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 Commitment
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
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

1. Receipt of Research Misconduct Allegations
   - Credible and Specific
     - Assessment for Credibility and Specificity
       - Not credible or specific
         - The process ends with reputation restoration
       - Investigation Unwarranted
         - Investigation Committee
     - Investigation Warranted
       - Investigation Committee
         - No Findings
         - Research Misconduct Findings
           - Additional Reporting
Recognizing Research Misconduct
Questionable Practices Can Result in Research Misconduct

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.
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
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.

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

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

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

- 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

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.
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 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 utmost 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.

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

• Retaliation
  o 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.
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.
For compliance with federal agency requirements, external reporting and notifications may be needed, to meet timelines mandated by the applicable regulatory agency.
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
<table>
<thead>
<tr>
<th>RACI Chart Tasks</th>
<th>Responsible</th>
<th>Accountable</th>
<th>Consulted (as applicable)</th>
<th>Informed (as applicable)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Trigger:</strong> receive noncompliance allegation</td>
<td>RCRA</td>
<td>RCRA</td>
<td>School Leadership</td>
<td>Relevant RCRA/ORA offices</td>
</tr>
<tr>
<td><strong>Triage:</strong> evaluate allegation; classify issue; identify relevant policies/procedures/regulatory requirements and departments/units/committees</td>
<td>RCRA</td>
<td>RCRA</td>
<td>Relevant RCRA/ORA offices</td>
<td>School Leadership</td>
</tr>
<tr>
<td><strong>Plan &amp; Assign:</strong> assemble investigation team; develop assessment plan (interview list, document/evidence list); assign roles</td>
<td>RCRA</td>
<td>RCRA</td>
<td>Relevant RCRA/ORA offices</td>
<td>School Leadership</td>
</tr>
<tr>
<td><strong>Investigation &amp; Evaluation:</strong> gather and review documents; conduct interviews; summarize findings; review and evaluate results recommend action, if appropriate</td>
<td>RCRA</td>
<td>School Leadership</td>
<td>Relevant RCRA/ORA offices</td>
<td>School Leadership</td>
</tr>
<tr>
<td><strong>Report:</strong> prepare report of investigation; circulate; review with appropriate leadership</td>
<td>RCRA</td>
<td>RCRA</td>
<td>Relevant RCRA/ORA offices</td>
<td>School Leadership</td>
</tr>
<tr>
<td><strong>Resolution:</strong> decide corrective action, if any; implement corrective action</td>
<td>RCRA</td>
<td>School Leadership</td>
<td>SVPR/VPRA</td>
<td>OGC</td>
</tr>
<tr>
<td><strong>Closeout:</strong> execute external reporting, if required; update/finalize case report; closeout case</td>
<td>RCRA</td>
<td>RCRA</td>
<td>OGC/SVPR</td>
<td>School Leadership</td>
</tr>
<tr>
<td><strong>Monitoring:</strong> monitor corrective action; follow-up at 30-60-90 business days</td>
<td>RCRA</td>
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<td>SVPR/ORA</td>
<td>School Leadership</td>
</tr>
</tbody>
</table>
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 DEIOffice directly.
Questions?
Links shared during Q and A

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