RESEARCH WEEK 2023
PURPOSE • PASSION • PERSEVERANCE

Research Misconduct or Research Noncompliance?

When to contact RCRA

Meet the Presenter(s)

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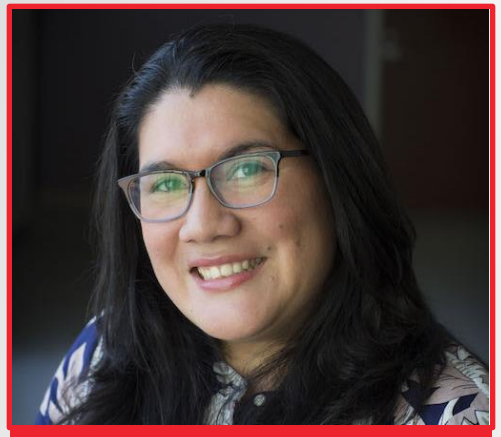
Deepika Bhatia
dbsivak@emory.edu

Associate Vice President, Research Integrity Officer / Chief Research Security Officer



Maria Davila
maria.davila@emory.edu

Director / Deputy Research Integrity Officer

LeBrit Nickerson
lebrit.nickerson@emory.edu

Administrator, Research Compliance Effectiveness Program

Danisha Biossat
danisha.biossat@emory.edu

Compliance Manager

Session Objectives

- Participants will learn the differences between research misconduct vs. research noncompliance and the ORA administrator's responsibilities when encountering allegations.
- Participants will also learn how to report instances of research misconduct or research noncompliance to the appropriate groups.

Poll Question 1

From your perspective, what is the role of compliance?

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Agenda

01 Lifecycle of an Investigation

- How are investigations conducted
- When to reach out to RCRA

02 Research Misconduct

- Recognizing Research Misconduct
- Reporting Concerns

03 Research Misconduct Policy

- What is covered in the policy?
- Possible outcomes for substantiated cases

04 Research Noncompliance

- Managing Research Noncompliance
- Research noncompliance vs Research Misconduct- Case examples

Poll Question 2

Are investigations important and if so why?

Lifecycle of an Investigation

What is an Investigation, How are Issues Reported?

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- For this presentation, we refer to “investigation” as follows:
  - Research Misconduct- the last stage of the review of an allegation of research misconduct
  - Research Noncompliance- a process involving interviews, data seeking, and a report conducted after a noncompliance issue has been assessed as potential noncompliance.
- We receive issues, complaints, tips, and concerns (collectively allegations) via the Trustline, directly in person or via phone/email, social media, media reports, supervisor or leadership reports, audit findings, or reports from external agencies.
- If your issue involves a DEI (harassment/discrimination), HR or Title IX (sexual harassment), we report it to these offices immediately and/or work with respective School leaders to triage these cases.

Intake & Review

- Does the allegation sufficiently specify facts, so that potential evidence of a violation can be identified?
- Is this a student, faculty or staff member? What sources are funding the research? Who are the stakeholders?

Investigation Planning

- Investigation team is assembled
- Information is reviews by the team and roles assigned
- Plan interviews and invite required stakeholders
- Confidentiality is key!

Assessment and Evaluation

- Review data collected with the investigation team and stakeholders
- Outcomes: not substantiated, substantiated with actions or no actions recommended, or insufficient information to make a determination

Reporting

- The investigation team works on a report; stakeholders are involved
- After the report is final, the information is reported externally and internally as required by federal regulations and Emory Policy.

Lifecycle

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Research Misconduct

What is Research Misconduct?

- Research Misconduct is defined as “fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.”
- According to NIH ORI:
  - Fabrication occurs when researchers make up the data used to support their findings or the sources of information used.
  - Falsification involves “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 occurs when researchers use the ideas, information, processes, or results produced by others but do not provide appropriate credit.

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TIME	RESULTS	LACK OF TRANSPARENCY
• Usable data is only created with a deadline • Research procedures are completed faster than usual	• If data is too good to be true • Data cannot be replicated	• Raw data does not exist or cannot be accessed • Materials and protocols are hidden • Research is completed with no one around

How to recognize Research Misconduct?

Culture of Integrity

From: ORI's [5 Ways Supervisors Can Promote Research Integrity]

1 BE AVAILABLE & APPROACHABLE

Your team wants to learn from YOU!

REVIEW RAW DATA

2 You are responsible for the integrity of your team's data.

3 COMMUNICATE EXPECTATIONS

Prevent misunderstandings by making sure everyone is on the same page.

PROVIDE TRAINING and GUIDANCE 4

Avoid making assumptions about anyone's skills or knowledge.

KNOW YOUR RESEARCH INTEGRITY OFFICER 5

Be prepared in case you ever suspect research misconduct.

Research Integrity Team @ Emory

DECIDING OFFICIAL (DO)

Robert Nobles, DrPH, MPH, CIP

RESEARCH INTEGRITY OFFICER (RIO)

Deepika Bhatia, MSBME, CCRP, CHRC, CHPC, CCEP

DEPUTY RIO

Maria Davila, MD, MA (Bioethics), CCRC, CIP

RESEARCH INTEGRITY MANAGER

Danisha Biossat, BA

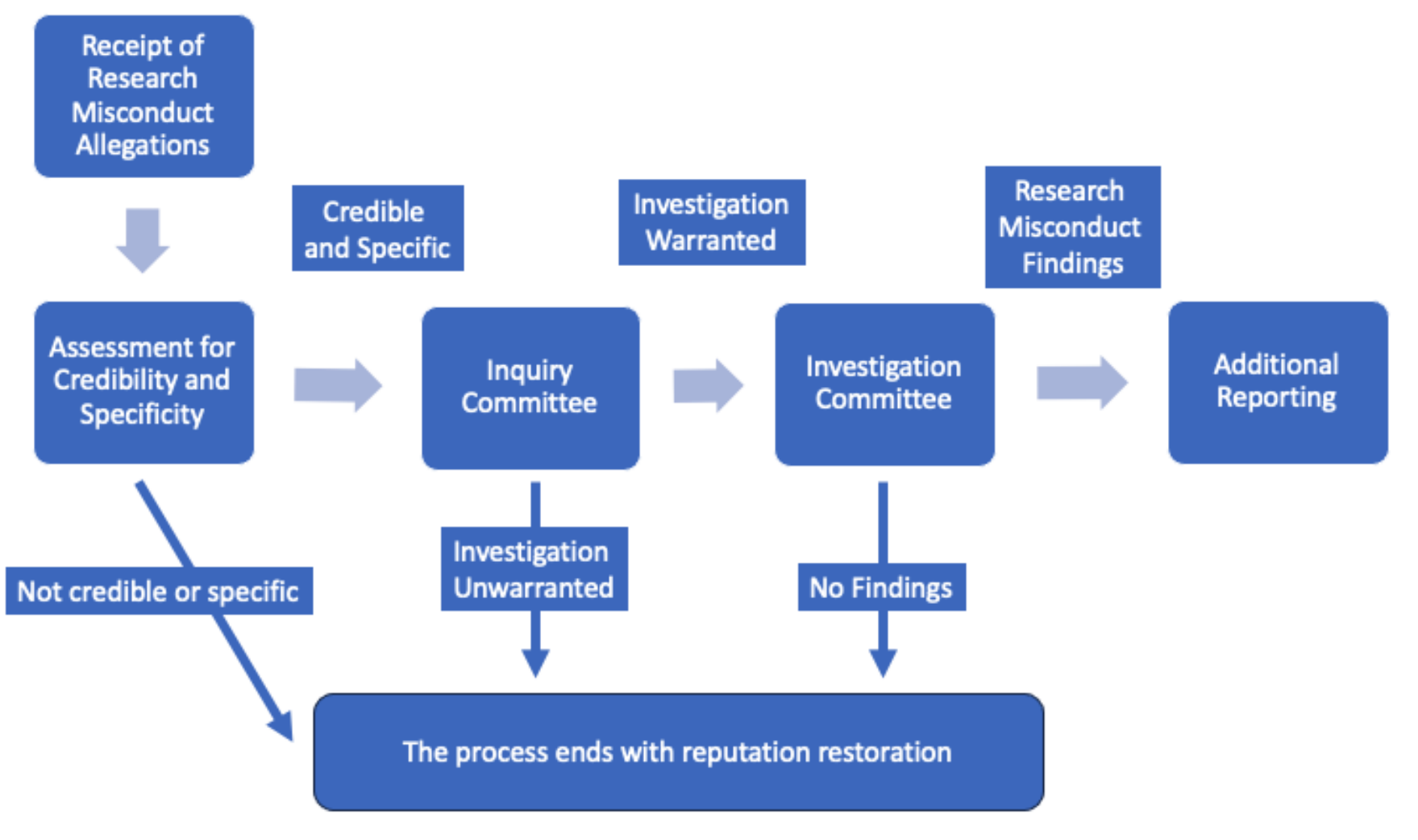
Research Misconduct Policy

Poll Question 3

Do you know we had a policy?

Policy 7.8

- Policy 7.8 on Research Misconduct has been updated with Dr. Nobles as our Deciding Official and Deepika Bhatia as our Research Integrity Officer (RIO)
- The information in the policy was streamlined to increase readability and make it more accessible
- The policy details the process of reviewing allegations of research misconduct and the repercussions



Review Process

Outcomes of Research Misconduct Investigations

In making a determination of Research Misconduct, the committee needs to conclude whether the research misconduct was done knowingly, recklessly, or intentionally. Also, the committee/ORI has ruled out that the issue was an honest error

Even if someone claims they did not know that a practice was not common, that will not exempt them from being found in research misconduct

Common Consequences:

- Certifications
- Assurances
- Prohibited from serving
- Debarment

Research Noncompliance

Your Role

See Something. Say Something.

See Something …..

Say Something

Report any research/data integrity concerns

rio@emory.edu

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What is Research Noncompliance?

- This may include research noncompliance, protocol noncompliance, research finance issues, research privacy violations or any other research-related concerns.
- Deviations from the approved research protocol, contract, agreement, or federal regulations.

Reporting Research Noncompliance

- Any research noncompliance issue (an egregious event that could be also in the purview of the Emory IRB or the Emory IACUC) should be reported to RCRA.
- Report research noncompliance issues to RCRA at researchcompliance@emory.edu.
- You can also use the Emory Trustline
- Report DEI or Title IX issues directly to them at the Emory DEI Office.

Research Noncompliance Investigations Processes

Intake, Triage & **Planning**

Assessment & Evaluations

Analysis

Investigation Report

Case Closeout & Appeals

External Reporting – Disclosures & Notifications

RACI Chart-Tasks	Responsible	Accountable	Consulted (as applicable)	Informed (as applicable)
Trigger: receive noncompliance allegation	RCRA	RCRA	School Leadership	Relevant RCRA/ORA offices Complainant (of receipt)
Triage: evaluate allegation; classify issue**;** identify relevant policies/procedures/regulatory requirements and departments/units/committees	RCRA	RCRA	Relevant RCRA/ORA offices	School Leadership OGC Provost Office
Plan & Assign: assemble investigation team; develop assessment plan (interview list, document/evidence list); assign roles	RCRA	RCRA	Relevant RCRA/ORA offices School Leadership OGC/Provost Office	HR
Investigation & Evaluation: gather and review documents; conduct interviews; summarize findings; review and evaluate results recommend action, if appropriate	RCRA School Leadership	RCRA	Relevant RCRA/ORA offices School Leadership OGC	SVPR/VPRA School Dean Provost Office
Report: prepare report of investigation; circulate; review with appropriate leadership	RCRA	RCRA	Relevant RCRA/ORA offices School Leadership OGC-Provost Office	SVPR/VPRA School Dean Provost Office
Resolution: decide corrective action, if any; implement corrective action	RCRA School Leadership SVPR/VPRA	RCRA	OGC	Provost Office
Closeout: execute external reporting, if required; update/finalize case report; closeout case	RCRA	RCRA	OGC	School Leadership Complainant Respondent
Monitoring: monitor corrective action; follow-up at 30-60-90 business days	RCRA	RCRA	SVPR/ORA	School Leadership Respondent

Research Noncompliance or Research Misconduct?

Case Examples

Poll Question 4

What are your first 2 steps when a concern is brought to you?

Research Noncompliance vs Research Misconduct

- A participant was involved in a research study, and it has been discovered that some of the recorded visits did not occur. The data obtained was recorded in the research record by the main coordinator.
- What type of issue is this?
  - Potential research misconduct
- What are the next steps?
  - Report it at rio@emory.edu.

Research Noncompliance vs Research Misconduct

- A RAS professional tried to reconcile information in an expense report and asked the PI why charges were made when there was no record of research activity in the last month. The PI said he charged the account because he had money.
- What type of issue is this?
  - Potential research noncompliance
- What are the next steps?
  - Please report it to researchnoncompliance@emory.edu.

Research Noncompliance vs Research Misconduct

- A participant was part of an Emory research study that involved implanting a device in their leg. The participant had the surgery and the PI discovered that the device was erroneously implanted in the wrong leg and this information was then shared broadly via social media by the study team.
- What type of issue is this?
  - Potential research noncompliance (egregious)
- What are the next steps?
  - Please report it to researchnoncompliance@emory.edu as well as the Emory IRB.

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Thank you!

Please provide your feedback using the conference app.