COMING UP! HHS Office of Research Integrity (ORI) Notice of Proposed Rule Making (NPRM)

In this Notice of Proposed Rulemaking (NPRM) released in October 2023, the Department of Health and Human Services (HHS), Office of the Secretary, Office of the Assistant Secretary for Health (OASH), Office of Research Integrity (ORI) proposed to revise the Public Health Service (PHS) Policies on Research Misconduct. The proposed revisions are based on the experience ORI and institutions have gained with the regulation since it was released in 2005. Research Misconduct allegations are managed in accordance with Emory Research Misconduct Policy 7.8. Emory’s Research Integrity team submitted comments to voice our opinions on the NPRM. We will keep the Emory research community updated as we receive more information on the new ORI regulations.

Know your Emory Research Integrity Team:

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<tr>
<th>RESEARCH INTEGRITY TEAM</th>
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<td>DECIDING OFFICIAL (DO)</td>
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<td>Robert Nobles, DrPH, MPH, CIP</td>
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<td>Deepika Bhatia, MSBME, CCRP, CHRC, CHPC, CCEP</td>
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<td>Maria Davila, MD, MA (Bioethics), CCRC, CIP</td>
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<td>Danisha Blossat, BA</td>
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NEW! Regulations in Effect:

Federal Interim Rule Implements TikTok Ban on Devices Used in the Performance of Federal Contracts

A new Federal Acquisition Regulation (FAR 52.204-27) clause prohibits federal contractors and subcontractors from “having or using” the social networking service TikTok or any “successor application” developed by ByteDance, a Chinese internet technology company headquartered in Beijing, on any information technology system used or provided by the contractor in the performance of a government contract. This ban affects not only institutionally owned and managed devices used for the conduct of federal research, but potentially personally owned devices of personnel involved in federally funded research, when those devices are used to conduct Emory business. As a federal contractor and subcontractor on various grants/contracts Emory is required to comply with the FAR statement above. See more information on Emory’s compliance efforts with the ban and responses to frequently asked questions on this topic - https://rcra.emory.edu/research-security/tik-tok.html

NIH Final Policy on Foreign Subawards (issued September 2023)

The NIH announced policy guidance that would require foreign subrecipients of NIH-funded grants to provide copies of lab notebooks, data, and documentation supporting research outcomes to the prime recipient. This guidance was originally effective Oct. 1, 2023. NIH has issued a final updated guidance, and the key changes are as follows:

- The new effective date is January 1, 2024. NIH expects recipients to update existing subaward agreements to address this requirement within 60 days of the effective date.
- NIH is modifying the requirement for the required documentation from every quarter to “no less than once per year, in alignment with the timing requirements for Research Performance Progress Report submission.”
- NIH will change the language from requiring foreign subrecipients to “provide copies” of lab notebooks, data, and documentation to “provide access to copies” and notes that this access may be entirely electronic.

Here is more information from our Research Security team - https://rcra.emory.edu/research-security/nih-foreign-subawards.html
Benefits of ORCID include:

- Differentiate yourself from other researchers with the same or similar names
- Collect works published under different versions of your name
- Provide your ORCID iD to funders and publishers when required, and to colleagues who wish to view your works
- Create an online research CV
- ORCID iDs are increasingly being used by publishers, funders and other organizations to confirm identity and improve their workflows.

To get started with ORCID, follow these three steps:

1. Get an ORCID iD for free: Navigate to https://orcid.emory.edu/ and click on "Create and Connect an ORCID iD" to register for an iD and connect it to Emory.
2. Add your scholarly works: Once you’ve created your ORCID iD, you can add works to your record, set up automatic updates, or delegate management of your account to someone else.
3. Use your ORCID iD: Include your ORCID iD on your webpage, when you submit publications, on grant applications, and in other research workflows to ensure that you get credit for your work.

IMPORTANT! When registering, make sure to click on "EVERYONE" in the "Visibility Settings" portion of the form. Doing so will make your research more visible and discoverable, and you will reap all the benefits of having an ORCID iD. Note: your email address(es) are always kept private.

**NIH Appropriate Workplace Conduct Requirements**

NIH supports safe and respectful work environments that are free from harassment, including sexual harassment, discrimination, or other forms of inappropriate conduct that can result in a hostile work environment. Learn who to contact with questions or concerns, and what NIH’s expectations are for institutions and the individuals supported on NIH-funded awards.

In accordance with NIH Notice NOT-OB-22-129, NIH requires institutions to notify NIH when a Program Director/Principal Investigator (PD/PI) or other Senior/Key personnel on an NIH grant or cooperative agreement notice of award is removed or otherwise disciplined due to concerns about harassment, bullying, retaliation, or hostile working conditions.

Emory is committed to NIH’s expectation that all NIH-funded research occurs in a harassment-free environment. Emory has effective measures in place to address concerns and to safeguard the research environment. Allegations of harassment and bullying are investigated by the university when reported. Moreover, concerns about harassment and bullying can be reported through numerous means including, but not limited to, Human Resources, the Department of Equity and Inclusion, and through the Trust Line.

The Trust Line is run by an independent third-party and is designed for reporting potential ethical, legal, and/or business conduct violations or concerns at Emory in a confidential manner. Concerns received via the Trust Line are then triaged to the appropriate office at Emory for review. The Trust Line is available by telephone and through an online reporting tool.
Preventing Research Misconduct

Enhancing images for results presentation is acceptable if they represent the obtained results. According to the Office of Research Integrity (ORI), “minor image processing may be acceptable...but there’s a fine line between enhancing an image and distorting it.” 67% of ORI cases closed research misconduct cases between 2011 and 2015 involved image manipulation. See this infographic for some examples. Prevent any misunderstanding by always disclosing the changes made to presented images, following the publisher instructions, and keep the original (unprocessed) images in your research record.

When Do Financial Conflicts of Interest (COI) Need to be Disclosed?

- Emory’s annual certification period began on December 1st, 2023 and concludes on February 29th, 2024.
- All research applications need to have an up-to-date disclosure on file.
- If you are responsible for design, conduct, or reporting of research, you need to disclose:
  - During the annual certification period
  - Within 30 days of discovering or acquiring a new Significant Financial Interest (e.g., through purchase, marriage, or inheritance)
  - Within 30 days of hire

Grant proposals will not be submitted if the disclosure profile is not completed and/or updated.

If you have any questions, you can contact us at edisclose@emory.edu.