - ✓ Repayment of stolen stipend funds

ORI*

- **Research misconduct***
  - ✓ Knowing and intentional falsification of human research subjects' clinical data
  - ✓ Knowing and intentional recording falsified data in the EMR
- **HHS (ORI) Administrative Action(s)**
  - ✓ Federal Register Publication of Findings
  - ✓ Publication on ORI's website
  - ✓ Referral to OIG-re: grant fraud
  - ✓ Referral to OHRP for protocol deviations and serious noncompliance

*The significance of the misconduct and issues with the Institutions' research misconduct proceedings are considerations in the recommendation for a separate determination of research misconduct

Case 4

The P.I. for a PHS supported clinical trial evaluating the effects of a new medication to treat HTN. The study is performed outside the U.S. by a clinic that received PHS funds from a subcontractor. The P.I. submits an adverse event notification after a study participant suffers a CVA after recording a blood pressure of 220/130. Upon review of the participant's study chart, the P.I. identified that all of the previous BP measurements were ≤ 130/85. After having brief discussions with the study's clinical staff, the P.I. identifies that some of the data recorded in the study's EMR by one staff member, are not accurate. The study P.I. contacted the subcontractor, who instructed the P.I. to: 1) interview the staff member, 2) collect the human research subjects' raw and manipulated data, and 3) share the information with their study monitor. The study monitor determined that further investigation is warranted and instructed the P.I. to evaluate all the data collected for the study, identify any discrepancies, interview study staff, and report the findings to the subcontractor.

- **Are the subcontractor's instructions/procedures used to address potential research misconduct compliant with 42 C.F.R. Part 93?**
  - ✓ Yes
  - ✓ No
  - ✓ Unsure

Case 4 Cont'd

The study monitor determined that further investigation is warranted; and instructed the P.I. to evaluate all of the data collected for the study, identify any discrepancies, interview staff, and report the findings to the subcontractor.

- **Who should perform the inquiry and/or investigation?**
  - ✓ Subcontractor
  - ✓ On-site study monitor
  - ✓ Independent entity

- **Who should be notified of the PI's concerns?**
  - ✓ OHRP
  - ✓ ORI
  - ✓ OIG
  - ✓ NIH
  - ✓ More than one of the above

Quick Considerations

- The institution applying for or receiving PHS funding for any activities or programs that involves biomedical or behavioral research, biomedical or behavioral research training or activities related to that training is responsible for responding to each allegation of research misconduct in a thorough, competent, objective and fair manner, including ensuring that individuals responsible for carrying out any part of the research misconduct proceeding do not have unresolved personal, professional, or financial conflicts of interest with the complainant, respondent., or witnesses. § 93.300(b)
- What policies and procedures apply?
  (e.g., IRB, Research Misconduct, Research Protocol)
- What regulations may be applicable?
  (42 CFR Part 93; 45 CFR Part 46 etc.)
- What are the institution's reporting requirements?
  (OHRP, Funding Agency, ORI, FDA, etc.)

Case 4: Institution's Determination + ORI's oversight

Institution

- **Research misconduct Findings**
  - ✓ Knowing and intentional falsification and/or fabrication of BP data and medication data
- **Institutional Administrative Action(s)**
  - ✓ Termination of employment

ORI

- **Research misconduct**
  - ✓ Knowing and intentional falsification of BP data and medication data recorded in the EMR
  - ✓ Knowing and intentional fabrication of BP data and medication data recorded in the EMR
- **HHS (ORI) Administrative Action(s)**
  - ✓ Federal Register Publication of Findings
  - ✓ Publication on ORI's website
  - ✓ Referral to OHRP
  - ✓ Referral to NIH

Case 5

The former mentor (complainant) of the respondent, and former co-investigator in the questioned clinical research, raised the same allegations of falsification of human research subjects' responses to a new cancer treatment and their survival in the study database and in one (1) published paper in 2018 and again in 2019. The institution assessed the 2018 and 2019 allegations separately. Both times, the institution closed the matter without further inquiry and did **NOT** notify ORI of its determinations.

- **Are the institution's actions compliant with 42 C.F.R. Part 93?**
  - ✓ Yes
  - ✓ No
  - ✓ Unsure

Quick Considerations

- The institution is required to report to ORI on the decision to initiate an investigation §93.309.
- ORI may not be informed if the institution has assessed that the allegation does not meet the requirements of §93.102; §93.103; §93.105.
- Institutions must keep sufficiently detailed documentation of inquiries to permit a later assessment by ORI of the reasons why the institution decided not to conduct an investigation. Consistent with § 93.317, institutions must keep these records in a secure manner for at least 7 years after the termination of the inquiry, and upon request, provide them to ORI or other authorized HHS personnel. §93.308(c).

Case 5 Cont'd

Although being instructed to maintain confidentiality in accordance with the institutional policy and federal regulations regarding matters that were considered closed, the complainant continued to raise the same concerns to third parties and asserted that the former institution did not properly investigate the allegations.

- **Are there any compliance issues in this situation?**
  - ✓ Yes
  - ✓ No
  - ✓ Not sure

Quick Considerations

- Disclosure of the identity of respondents and complainants in research misconduct proceedings is limited, to the extent possible, to those who need to know, consistent with a thorough, competent, objective and fair research misconduct proceeding, and as allowed by law. §93.108(a)
- Except as may otherwise be prescribed by applicable law, confidentiality must be maintained for any records or evidence from which research subjects might be identified. Disclosure is limited to those who have a need to know to carry out a research misconduct proceeding. §93.108.
- The institution is required to establish policies and procedures that include protections for respondents, complainants, and research subjects identifiable from research records or evidence § 93.304; §93.300.

Case 5 Cont'd

- **In accordance with the federal regulations and the institutional policy, what should the institution do?**

  ✓ Remind the complainant of his/her obligation under 42 C.F.R. Part 93

  ✓ Take reasonable and practical steps as appropriate, to protect or restore the reputation of persons alleged to have engaged in research misconduct but against whom no finding of research misconduct is made.

  Note: These steps may include working in collaboration with the respondent to address any concerns that may directly or indirectly affect the continuity of the respondent's research related activities.

Example of Institution's letter to the complainant:

"*…We have made available to you avenues to raise your concerns, which you have done on multiple occasions, each time without evidence or merit. Therefore, in our effort to take steps to repair the respondent's reputation, we now require that you cease and desist from communication that could constitute a breach of federal and institutional confidentiality requirements.*

…I look forward to your cooperation but at this point understand that xxx (institution) will take additional actions should that cooperation not be forthcoming. "

Quick Considerations

- Consistent with the provisions of the PHS regulation at § 93.108, an institution subject to 42 C.F.R. Part 93 must:
- ✓ Provide confidentiality to the extent required by § 93.108 to all respondents, complainants, and research subjects identifiable from research records or evidence. §93.300(e).
- ✓ Take all reasonable and practical steps to ensure the cooperation of respondents and other institutional members with research misconduct proceedings, including, but not limited to, their providing information, research records, and evidence. §93.300(f).

- The PHS regulation requires that institutions include as part of their research misconduct policies and procedures "[a]ll reasonable and practical efforts, if requested and as appropriate, to protect or restore the reputation of persons alleged to have engaged in research misconduct but against whom no finding of research misconduct is made." § 93.304(k).

Questions?

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