

Research Misconduct & Detrimental Research Practices: Overview & Case Studies

October 14, 2022
NIH Virtual PreCon Event

Moderator:

Elyse Sullivan, PhD

Communications Strategist
Office of Extramural Research, NIH

Presenters:

Patricia Valdez, PhD

Chief Extramural Research Integrity Officer
Office of Extramural Research, NIH

Ranjini Ambalavanar, PhD

Scientist-Investigator
Office of Research Integrity, HHS



Research Misconduct & Detrimental Research Practices: Today's Format

NIH & HHS Presentation

Q&A

Break

Case Studies



Everyone's Responsibility



Who Are Our Partners?



HHS
ORI

Recipient
Institutions

NIH
OPERA



HHS
OCR

NIH
OER-RI

NIH
OLAW

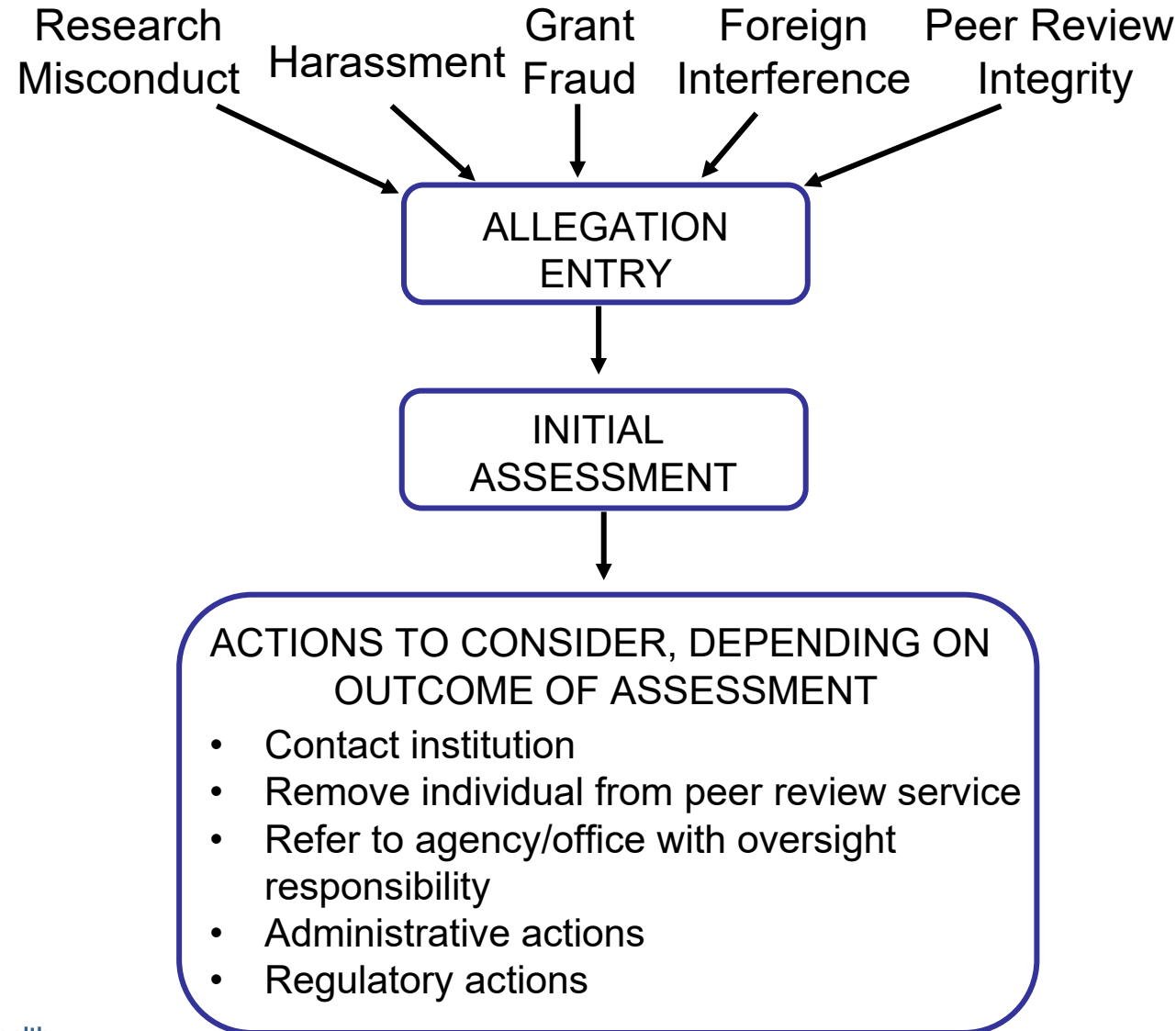
HHS
OHRP

HHS
OIG

NIH
OMA



Overview of NIH Allegation Review Process



Research Misconduct and Detrimental Research Practices

Ranjini Ambalavanar, Ph.D.

Division of Investigative Oversight (DIO)

Office of Research Integrity (ORI)

October 2022



OASH

Office of the
Assistant Secretary
for Health

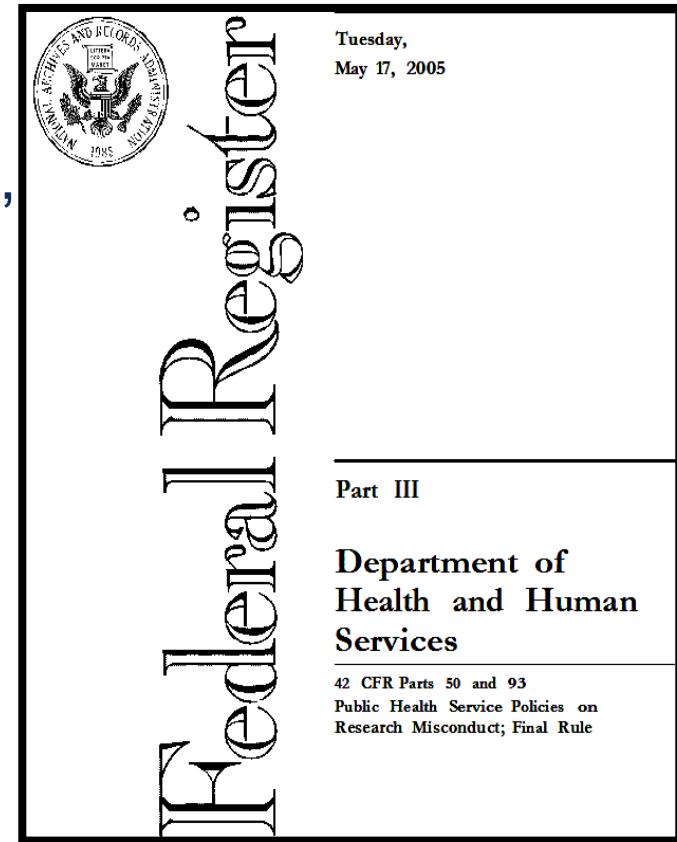
Research misconduct - 42 CFR § 93.103

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.

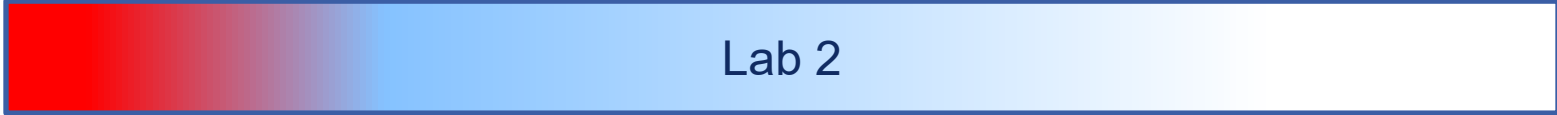
(c) Plagiarism is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit.



[PHS Policies on Research Misconduct](#)

Is Integrity in Research High? **Yes**

Majority of the scientists conduct research with a high degree of integrity, contributing to advancement in science



Research Misconduct

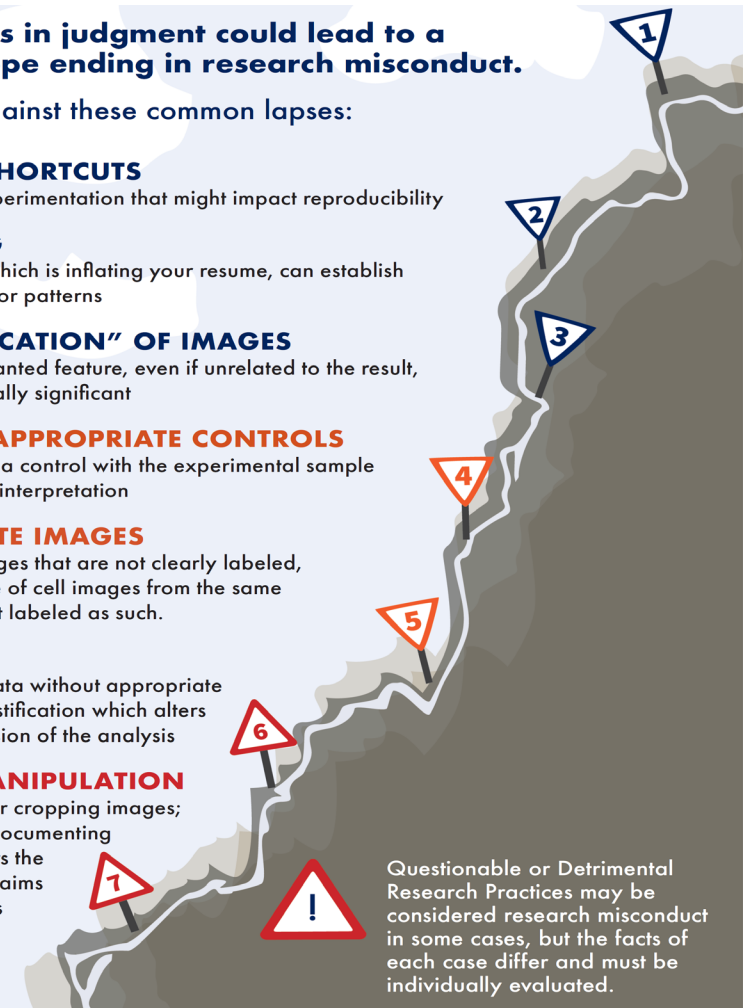
Questionable Research Practices/Sloppy Science

High Degree of Integrity

Small lapses in judgment could lead to a slippery slope ending in research misconduct.

Be vigilant against these common lapses:

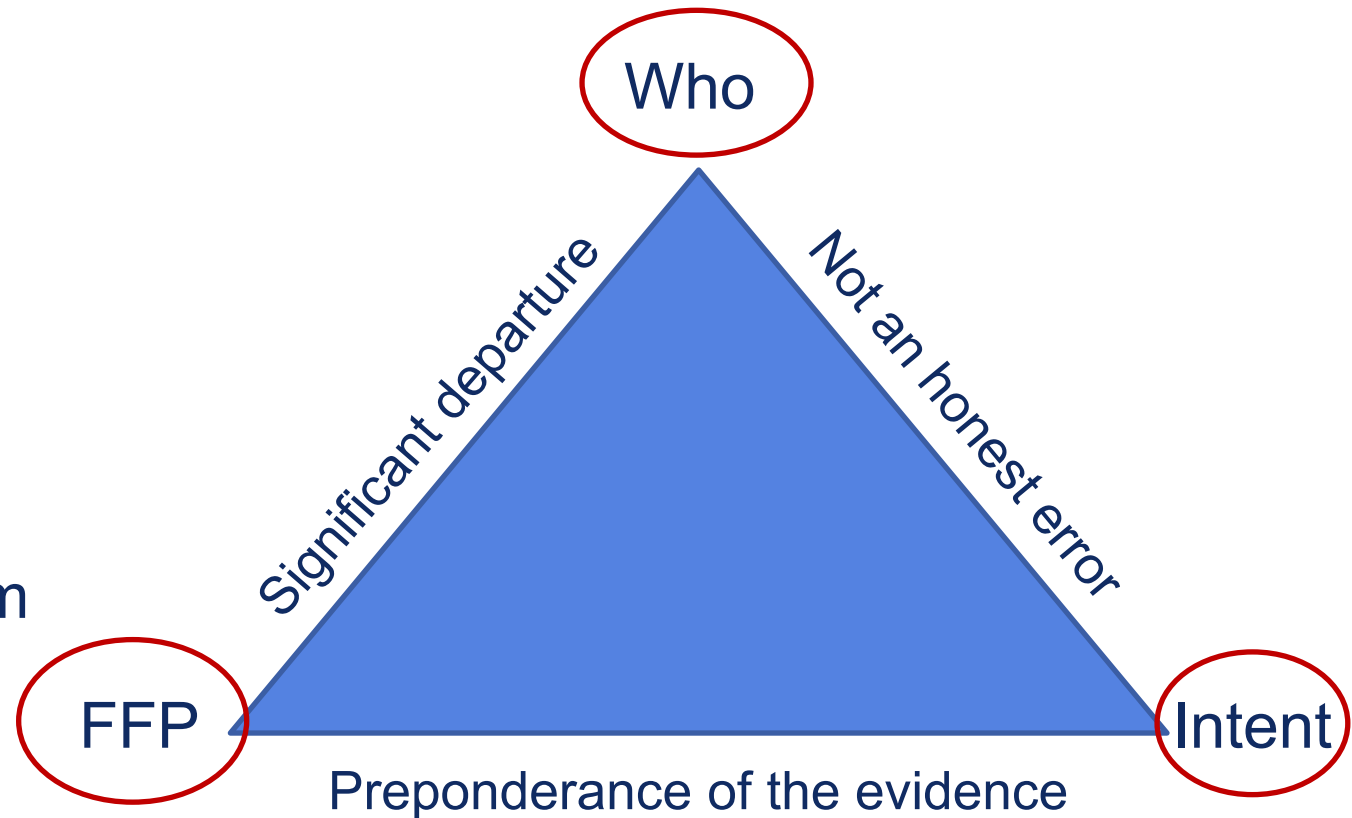
- 1. TAKING SHORTCUTS**
Lack of care in experimentation that might impact reproducibility
- 2. CHEATING**
Such as puffery, which is inflating your resume, can establish dangerous behavior patterns
- 3. "BEAUTIFICATION" OF IMAGES**
Removing an unwanted feature, even if unrelated to the result, could be scientifically significant
- 4. LACK OF APPROPRIATE CONTROLS**
Failure to perform a control with the experimental sample could affect result interpretation
- 5. COMPOSITE IMAGES**
Assemblies of images that are not clearly labeled, such as a montage of cell images from the same experiment but not labeled as such.
- 6. OUTLIERS**
Omitting outlier data without appropriate pre-experiment justification which alters the overall conclusion of the analysis
- 7. IMAGE MANIPULATION**
Splicing, cutting, or cropping images; without properly documenting changes, that alters the results or falsely claims a result which was not obtained.



Questionable or Detrimental Research Practices may be considered research misconduct in some cases, but the facts of each case differ and must be individually evaluated.

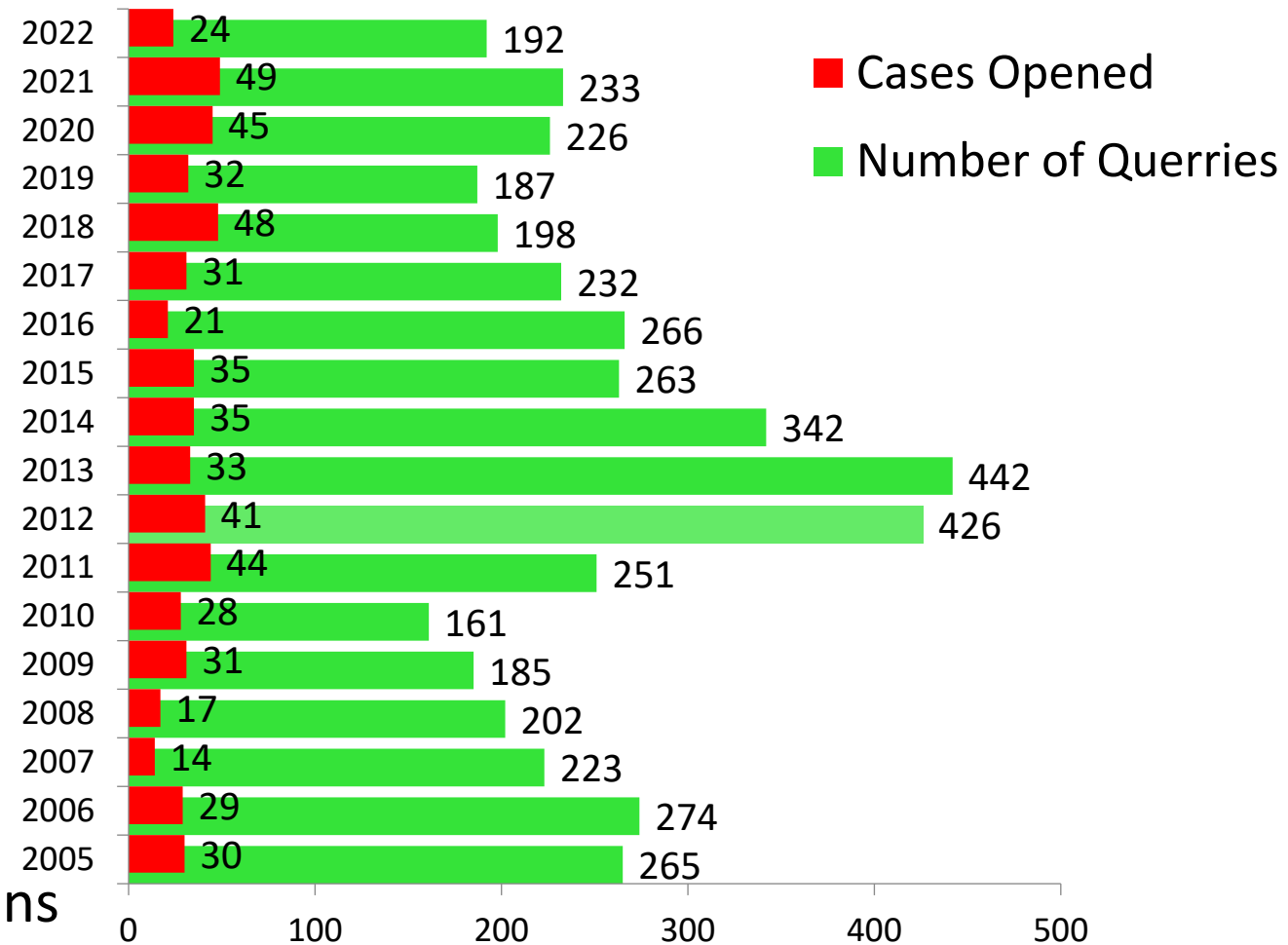
Research Misconduct Findings are made when

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



More Queries than Misconduct Cases Opened Data from 2005-2022

- Authorship or credit disputes
- Duplicate publication
- Intellectual property/patents
- Misuse of human subjects or animals
- Conflict of interest issues
- Financial mismanagement
- Radiation or biosafety hazards
- Other regulatory violations (FDA)
- Honest error or differences in interpretations
- Other questionable practices in research



Practice Caution

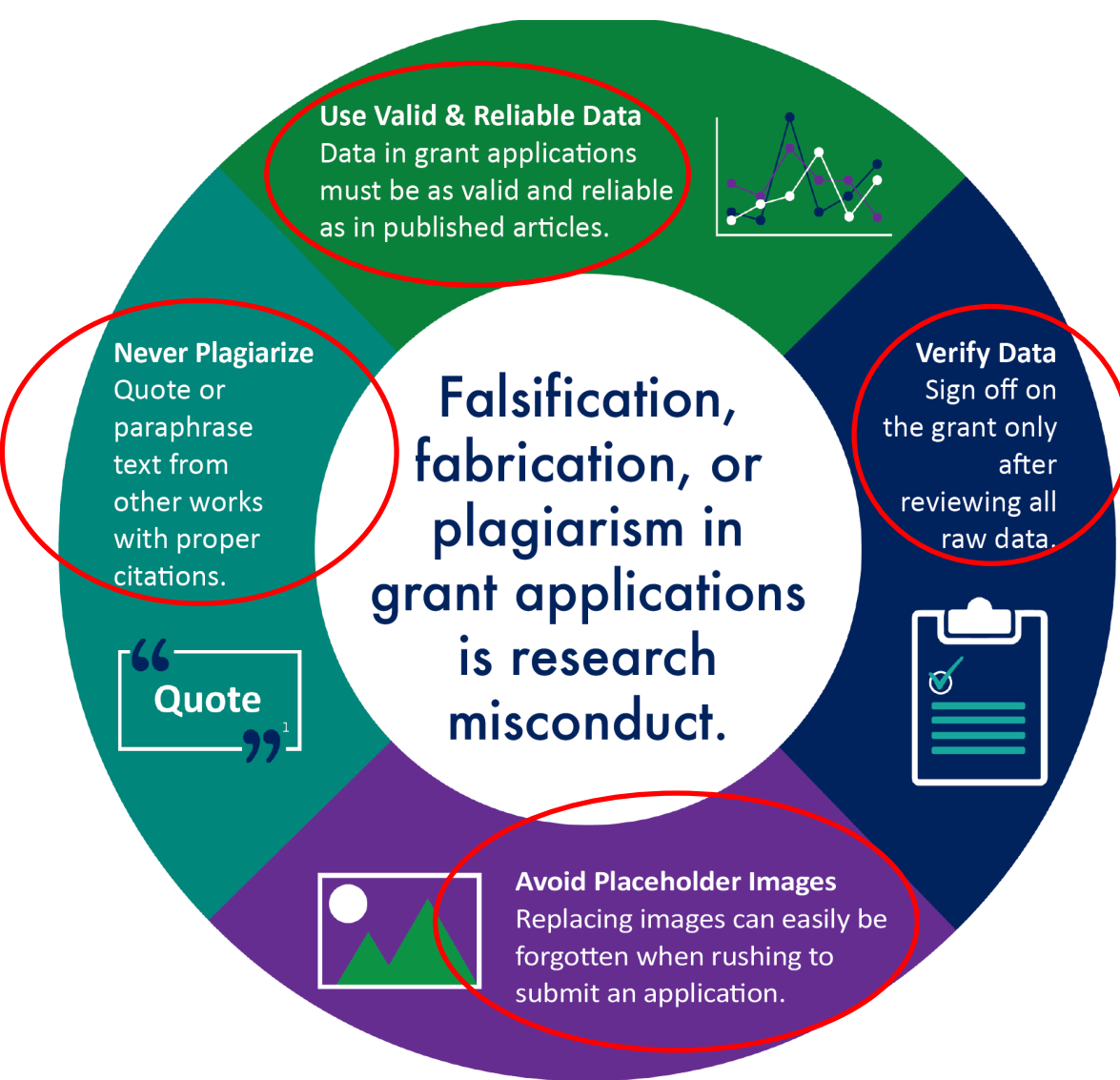
A question for you:

You submit an NIH grant application not aware that the data and/or text included by others were falsified and/or plagiarized.

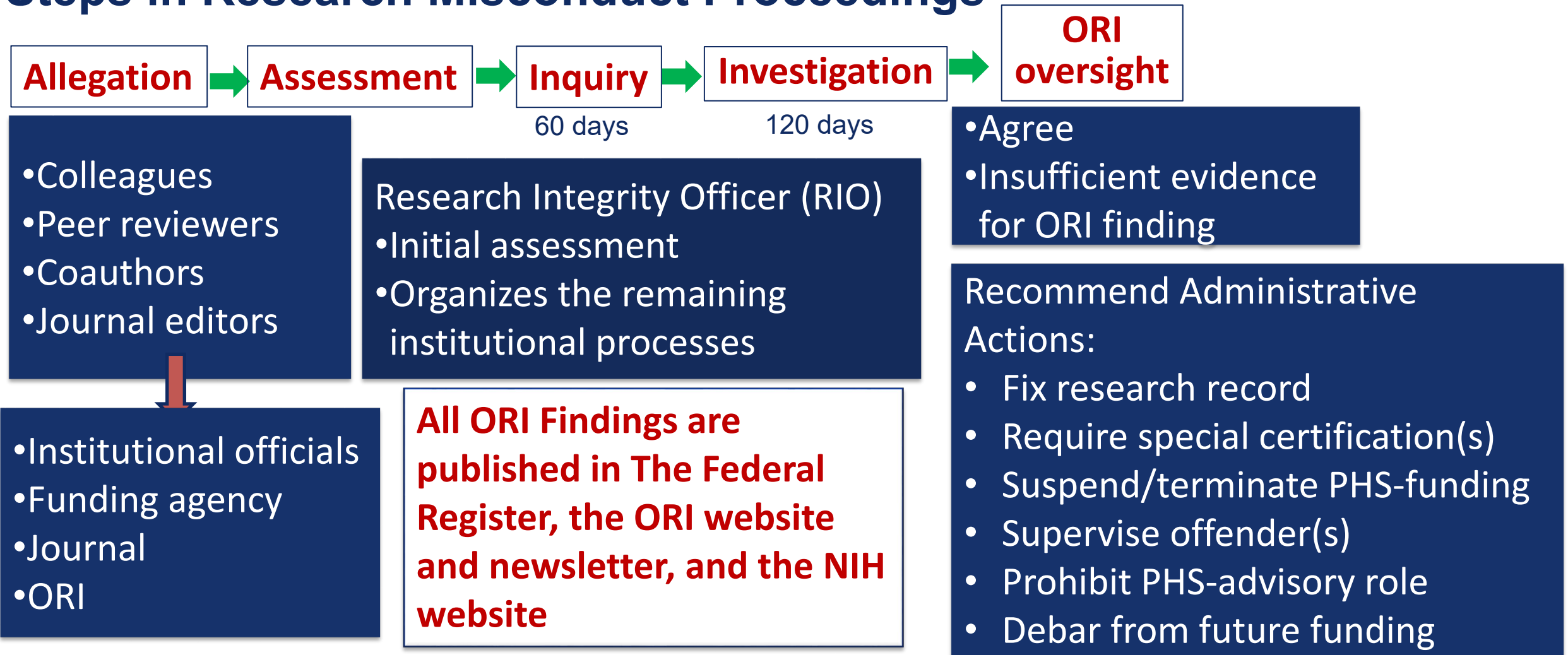
Are you liable for research misconduct?

Yes!

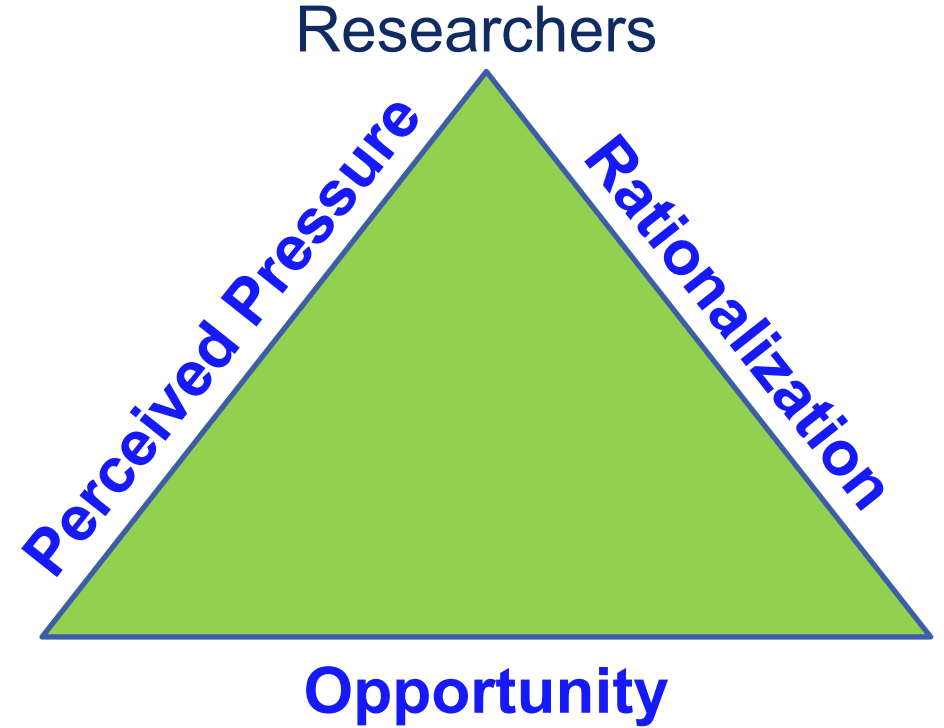
Decisions by an ALJ on a recent case established that a PI and/or corresponding author, can be liable for research misconduct even if he/she was completely unaware of any falsification or plagiarism.



Steps in Research Misconduct Proceedings



Role in Preventing Research Misconduct



Statements From Case Interviews

COMPETITIVE PRESSURES




“ I FELT IT WAS NECESSARY TO GET A PAPER IN A HIGH-PROFILE JOURNAL IN ORDER TO GET A FACULTY POSITION. ”

PERSONAL CIRCUMSTANCES



“ [I] HAD BEEN APPLYING FOR A GREEN CARD AND FELT **PRESSURED** TO MAKE A GOOD PAPER AND GET GOOD PUBLICATIONS. ”

INDIVIDUAL PSYCHOLOGY



“ HALF OF ME WANTED TO **MAKE [MY PI] PROUD**. THE OTHER HALF WAS **TERRIFIED OF FAILING...** SO I **FABRICATED** A PIECE OF DATA. ”

POOR SUPERVISION

“ **I WAS SCARED** TO GO TO [MY PI]. HE USED TO **SCREAM & YELL** AT ME WHEN THINGS DID NOT **WORK AS PLANNED.** ”

INADEQUATE TRAINING



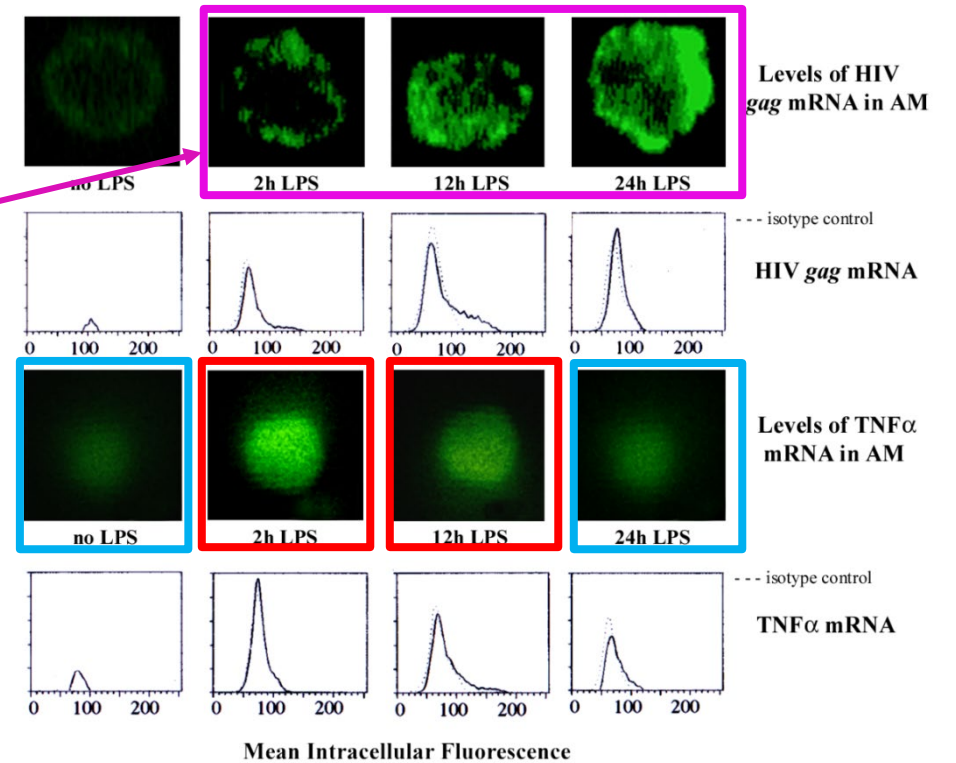
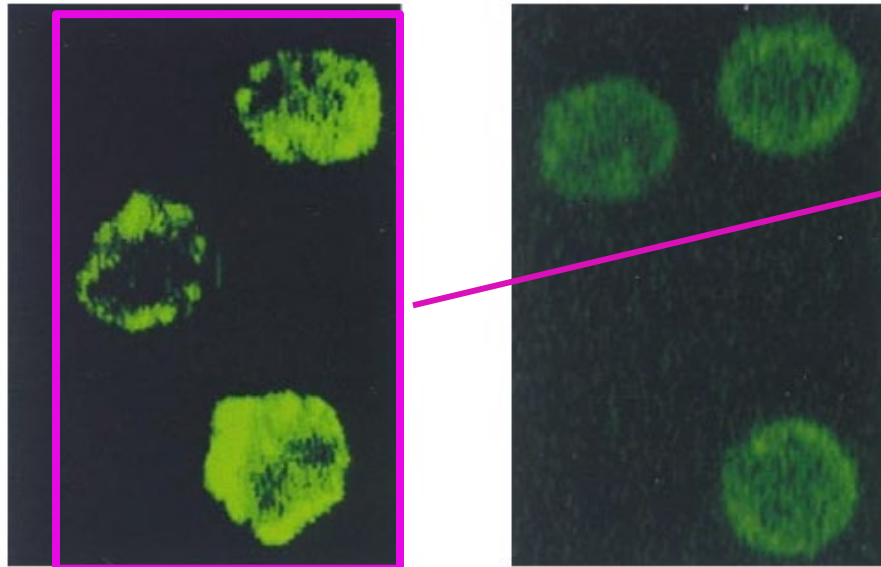
“ AFTER TWO YEARS OF A POSTDOCTORAL FELLOWSHIP... **I STILL DON'T KNOW HOW TO PROPERLY PUBLISH WESTERN BLOT DATA.** ”

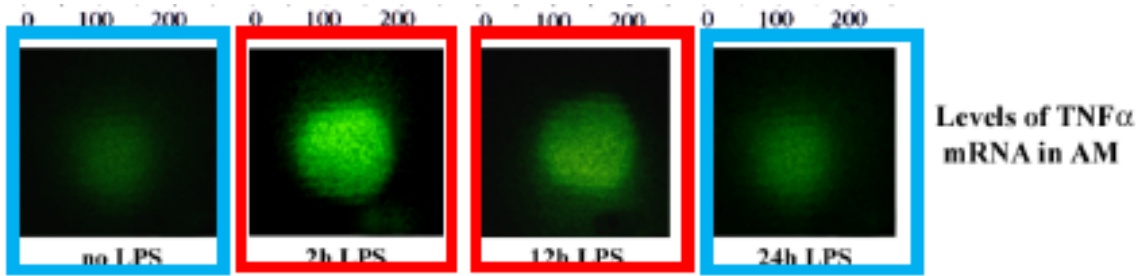
Same Cell Images to Represent Different Results

Figure 3c in *Nature Medicine*

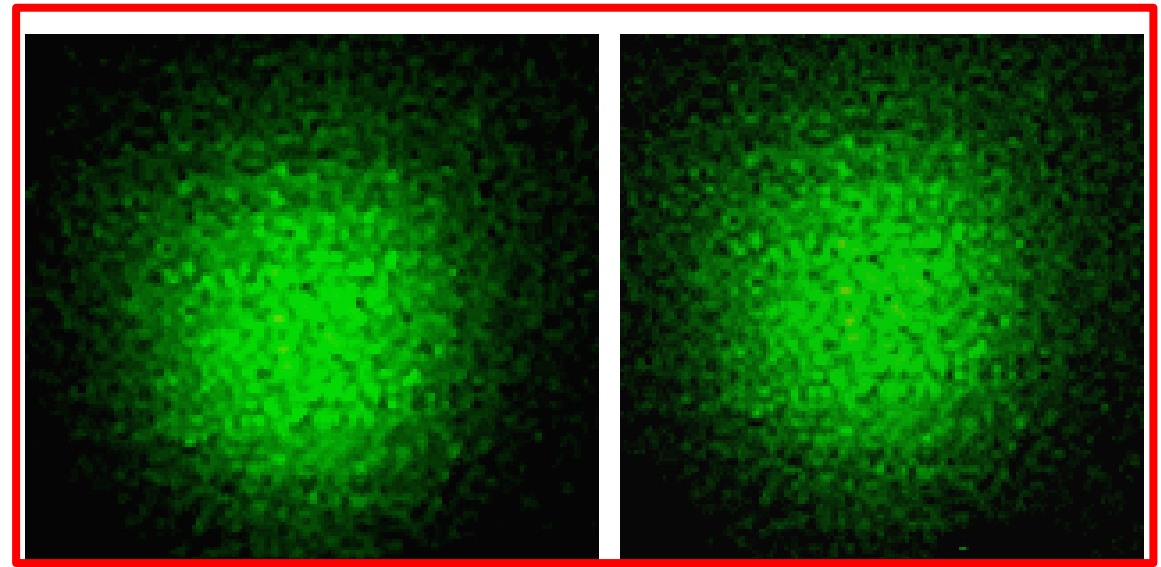
Figure C.2.5 in NIH grant application

C



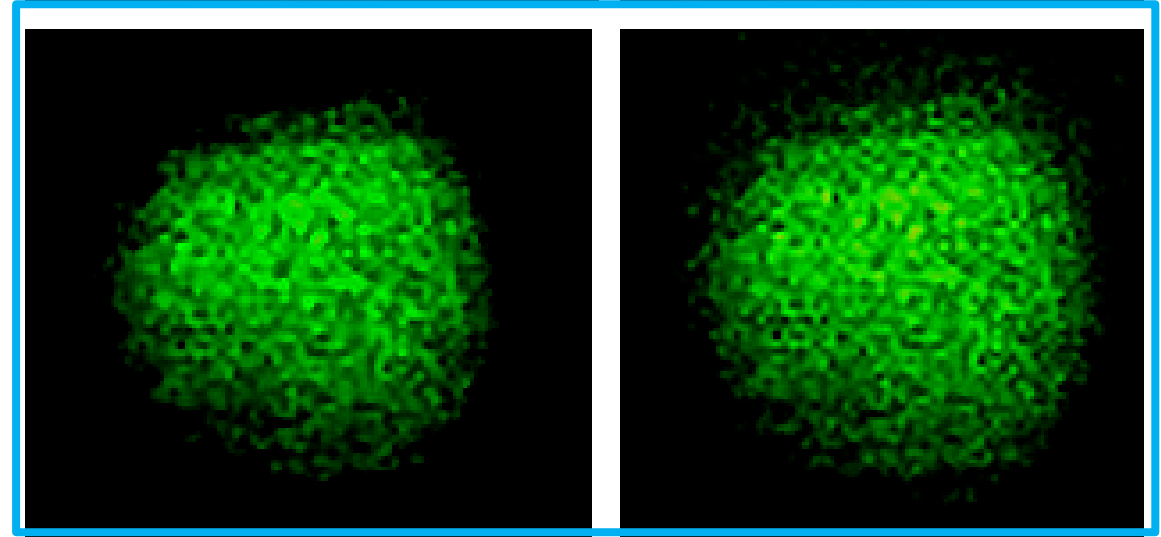


Same cell images representing
“2h LPS” and “12h LPS”



Intensity Enhanced and size adjusted

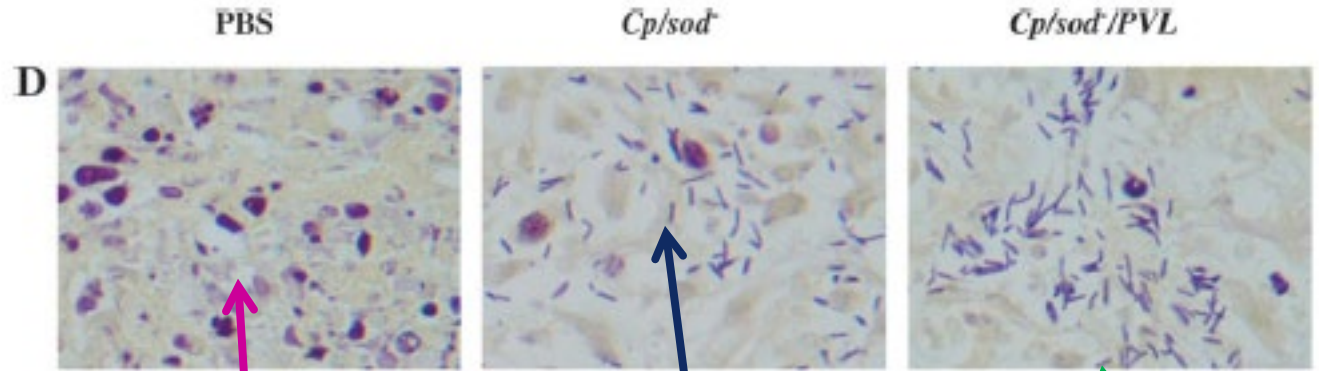
Same cell images representing
“no LPS” and “24h LPS”



JCNI Figure 4D = Figure 6 in R21 CA120017-01+ Figure 6C in R21 CA120017-02 + Figure 10D R01 CA130897 01 A1

Pancreatic tumor

JNCI 2008
Figure 4D



Rectangular section from Figure 6C in R21 CA120017-02 was rotated 90 degrees counter-clockwise

Figure 6C in R21 CA120017-02 pancreatic tumors, 5 days post injection with bacterial strain *Cp/sod-*

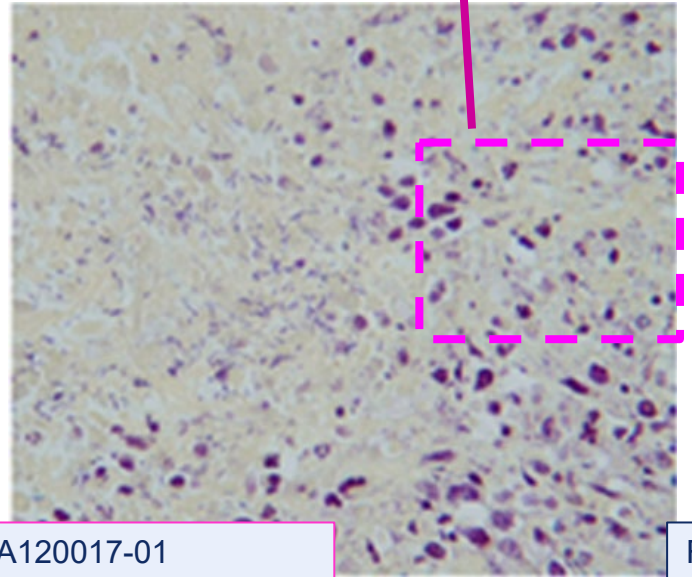


Figure 6 in R21 CA120017-01 submitted 2/05
hepatic tumor 2 days post iv *Cp/plc-*

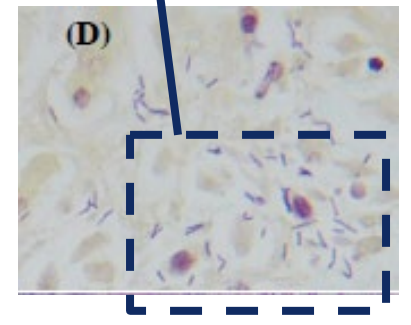
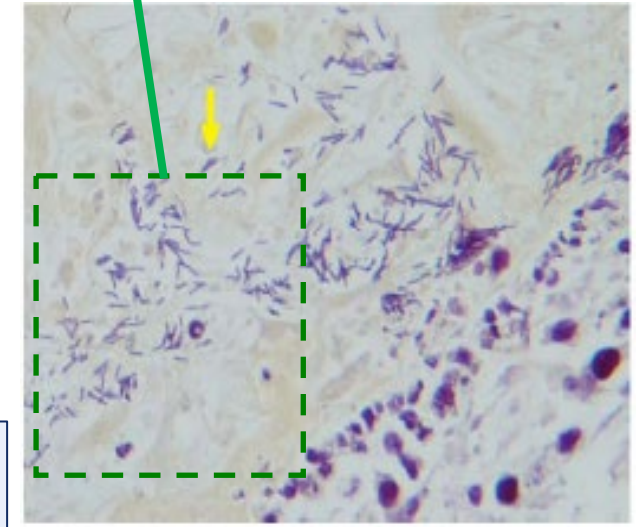


Figure 10D R01 CA130897 01 A1 submitted 10/07
2 days pancreatic tumor 2days post *cp/sod-* in mice treated with control liposomes



Follow up Visits For Patient 10: dated "01-18-88" and "11-29-88"

NSABP BREAST CANCER FOLLOW-UP FORM

Submit every 3 months during the first 3 years following surgery, every 6 months thereafter. Answer all questions. When information unknown, so state. Distribution: First copy to Biostatistical Center, second copy for Institution.

FORM F

INSTITUTION <i>St. Luc M.H.</i>		PROTOCOL <i>R13</i>
PATIENT'S LAST NAME <i>Vincent</i> FIRST <i>CAROLLE</i> MIDDLE INITIAL		STUDY NUMBER <i>13050</i>
EXAMINING PHYSICIAN - NAME AND ADDRESS <i>R. Poirson</i>		DATE FORM COMPLETED <i>01-18-88</i>
ASSIGNED TREATMENT ARM <i>-</i>		DATE PATIENT LAST SEEN OR CONTACTED <i>01-18-88</i>

METHOD OF PATIENT CONTACT:

SEEN IN HOSPITAL OR CLINIC (Specify) *Medical* TELEPHONE CONTACT TO PATIENT OR PHYSICIAN (Specify) *Medical* OTHER (Specify)

PHYSICAL FINDINGS

DATE OF PHYSICAL EXAM
n/a

SIDE OF MASTECTOMY

SCAR NEG. SUSP. POS.
 BREAST NEG. SUSP. POS.
 PARASTERNAL NODULES NEG. SUSP. POS.
 AXILLARY NODES NEG. SUSP. POS.
 SUPRACLAVICULAR NODES NEG. SUSP. POS.
 SKIN NEG. SUSP. POS.

OPPOSITE SIDE

BREAST NEG. SUSP. POS.
 CHEST WALL NEG. SUSP. POS.
 PARASTERNAL NODULES NEG. SUSP. POS.
 AXILLARY NODES NEG. SUSP. POS.
 SUPRACLAVICULAR NODES NEG. SUSP. POS.
 SKIN NEG. SUSP. POS.

OTHER PHYSICAL FINDINGS:
Patient is fine.

INSTITUTION <i>St. Luc M.H.</i>	PROTOCOL <i>2-13</i>
PATIENT'S LAST NAME <i>Vincent</i> FIRST <i>CAROLLE</i> MIDDLE INITIAL	STUDY NUMBER <i>13050</i>
EXAMINING PHYSICIAN - NAME AND ADDRESS <i>Noire Dame Hospital</i>	DATE FORM COMPLETED <i>11-29-88</i>
ASSIGNED TREATMENT ARM <i>-</i>	DATE PATIENT LAST SEEN OR CONTACTED <i>11-29-88</i>

METHOD OF PATIENT CONTACT:

SEEN IN HOSPITAL OR CLINIC (Specify) TELEPHONE CONTACT TO PATIENT OR PHYSICIAN (Specify) OTHER (Specify)

PHYSICAL FINDINGS

DATE OF PHYSICAL EXAM
11-88

SIDE OF MASTECTOMY

SCAR NEG. SUSP. POS.
 BREAST NEG. SUSP. POS.
 PARASTERNAL NODULES NEG. SUSP. POS.
 AXILLARY NODES NEG. SUSP. POS.
 SUPRACLAVICULAR NODES NEG. SUSP. POS.
 SKIN NEG. SUSP. POS.

OPPOSITE SIDE

BREAST NEG. SUSP. POS.
 CHEST WALL NEG. SUSP. POS.
 PARASTERNAL NODULES NEG. SUSP. POS.
 AXILLARY NODES NEG. SUSP. POS.
 SUPRACLAVICULAR NODES NEG. SUSP. POS.
 SKIN NEG. SUSP. POS.

OTHER PHYSICAL FINDINGS:
Patient is fine.

Follow up Visits For Patient 10: dated "03-21-89" and "02-02-90"

INSTITUTION <i>St. Luc mch.</i>		PROTOCOL <i>B-13</i>	
PATIENT'S LAST NAME <i>VINCENY</i>		FIRST <i>CHARLENE</i>	MIDDLE INITIAL <i></i>
EXAMINING PHYSICIAN - NAME AND ADDRESS <i>Dr. Norris Davis Hospital</i>		STUDY NUMBER <i>13050</i>	DATE FORM COMPLETED <i>03-21-89</i>
		ASSIGNED TREATMENT ARM <i></i>	DATE PATIENT LAST SEEN OR CONTACTED <i>03-21-89</i>
METHOD OF PATIENT CONTACT			
<input type="checkbox"/> SEEN IN HOSPITAL OR CLINIC (Specify)		<input checked="" type="checkbox"/> TELEPHONE CONTACT TO PATIENT OR PHYSICIAN (Specify)	
		<input type="checkbox"/> OTHER (Specify)	
PHYSICAL FINDINGS		DATE OF PHYSICAL EXAM <i>N/A</i>	
SIDE OF MASTECTOMY			
SCAR <input type="checkbox"/> NEG <input type="checkbox"/> SUSP <input type="checkbox"/> POS	BREAST <input type="checkbox"/> NEG <input type="checkbox"/> SUSP <input type="checkbox"/> POS	CHEST WALL <input type="checkbox"/> NEG <input type="checkbox"/> SUSP <input type="checkbox"/> POS	
PARASTERNAL NODULES <input type="checkbox"/> NEG <input type="checkbox"/> SUSP <input type="checkbox"/> POS	AXILLARY NODES <input type="checkbox"/> NEG <input type="checkbox"/> SUSP <input type="checkbox"/> POS	SUPRACLAVICULAR NODES <input type="checkbox"/> NEG <input type="checkbox"/> SUSP <input type="checkbox"/> POS	
SKIN <input type="checkbox"/> NEG <input type="checkbox"/> SUSP <input type="checkbox"/> POS	COMMENTS		
OPPOSITE SIDE			
BREAST <input type="checkbox"/> NEG <input type="checkbox"/> SUSP <input type="checkbox"/> POS		CHEST WALL <input type="checkbox"/> NEG <input type="checkbox"/> SUSP <input type="checkbox"/> POS	
AXILLARY NODES <input type="checkbox"/> NEG <input type="checkbox"/> SUSP <input type="checkbox"/> POS		SUPRACLAVICULAR NODES <input type="checkbox"/> NEG <input type="checkbox"/> SUSP <input type="checkbox"/> POS	
SKIN <input type="checkbox"/> NEG <input type="checkbox"/> SUSP <input type="checkbox"/> POS		COMMENTS	
OTHER PHYSICAL FINDINGS			
MANAGEMENT OF PATIENTS (FOR SUSPICIOUS OR POSITIVE FINDINGS, SUBMIT DOCUMENTATION) <i>Patient is doing well.</i>			
Score	Date(s) performed	Findings	
Site		<input type="checkbox"/> NEG <input type="checkbox"/> SUSP <input type="checkbox"/> POS	
Case			

Date patient last seen or contacted

NSABP BREAST CANCER FOLLOW-UP FORM

Submit every 3 months during the first 3 years following surgery, every 6 months thereafter. Answer all questions. When information unknown, so state. Distribution: First copy to Biostatistical Center; second copy for Institution.

INSTITUTION		PROTOCOL	
PATIENT'S LAST NAME <i>VINCENY</i>		FIRST <i>CHARLENE</i>	MIDDLE INITIAL <i></i>
EXAMINING PHYSICIAN - NAME AND ADDRESS <i>Dr. Norris Davis Hospital</i>		STUDY NUMBER <i>13050</i>	DATE FORM COMPLETED <i>03-21-89</i>
		ASSIGNED TREATMENT ARM <i></i>	DATE PATIENT LAST SEEN OR CONTACTED <i>02/02/90</i>
METHOD OF PATIENT CONTACT			
<input type="checkbox"/> SEEN IN HOSPITAL OR CLINIC (Specify)		<input checked="" type="checkbox"/> TELEPHONE CONTACT TO PATIENT OR PHYSICIAN (Specify)	
		<input type="checkbox"/> OTHER (Specify)	

Patient 10: Death Certificate “September 29, 1987”
28 months prior to last reported follow-up (2-2-90)
4 months prior to first shown (1-18-88) follow up

Hôpital Notre-Dame
Montréal
1560 est. rue Sherbrooke
Montréal, Québec H2L 4M1

ATTESTATION DE DÉCÈS

NOM
(À la naissance)

ADRESSE 4648 Cartier, Montréal, Québec

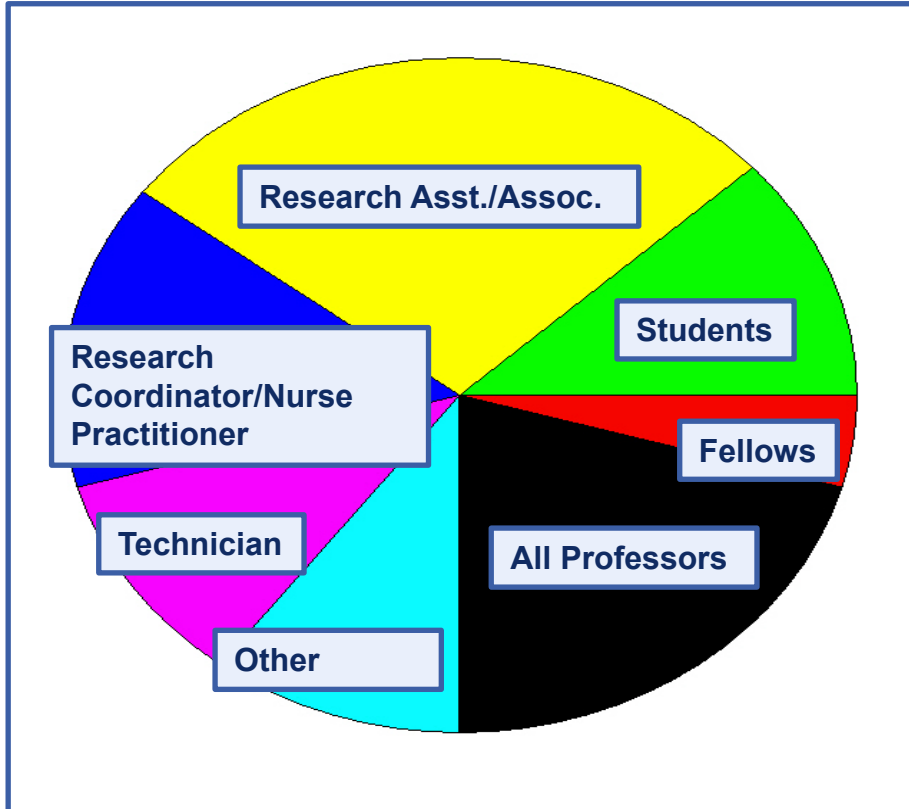
DATE DE NAISSANCE 31 décembre 1924

DATE DU DÉCÈS 29 septembre 1987

- FFP in clinical research involves
 - Interviews
 - Entry criteria
 - Screening logs
 - Approval forms
 - Follow-up visits, exams/data
 - Consent forms
 - Test scores
 - Laboratory results
 - Patient data
 - Number of subjects
 - Dates of procedures
 - Study results

Common in Research Misconduct Cases

Respondents in 68 cases with finding



- Inadequate supervision, guidance or training
- Excessive work-load
- PI accepting summary data or prepared tables/graphs
- PI not present in the laboratory
- Demanding desired results to meet a deadline
- Use of threats and intimidation as tactics to obtain results
- Sloppy research records
- No guidance or standards for keeping data



Lack of Policies/guidelines

- Culpability lies on the grantee –i.e the Institution receiving the grant
- Make sure to have up to date Policies and procedures
 - Data storage and retention
 - Acceptable image manipulation
 - RCR training requirement
 - Return of funds in cases of research fraud
- Research Misconduct can happen at any level.
- Evaluation of the raw data is critical for early detection of problems.
- ORI can provide advice confidentially regarding potential Research Misconduct questions.



What can you do?

- As a senior official
 - set the tone for the institution and make integrity a high priority
- As an administrator
 - develop and implement policies that support integrity
- As a principal investigator
 - establish specific standards for the staff on recording, reporting, and publishing data
 - Be prepared to respond to a wider scrutiny
- As a staff scientist in the lab
 - commit to integrity and practice it on a daily basis



Research Misconduct & Detrimental Research Practices

Patricia Valdez, PhD

Chief Extramural Research Integrity Officer

Office of Extramural Research, NIH



National Institutes of Health
Office of Extramural Research

NIH Interim Actions for Integrity Concerns

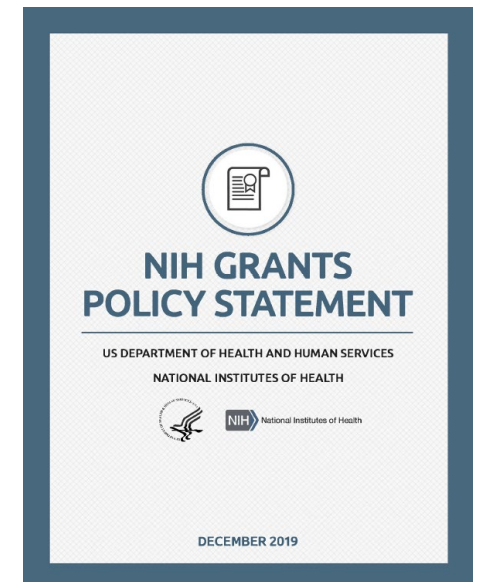
- Protect public, research participants, research, research process, and public funds
- Interim actions include, but not limited to:
 - Specific award conditions
 - Additional supervision
 - Certification of data
 - Request change of PI
 - Restrict funds
 - Suspend or Terminate award
- Also, referral to HHS Office of the Inspector General



When to Contact NIH: Changes in Project and Budget

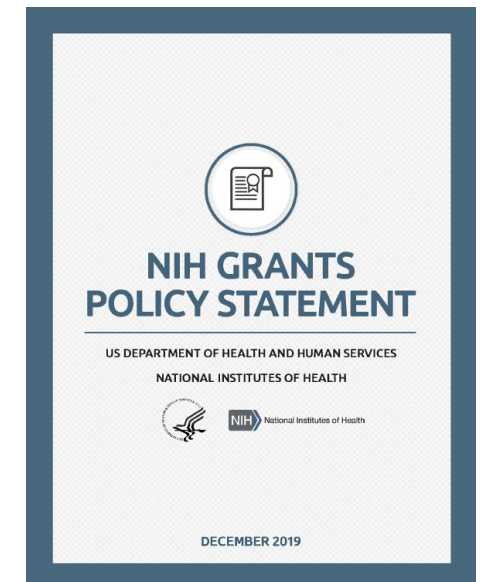
- Notify NIH of developments that have a significant impact on the award-supported activities
- Notify NIH of problems, delays, or adverse conditions which materially impair the ability to meet the objectives of the award
- Notification shall include a statement of the action taken or contemplated, and any assistance needed to resolve the situation

[NIH Grants Policy Statement: Changes in Project and Budget](#)



When to Contact NIH: Fraud, Waste & Abuse of NIH Grant Funds

- Report false statements related to research misconduct to NIH or HHS OIG.
- NIH may administratively recover misspent grant funds.
- The Federal government may pursue administrative, civil, or criminal action under a variety of statutes relating to fraud and making false statement or claims.



[NIH Grants Policy Statement: Fraud, Waste, and Abuse of NIH Grant Funds](#)

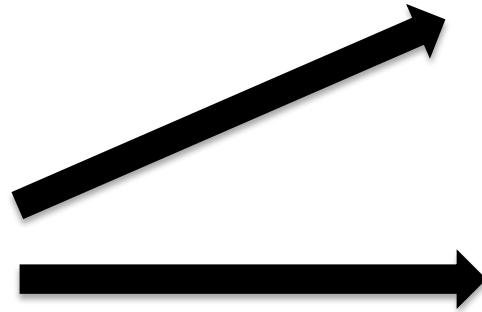


Research Misconduct & False Claims

**Research
Misconduct**



False Claims



False Claims and False Statements

- Civil:
 - 31 U.S.C. § 3729 – 3733 The False Claims Act
 - knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;
 - knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim;
- Criminal:
 - 18 U.S.C. § 287 False, fictitious or fraudulent claims
 - 18 U.S.C. § 1001 Statements or entries generally

How Does This Apply to NIH Applications?

- False records or statements included in grant applications may be considered false claims or false statements.
- Examples include:
 - Falsified/fabricated data
 - Failure to disclose other support and/or grant overlap
 - Misrepresenting level of effort of key personnel
- Must demonstrate materiality.

False Claims Settlement



The screenshot shows the top portion of a news article on the website of the United States Department of Justice, District of Massachusetts. The header includes the department name and navigation links. The article title is "Former Newton Scientist Agrees to Pay \$215,000 to Resolve Allegations of False Statements in Grant Application", dated Friday, August 6, 2021. The lead paragraph states that a former Newton scientist sponsored by Massachusetts General Hospital (MGH) has agreed to resolve allegations of false statements on a grant application to the National Institutes of Health (NIH).

United States Department of Justice

THE UNITED STATES ATTORNEY'S OFFICE
DISTRICT of MASSACHUSETTS

HOME ABOUT DIVISIONS NEWS OUTREACH & INITIATIVES RESOURCE

U.S. Attorneys » District of Massachusetts » News

Department of Justice
U.S. Attorney's Office
District of Massachusetts

SHARE

FOR IMMEDIATE RELEASE Friday, August 6, 2021

Former Newton Scientist Agrees to Pay \$215,000 to Resolve Allegations of False Statements in Grant Application

BOSTON – A former Newton scientist sponsored by Massachusetts General Hospital (MGH) has agreed to resolve allegations that he submitted false statements on a grant application to the National Institutes of Health (NIH).

“The NIH grant application process relies on scientific integrity, accuracy and honesty from individual principal investigators, but Dr. Lee supplied falsified results, inauthentic data and false statements instead, ...”

www.Justice.gov - Former Newton Scientist Agrees to Pay to \$215K to Resolve Allegations of False Statements in Grant Application



Why It Matters

“... said Acting [US] Attorney Nathaniel R. Mendell. ‘Defrauding the NIH wastes taxpayer money, limits the availability of funding for other research and undermines the central purpose of scientific inquiry. We commend MGH for disclosing the alleged false statements, for repaying funds and for taking meaningful steps to prevent future recurrences.’”

www.Justice.gov - [Former Newton Scientist Agrees to Pay to \\$215K to Resolve Allegations of False Statements in Grant Application](#)



Q&A



National Institutes of Health
Office of Extramural Research

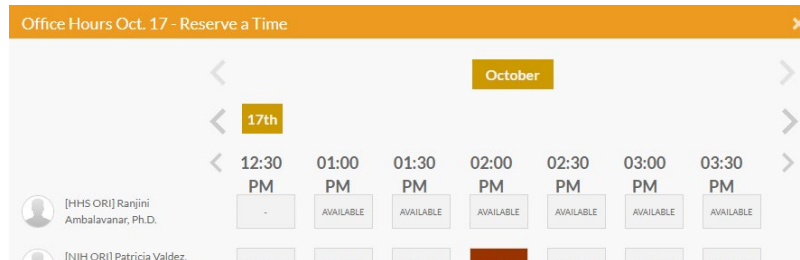
OFFICE HOURS: Reserve Your 20-Minute Appointment Today



Office Hours on Monday, October 17

ORI Expert: 9:00 AM - 4:00 PM ET

NIH Expert: 12:00 PM - 5:00 PM ET



"See Something, Say Something!" Booth

How to Reserve Your Time with Experts:

- *1. Log into the NIH Grants Conference Center.
2. Choose how you would like to access:
 - Go to the NIH Exhibit Hall and locate the See Something, Say Something! booth in the NIH Central Resource Room.
 - OR
 - Visit the Research Misconduct PreCon Event Page and click the "Schedule Appointment" button on the banner.
3. Select your time and you will receive an email confirmation with instructions.

Research Misconduct & Detrimental Research Practices

CASE STUDIES

Moderator:

Elyse Sullivan, PhD

Communications Strategist

Office of Extramural Research, NIH

Presenters:

Patricia Valdez, PhD

Chief Extramural Research Integrity Officer

Office of Extramural Research, NIH

Ranjini Ambalavanar, PhD

Scientist-Investigator

Office of Research Integrity, HHS



CASE STUDY #1



You as a Principal Investigator

You are the PI of a Phase II clinical trial on a new cancer drug that your university has patented. One of the subjects in your trial dies, but you don't believe that the death was related to your trial. What do you do?

- A. Note the death in your notes, but continue your research as planned.
- B. Include this as a serious adverse event in your next scheduled communications with the IRB
- C. Immediately report this to the IRB as a serious adverse event.

As the Institutional Official (IO) for human research protections.

- You are the Institutional Official (IO) for human research protections and the RIO reports to you.
- You regularly review IRB minutes, and, on this day, you noticed a report of a death in a Phase II clinical trial on a new cancer drug the university has patented.
- The IRB has determined that the death was a result of the trial, and that it should be put on hold.
- Also, in the IRB minutes the consent form in the deceased patient's file was not signed. The minutes state that the IRB will investigate the matter further.
 - **What questions should you as the IO be asking?**
 - A. How long does the IRB plan to pause the research?**
 - B. Who was funding the trial?**
 - C. Has the IRB been in contact with anyone outside the university about this adverse event?**



-
- The next day the IRB chair calls you, the IO, to report that there was also a discrepancy between the information in the deceased patient's clinical file (age, time since original diagnosis, previous therapy) and the information listed on the research intake form for that patient. The research intake form was signed by one of the research nurses for that drug trial, Nurse Y.
 - **Who should you report this to at this time?**
 - A. ORI**
 - B. The university's RIO**
 - C. The PI's department chair**
 - D. OHRP**



-
- The RIO and the IRB chair coordinate review of all relevant clinical and research records.
 - After an hour they have found three other cases where the information regarding eligibility criteria on the research intake form does not appear to match that in the patient's clinical file.
 - They also find several instances where records completed by the same nurse for patients' follow-up visits to monitor health after conclusion of therapy do not include the subject's initials, as required by the protocol.
 - **Should this matter proceed from assessment to inquiry?**



CASE STUDY #2



Part 1

- **Rebecca RIO informs HHS ORI of a decision to move to investigation after an inquiry into allegations of falsified data in multiple NIH-supported publications belonging to the PI, Dr. Smith. The publications span several years, and Dr. Smith is corresponding author on all of them.**
- **The inquiry committee found that the data in question were also used in an NIH grant application that was recently awarded, so the investigation committee will consider those data as well.**

QUESTION: Should Rebecca RIO also inform NIH of the ongoing investigation?



Part 2

Shortly after the investigation begins, Dr. Smith sends an email to his lab asking that the person responsible for the data falsification come forward immediately to end the investigation. One of the lab members forwards the email to Rebecca RIO.

QUESTION: What should Rebecca RIO do about Dr. Smith contacting lab members about the investigation?

Part 3

- **Rebecca RIO reprimands Dr. Smith for attempting to interfere in the research misconduct proceedings.**
- **The following week, Dr. Smith asks a few lab members to meet with him privately to discuss the allegation. During this meeting, he pounds his fist on his desk and demands the lab members to tell him who is responsible for the figures in question. When they fail to give him a name, he screams and throws a lab notebook at the wall, narrowly missing their heads.**
- **Paula Postdoc calls Rebecca RIO to tell her about Dr. Smith's questions and his violent behavior.**

QUESTION: To whom should Rebecca RIO report Dr. Smith's violent activity?



Part 4

- **Rebecca RIO files a report with HR. The HR investigation finds that Dr. Smith bullied his lab members and created a hostile work environment. As a result, university officials place Dr. Smith on Administrative Leave. Dr. Smith is not allowed on campus and is prohibited from communicating with members of his lab.**

QUESTION: Who needs to be notified about Dr. Smith's change of status?

Part 5

- **University officials notify NIH of disciplinary actions taken against Dr. Smith in response to bullying and creating a hostile work environment. They have put Paula Postdoc in charge of the NIH project while Dr. Smith is on Administrative Leave.**

QUESTION: Can the university decide to make Paula Postdoc the PI of the grant?

Part 6

- **Rebecca RIO works with the university's Authorized Organizational Representative to obtain prior approval from NIH for a change in PI on the active award.**
- **As the investigation proceeds, it becomes clear that the majority of the raw data for the figures in question are missing.**
- **Rebecca RIO and university officials decide to stop drawing down funds on the NIH project because they are uncertain about the authenticity of the data included in the application, and they are concerned that the subsequent research might be affected.**

QUESTION: Who needs to be notified if the university decides to stop drawing down funds or to stop spending on the NIH award?

Part 7

- **Several months later, the investigation continues, and Dr. Smith notifies university officials that he has a tentative job offer at a new university out of state. The job offer requires that he bring the NIH grant with him, so Dr. Smith asks his current university to transfer the active NIH grant to his new university.**
- **Rebecca RIO and other university officials have reservations about transferring the grant, especially since the data in the application may be unreliable.**
- **Dr. Smith mentions that he is contacting a lawyer to make sure his interests are protected.**

QUESTION: What are the university's options regarding the grant?



Part 8

- **The university decides to identify a suitable PI to take over the grant for the remainder of the project. The grant will stay at the university and Dr. Smith's trainees will continue to be supported.**
- **Dr. Smith receives an official job offer from the new university and he immediately resigns from his current university to start his new life, free of research misconduct allegations and investigations.**
- **Meanwhile, the investigation at his former university is nearing the end.**

QUESTION: Should Rebecca RIO mention the ongoing investigation to the new institution?

QUESTION: Should the new university ask Dr. Smith if he is currently under investigation or if his former institution made findings of research misconduct against him?



Part 9

- **The investigation is complete a few months later. The investigation committee was unable to determine who was responsible for falsified/fabricated data in 7 NIH-supported publications and two grant applications (including the active award). The deciding official agrees with the committee that the publications should be retracted.**
- **The report notes concerns about data management practices in Dr. Smith's lab. In particular, the raw data for the figures could not be located.**
- **The reports also notes that Dr. Smith's inclusion of falsified/fabricated data in an NIH grant application constitutes recklessness.**

QUESTION: To whom should Rebecca RIO send the report?

Part 10

- **HHS ORI receives the investigation report and notifies the NIH of the data retention concerns identified by the investigation committee.**
- **Rebecca RIO then emails the NIH RIO about the investigation committee's findings and provides a list of affected publications and grant applications along with details of the findings.**

QUESTION: Should the university consider returning funds to NIH?

QUESTION: What are some actions that NIH might take in response to Rebecca RIO's notification?

Policy References for Case Study #2

- [NIH GPS 8.1.3 Requests for Prior Approval](#)
- [NIH GPS 8.1.2.6 Change in Status, Including Absence of PD/PI and Other Senior/Key Personnel Named in the NoA](#)
- [NOT-OD-22-129: Updated Requirements for NIH Notification of Removal or Disciplinary Action Involving Program Directors/Principal Investigators or other Senior/Key Personnel](#)
- [GPS 8.1 Changes in Project and Budget](#)
- [NIH GPS 8.1.2.5 Change in Scope](#)
- [NIH GPS 8.1.2.7 Change of Recipient Organization](#)





POLICY & COMPLIANCE

Policy Topics

Research Integrity

[What is Research Integrity](#)[Why Does Research Integrity Matter?](#)[What can be done to Promote Research Integrity?](#)[Promoting Research Integrity - NIH Initiatives](#)[Integrity and Confidentiality in NIH Peer Review](#)

Research Integrity

The integrity of research is based on adherence to core values—objectivity, honesty, openness, fairness, accountability, and stewardship. - NASEM report on [Fostering Integrity in Research](#) (2017)

[ACCESS NIH Staff Resource](#)

To report research misconduct, and for any questions or comments on research integrity, contact [OER-RI](#).



Research Integrity

- [What is Research Integrity?](#)
- [Why does Research Integrity Matter?](#)
- [What can be done to Promote Research Integrity?](#)
- [Promoting Research Integrity - NIH Initiatives](#)
- [Integrity and Confidentiality in NIH Peer Review](#)
- [Glossary: Professional Codes, Norms, Ethics Training](#)

FAQs

RELATED RESOURCES

- [Core Values of Peer Review](#)
- [Open Mike Blog: Breaches of Peer Review Integrity](#)
- [Open Mike Blog: Working Together to Protect the Integrity of NIH-funded Research](#)

Got Questions? Ask ORI.

**HOW DO I MAKE AN ALLEGATION
OF RESEARCH MISCONDUCT?**

*I'm the RIO, and I'm not sure
what to do about...?*

How do I use ORI's
forensic image tools?

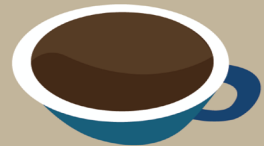
**I REPORTED MISCONDUCT BUT
HAVEN'T HEARD ANYTHING...
WHAT'S HAPPENING?**

*Is it okay to use ORI's educational
materials in my RCR course?*

I reported misconduct;
then my contract wasn't renewed.
Is this retaliation?

*I think someone plagiarized my work.
What do I do?*

If we can't answer your question, we
can refer you to the people who can.



Email us at AskORI@hhs.gov if you have questions about research integrity.



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THANK YOU!



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