Preventing and Addressing Research Misconduct and Noncompliance Allegations

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Agenda

RCRA Highlights

Research Misconduct (RM)

- RM Management @ Emory
- Recognizing & Preventing RM
- Outcomes of Research Misconduct Investigations
- Authorship and Plagiarism
- Building a Culture of Integrity

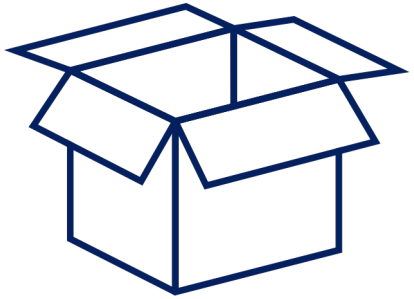
Research Noncompliance

- Investigation Lifecycle
- External Reporting
- Resolution and Monitoring
- Investigations RACI @ Emory

OFFICE OF RESEARCH COMPLIANCE AND REGULATORY AFFAIRS (RCRA)

[Institutional Animal Care and Use Committee]

[Conflict of Interest and Committment]



[Export Controls]

[Research Integrity and Compliance]

[Research Security]

RCRA High Five

Collaborate with Confidence & Compliance - Research Security & Export Controls

Focus on Disclosure Compliance – COI, ICOI, COC

Research Operational Compliance – IACUC & Controlled Substances Use

Navigating an Everchanging Regulatory Landscape – Tik Tok, NPRMs, NSPM-33, Data Sharing, ORA Policies and more

Research Ethics – research misconduct, research noncompliance, investigations, external agency disclosures and reporting

Managing Research Misconduct @ Emory

Research Misconduct

Research Misconduct is defined as "fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results."

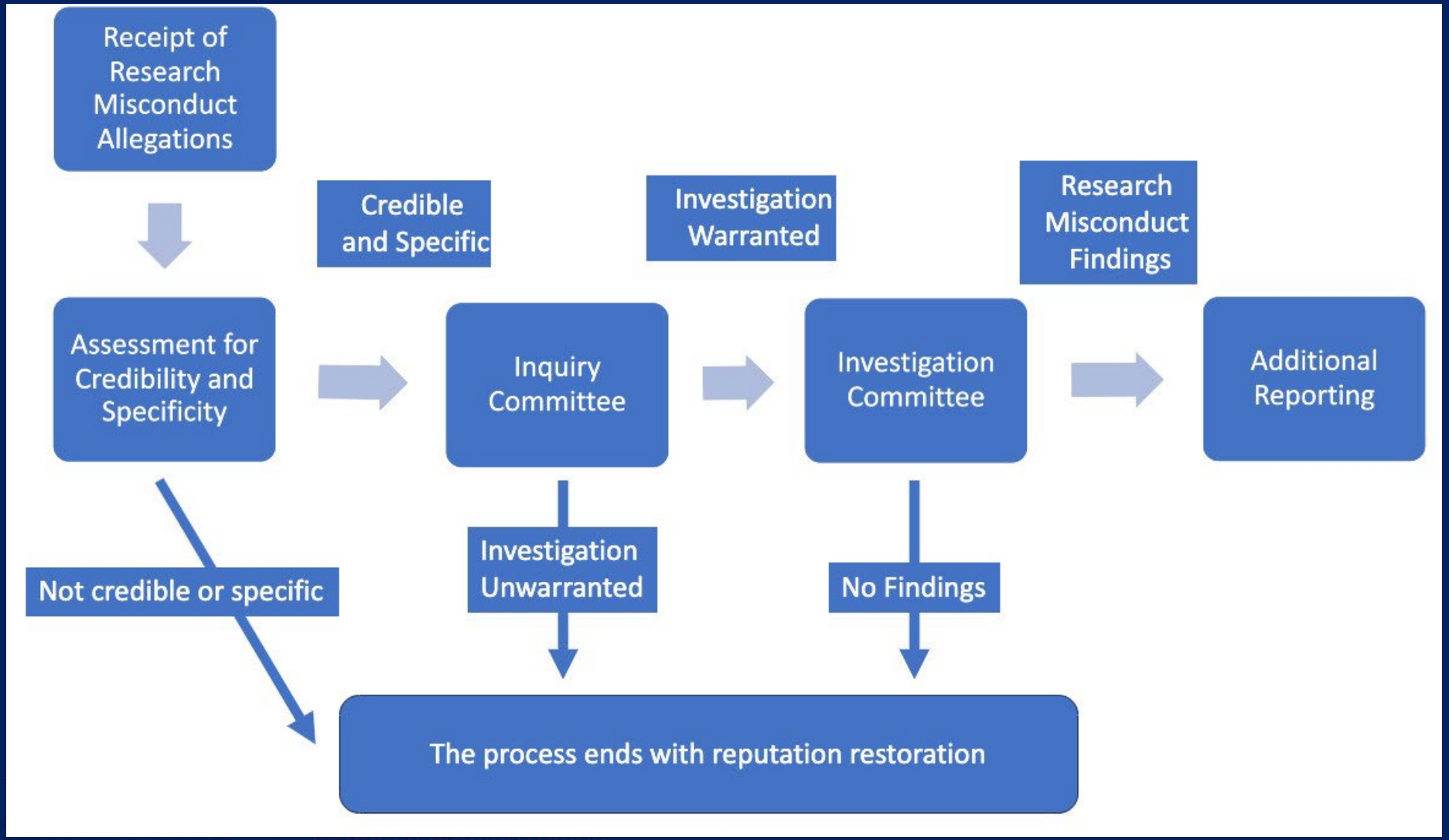
According to NIH ORI:

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

Policy 7.8

- Policy 7.8 on Research Misconduct has been updated with information in the policy streamlined for better readability and make it more accessible
- The policy details the process of reviewing allegations
- Research Integrity Team @ Emory defined in policy

Reporting and Case Management @ Emory



Recognizing Research Misconduct

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Questionable Practices Can Result in Research Misconduct

Recognizing Research Misconduct – Red Flags!

Time

- Usable data is only created to meet a deadline
- Research procedures are completed faster than usual

Results

- If data appears too good to be true
- Data cannot be replicated

Lack of Transparency

- Raw data does not exist or cannot be accessed
- Materials and protocols are hidden
- Research is completed when no one is around

Getting Ahead of Research Misconduct

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Proposal Submissions

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.

From **Research Misconduct & Detrimental Research Practices: Overview & Case Studies** at https://grants.nih.gov/learning-center/conference/precon-events/research-misconduct

Pre-Publication: Plagiarism Detection

NIH Library Resource

iThenticate is a widely recognized plagiarism detection tool for researchers and authors to check their manuscripts to feel

or damage their reputation.

- Use the NIH Library's iThenticate plagiarism checking service. This service is free and confidential for requesters who are the first, last, or corresponding author of NIH work-related, unpublished manuscripts.

iThenticate should not be used to check student coursework. Emory's Turnitin subscription integrated in Canvas is available to all classes for student use.

Post Publication Monitoring

PubPeer Surveillance

Routinely check your published articles for any negative comments in PubPeer that may reflect errors that could be reported as research misconduct allegations.

Journal Inquiries

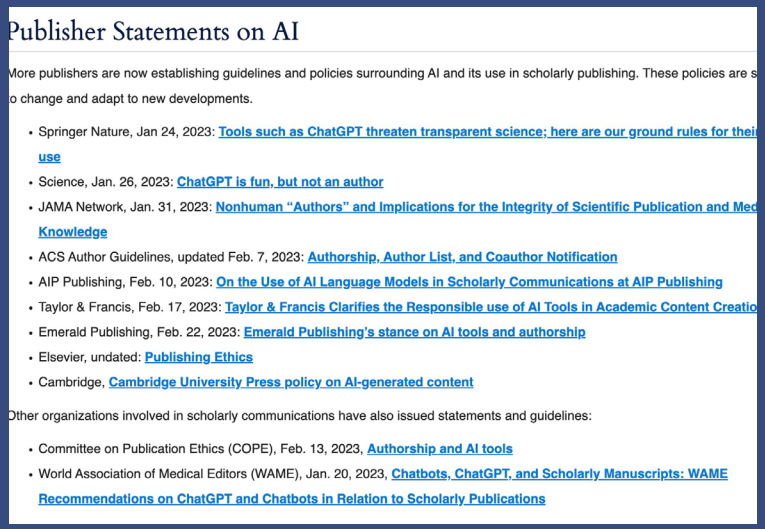
Ensure any clarifications requested by journals on your publications are promptly addressed and responded to in order to prevent these from resulting in research misconduct allegations.

Avoid AI Copyright & Authorship Issues

RCRA Infographic

An RCRA infographic on best practices for AI use in authorship to prevent copyright and plagiarism concerns is at: https://rcra.emory.edu/_includes/documents/sections/program-effectiveness/ai-authorship.pdf

AI Publisher Disclosure Guidelines



Publisher Statements on AI

More publishers are now establishing guidelines and policies surrounding AI and its use in scholarly publishing. These policies are s
o change and adapt to new developments.

- Springer Nature, Jan 24, 2023: Tools such as ChatGPT threaten transparent science; here are our ground rules for thei use
- Science, Jan. 26, 2023: ChatGPT is fun, but not an author
- JAMA Network, Jan. 31, 2023: Nonhuman "Authors" and Implications for the Integrity of Scientific Publication and Med Knowledge
- ACS Author Guidelines, updated Feb. 7, 2023: Authorship, Author List, and Coauthor Notification
- AIP Publishing, Feb. 10, 2023: On the Use of AI Language Models in Scholarly Communications at AIP Publishing
- Taylor & Francis, Feb. 17, 2023: Taylor & Francis Clarifies the Responsible use of AI Tools in Academic Content Creatio
- Emerald Publishing, Feb. 22, 2023: Emerald Publishing's stance on AI tools and authorship
- Elsevier, undated: Publishing Ethics
- Cambridge, Cambridge University Press policy on AI-generated content

Other organizations involved in scholarly communications have also issued statements and guidelines:

- Committee on Publication Ethics (COPE), Feb. 13, 2023, Authorship and AI tools
- World Association of Medical Editors (WAME), Jan. 20, 2023, Chatbots, ChatGPT, and Scholarly Manuscripts: WAME Recommendations on ChatGPT and Chatbots in Relation to Scholarly Publications

Emory resources related to publisher statements on AI are available at: https://guides.libraries.emory.edu/AI/publishing

Same image, different results!

Figure 3c in *Nature Medicine*

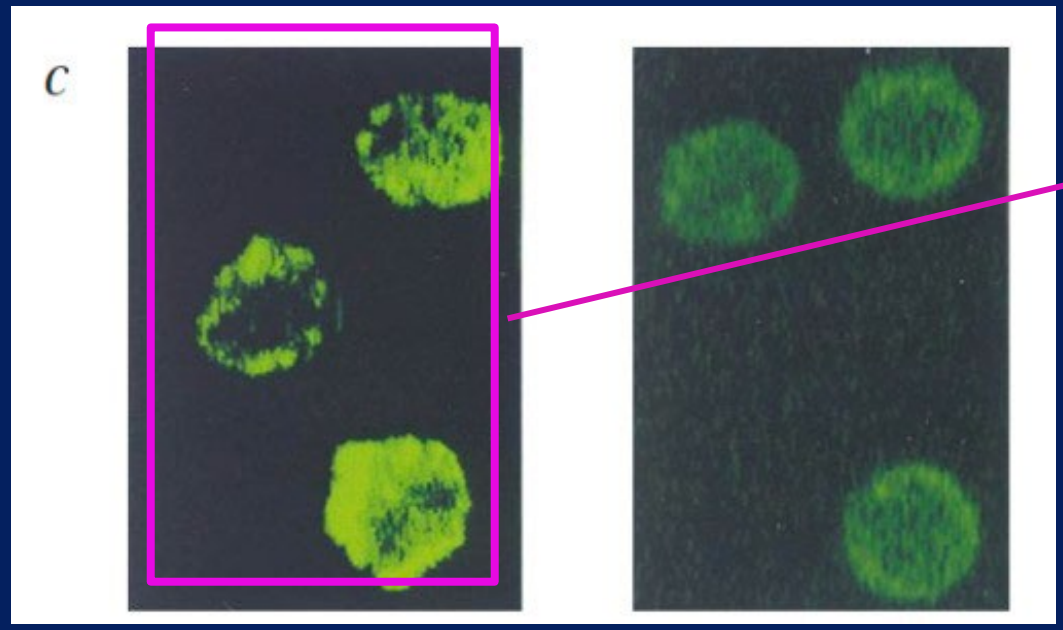
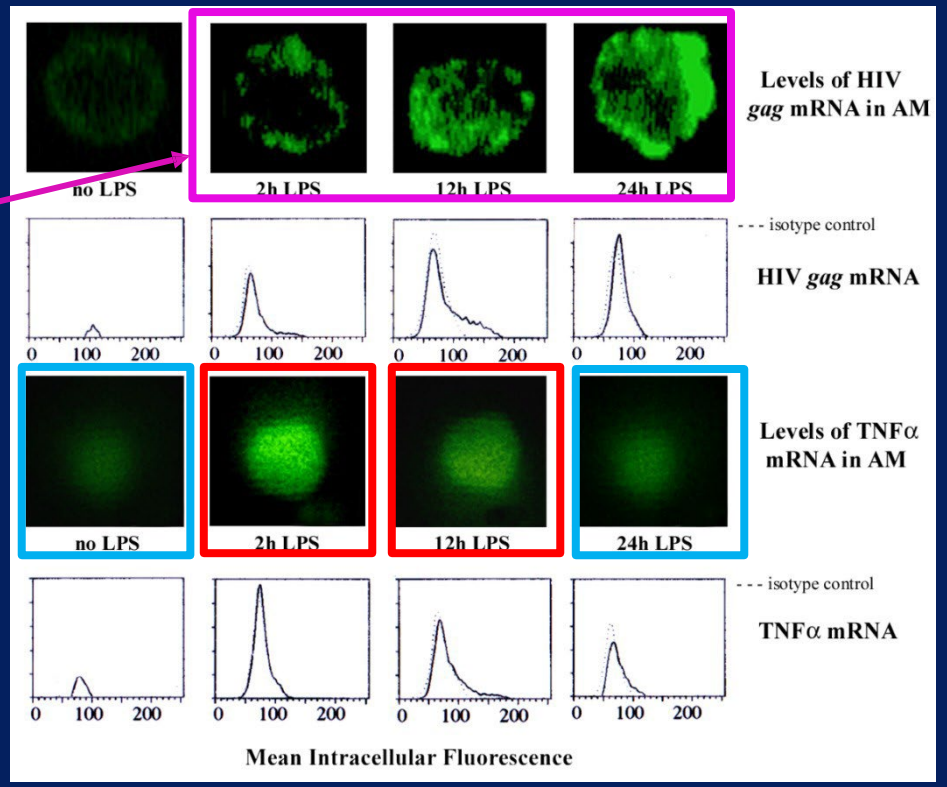


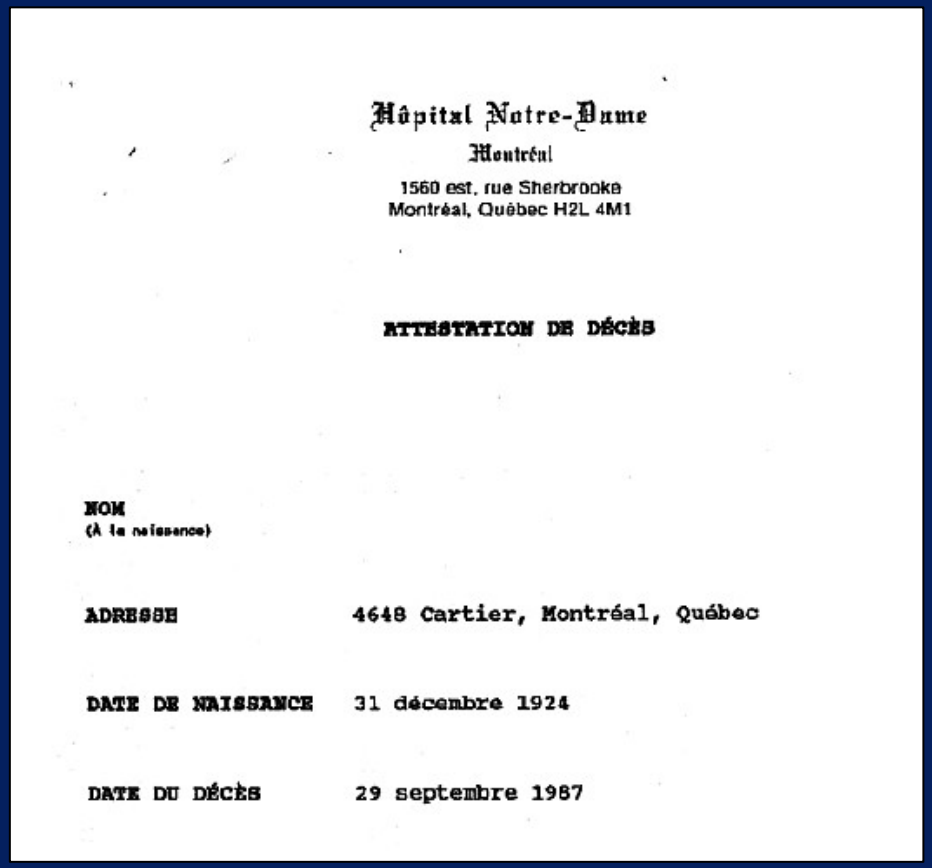
Figure C.2.5 in NIH grant application



From **Research Misconduct & Detrimental Research Practices: Overview & Case Studies** at https://grants.nih.gov/learning-center/conference/precon-events/research-misconduct

Medical Record alteration

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

From **Research Misconduct & Detrimental Research Practices: Overview & Case Studies** at https://grants.nih.gov/learning-center/conference/precon-events/research-misconduct

Dr. Eric T. Poehlman

Eric T. Poehlman, Ph.D., former Professor, Department of Medicine at the University of Vermont College of Medicine, engaged in scientific misconduct in research. The research was supported by National Institutes of Health (NIH) grants from the National Institute of Aging (NIA), the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), and the National Center for Research Resources (NCRR).

He falsified data for participants enrolled, including data for specifically he reported to the NAASO falsified RMR and fat mass data on 40 women followed over six years (17 pre-menopausal, 18 post-menopausal, and 5-peri-menopausal)

Dr. Poehlman agreed to enter into the comprehensive criminal, civil, and administrative settlement filed in U.S. District Court, and served one year in prision. In September 2001, Dr. Poehlman resigned from University of Vermont and moved to Montreal, Canada to work as an academic researcher. Dr. Poehlman has subsequently left his academic position in Canada.

From https://ori.hhs.gov/case-summary-poehlman-eric-t

Authorship and Plagiarism

- Generally, an authorship dispute involves members of the same research group who do not reach an agreement on the value of their effort to grant an authorship order
- Plagiarism involves someone taking information from someone else without giving them proper recognition
- If a student in a lab complains that a PI has taken their work without putting them on a publication, we consider that an authorship matter

Self – Plagiarism

- Not Research Misconduct
- While there are some situations where text recycling is an acceptable practice, it may not be so in other situations. Authors are urged to adhere to the spirit of ethical writing and avoid reusing their own previously published text unless it is done in a manner that alerts readers about the reuse or one that is consistent with standard scholarly conventions (e.g., by using quotations and proper paraphrasing).
- In academic context – DOUBLE DIPPING

Tips to Prevent Research Misconduct Allegations

Presenting a graphic? Ensure that you are following the publisher's requirements

Any image enhancements? Avoid changing the meaning of the graphic or results. Document changes in the image text at the time of submission

If you are adding one or more images in a graphic for publications, ensure you divide those graphics by a line and explain in in the text

Working with other disciplines? Make sure that information is share transparently so it can be checked by others with expertise in the area

Reinforce the idea that research integrity is of uttermost importance!

Outcomes of Research Misconduct Investigations

In deciding Research Misconduct, the committee needs to conclude that the RM was done knowingly, recklessly, or intentionally. Also, the committee/ORI has ruled out that the RM was an honest error

Claims that a practice is uncommon are not exempt from being substantiated as RM

Common Consequences:

- Certifications
- Assurances
- Prohibited from serving
- Debarment

Building a Culture of Integrity

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

Culture of Integrity

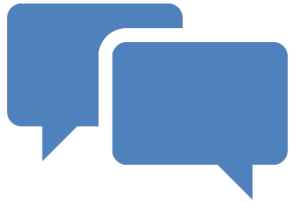
From: ORI's [5 Ways Supervisors Can Promote Research Integrity]

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

Your Role: See Something, Say Something.

See Something



Say Something

Report Any Research/Data Integrity Concerns to…

rio@emory.edu

Research Noncompliance

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
- Not all reportable events managed by IRB, but issues that need to be escalated as they affect Emory globally or present a reputation risk.

Investigation Lifecycle

Intake, Triage & **Planning**

Assessment & Evaluations

Analysis

Investigation Report

Case Closeout & Appeals

External Reporting – Disclosures & Notifications

Investigation Procedure: Triage

Evaluate

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?

Issue Spotting

Identify and classify issues

If DEI, Title IX: Stop and consult these groups

If this is a possible research misconduct: Stop and consult RCRA

Identify Policies and Procedures

Identify applicable policies, procedures, and regulatory requirements, including whether external reporting is required

Identify Stakeholders

Identify who to consult, inform, and/or include on the investigation team

Involving as necessary, RCRA offices, ORA offices, regulatory committee members, SMEs, University offices, and School Leadership

Confidentiality and Retaliation

- Confidentiality
  - Although confidentiality cannot be always guaranteed for compliance with certain federal requirements, RCRA will maintain the confidentiality, to the extent possible

- Retaliation
  - Emory prohibits retaliation against employees, who in good faith, report possible violations or participate in investigations. Complainant will be informed of the policy against retaliation and advised to report to RCRA if they feel retaliated against or have been threatened with retaliation related to a research compliance investigation.

Conflict of Interest

RCRA will determine whether any person involved in handling any aspect of the investigation has any personal, professional, or financial conflict of interest and take appropriate action, including recusal, to ensure that no person with such a conflict is involved in the proceedings.

External Reporting – Disclosure and Notifications

For compliance with federal agency requirements, external reporting and notifications may be needed, to meet timelines mandated by the applicable regulatory agency.

Resolution and Monitoring

The appropriate leadership will decide the corrective action(s) for the Respondent and/or the University, if any.

The appropriate leadership will implement the corrective action(s).

RCRA will monitor implementation of corrective action(s) and follow-up at 30-60-90 business day intervals to ensure completion.

Stakeholder Roles & Responsibilities

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Research Administration

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 o ffices	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/SVPR	School Leadership Complainant Respondent
Monitoring: monitor corrective action; follow-up at 30-60-90 business days	RCRA	RCRA	SVPR/ORA	School Leadership Respondent

How to Report Research Noncompliance

- Any research noncompliance issue (an egregious event that could also be in the Emory IRB or IACUC's purview) should be reported to RCRA.
- Report any concerns directly to RCRA at (researchcompliance@emory.edu) involving research at Emory University or under Emory's oversight.
- This may include research noncompliance, protocol noncompliance, research finance issues, research privacy violations or any other research-related concerns.
- To remain anonymous, report your concerns using the Emory Trust line.
- If the matter involves a Title IX or DEI issue, RCRA will forward the information you provide to the Emory DEI Office, or you can report to the Emory DEI Office directly.

Contact Information

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Research Compliance and Regulatory Affairs

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Director, Office of Research Integrity and Compliance / Deputy Research Integrity Officer

Questions?

Links shared during Q and A

Authorship Infographic
Policy 7.30 Policy on Authorship Guidelines and Dispute Resolution
Preventing Research Misconduct @ Emory