

US Department of Health and Human Services Office of Research Integrity

Karen Wehner, PhD

Director, Division of Education and Integrity
HHS Office of Research Integrity

October 18, 2023



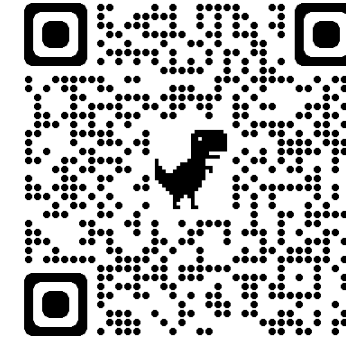
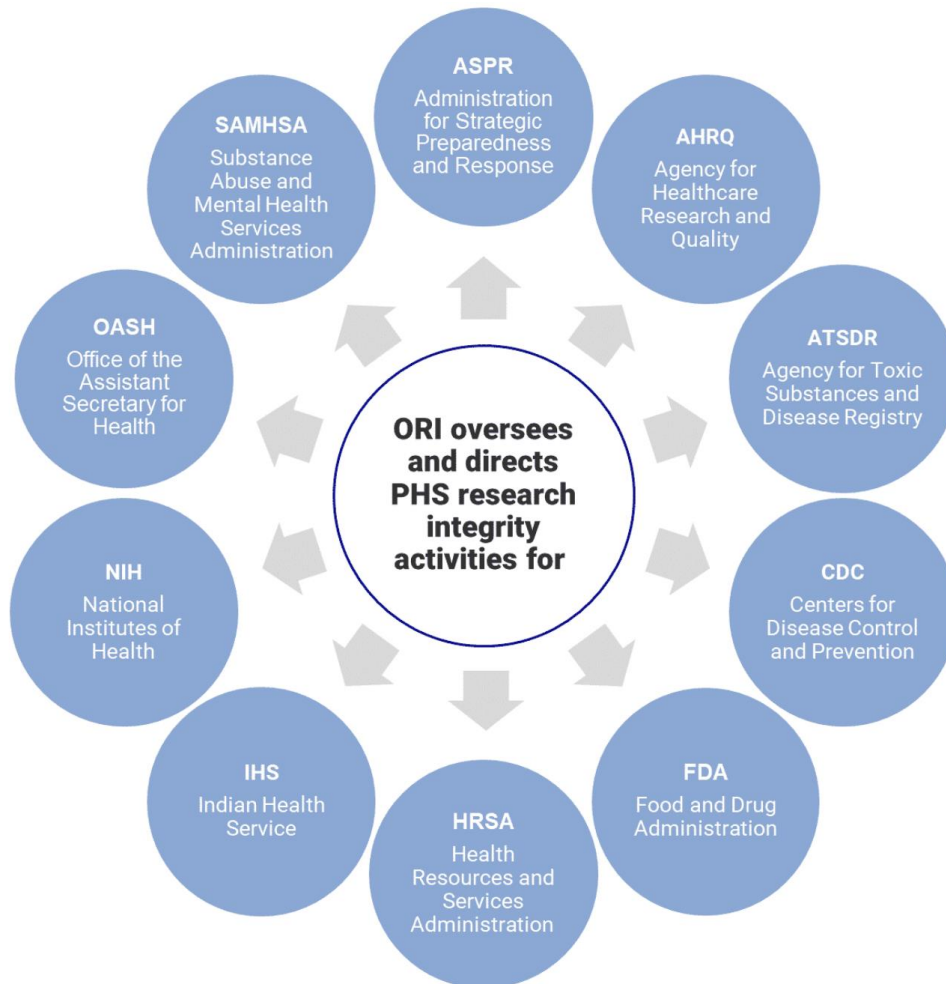
OASH

Office of
Research Integrity

HHS Office of Research Integrity: Mission


- Promote Research Integrity
- Prevent Research Misconduct
- Protect Science and Public Health, and
- Conserve Public Health Service (PHS) Funds

HHS Office of Research Integrity: Functions and Authority



<https://ori.hhs.gov/policies-ori-mission>

HHS Office of Research Integrity: Regulatory Authority



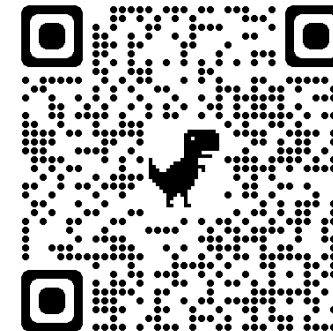
Federal Register

Tuesday,
May 17, 2005

Part III

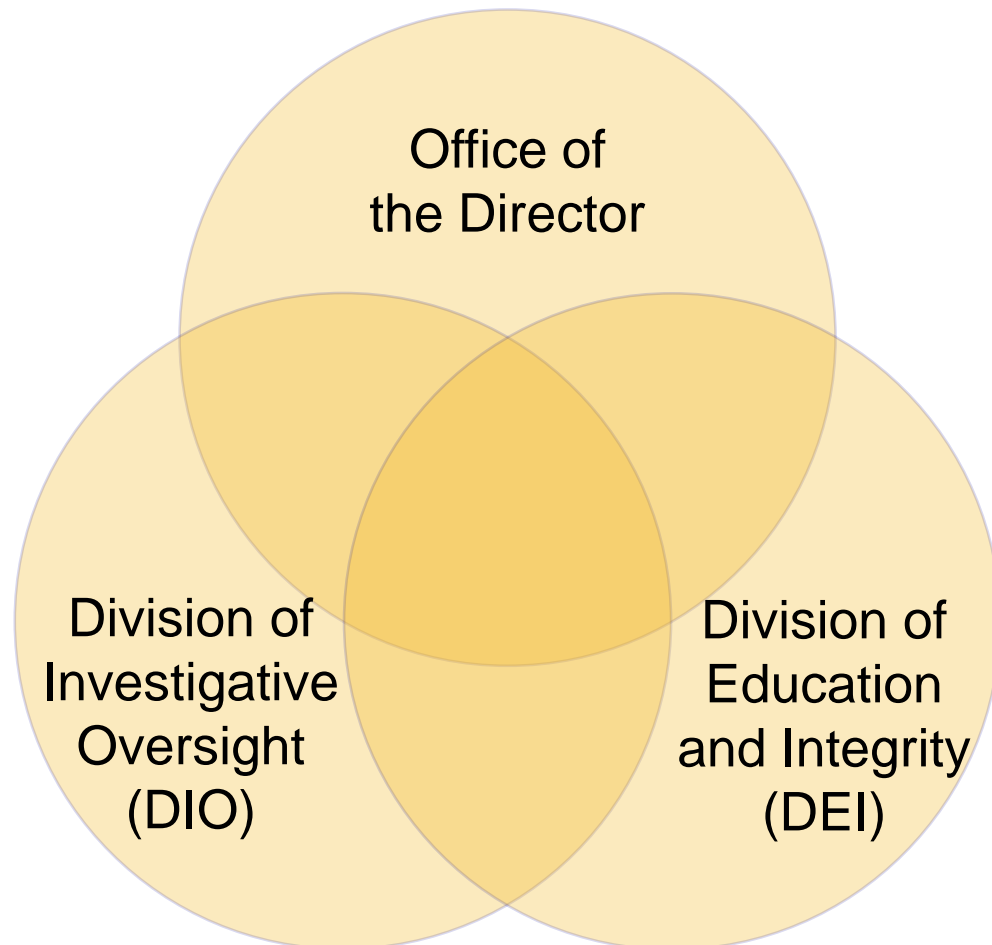
Department of Health and Human Services

42 CFR Parts 50 and 93
Public Health Service Policies on Research Misconduct; Final Rule



https://ori.hhs.gov/sites/default/files/42_cfr_parts_50_and_93_2005.pdf

The HHS Office of Research Integrity (ORI)



Office of the Director

- **ORI Director:**
Sheila R. Garrity, JD, MPH, MBA
- **ORI Deputy Director:**
Wanda K. Jones, DrPH, MT(ASCP)

Division of Investigative Oversight

- **Division Director: Alexander Runko, PhD**

Division of Education and Integrity

- **Division Director: Karen Wehner, PhD**

Division of Investigative Oversight (DIO): Overview

- Monitor, review, and assess research misconduct allegations and investigations
- Provide information on Public Health Service (PHS) research misconduct policies and procedures
- Provide guidance and technical assistance related to allegations of research misconduct
- Develop and recommend PHS findings of research misconduct and administrative actions



Division of Education and Integrity: Overview

- Manage ~6,000 Institutional ORI Assurances
- Review of Institutional Policies and Procedures for Addressing Research Misconduct
- For-cause review of case-related compliance issues
- Develop resources and conduct outreach to support institutional efforts to:
 - **promote a research environment that fosters research integrity and the responsible conduct of research, discourages research misconduct, deals promptly with allegations of research misconduct; and**
 - **implement and/or comply with the requirements of 42 CFR Part 93**
- Administer the ORI Grants Program
- Respond to FOIA and Privacy Act requests

Supporting Efforts to Promote Research Integrity and the Responsible Conduct of Research (1 of 4)

- Driven by the mission

Conduct outreach and develop educational resources, that aid institutional efforts, “to teach the responsible conduct of research, promote research integrity, prevent research misconduct, and... respond effectively to allegations of research misconduct....”

- 65 F.R. 30600, 30601 (May 12, 2000)

Supporting Efforts to Promote Research Integrity and the Responsible Conduct of Research (2 of 4)

- Driven by the mission

“Foster a research environment that promotes the responsible conduct of research...discourages research misconduct, and deals promptly with allegations or evidence of possible research misconduct”

- PHS Policies on Research Misconduct
(42 C.F.R. §93.300(c))

Supporting Efforts to Promote Research Integrity and the Responsible Conduct of Research (3 of 4)

- Driven by the mission
- Focused on stakeholders
 - **Researchers**
 - **Institutional Officials and Research Integrity Officers**
 - **Research Integrity Educators/Trainers**

Supporting Efforts to Promote Research Integrity and the Responsible Conduct of Research (4 of 4)

- Driven by the mission
- Focused on stakeholders
- Informed by observed and expressed need

Research Integrity and the Responsible Conduct of Research

(1 of 4)

- What are characteristics of research that has integrity and was conducted responsibly?
- Who plays a role in ensuring research has integrity and is conducted responsibly?
- How do we foster research integrity and the responsible conduct of research?

Research Integrity and the Responsible Conduct of Research

(2 of 4)

What are some of the characteristics of research that has integrity and was conducted responsibly? (select all that apply)

- Reliable
- Reproducible
- Transparent
- Rigorous
- Easy to achieve
- Robust
- Ethical
- Compliant
- _____

Research Integrity and the Responsible Conduct of Research

(3 of 4)

Who plays a role in ensuring research has integrity and is conducted responsibly? (select all that apply)

- Institutional leadership
- Research integrity staff
- Research integrity/RCR educators and trainers
- Researchers
- Mentors
- Principal investigators
- Faculty
- Trainees (students and postdocs)
- Research staff
- Funding/oversight agencies

Research Integrity and the Responsible Conduct of Research

(4 of 4)

- What are characteristics of research that has integrity and was conducted responsibly?
- Who plays a role in ensuring research has integrity and is conducted responsibly?
- How do we foster research integrity and the responsible conduct of research?
 - **Researchers – Our key stakeholders**
 - **The nature of research**
 - **Challenges**
 - **Needs as opportunities**
 - **A proposed approach**

Researchers and the Nature of Research (1 of 2)

Why research?

- Intellectual challenge
- Sense of accomplishment
- Pursuit of new knowledge
- For the benefit of others
- Prestige
- Interest in science
- It's a job

Common core goal: Making meaningful progress in their research

Researchers and the Nature of Research (2 of 2)

Research can be:

Exciting
Rewarding
Fulfilling
All Consuming

Frustrating
Discouraging
Exhausting
Disheartening
Slow
Hard

Challenges to Research Integrity and the Responsible Conduct of Research

- Disputes over data ownership
- Data that is lost
- Data that is essentially worthless due to poor recordkeeping
- Irreproducible data
- Lack of transparency in the conduct or reporting of research
- Authorship and/or collaborator disputes
- Conflicts of interest (not just financial)
- Pressure to: produce, publish, and/or obtain funding
- Stressors from outside the research space
- Toxic research environments

Challenges, Needs, and Opportunities

- Naming the challenges/issues helps to identify the needs
- Needs highlight opportunities to foster research integrity and the responsible conduct of research
- Needs represent opportunities to support researchers

Ensuring Research Integrity and the Responsible Conduct of Research

- Success in fostering and promoting research integrity and the responsible conduct of research requires:
 - **Buy-in**
 - **Uptake**
 - **Implementation of responsible research practices**
 - **Change in practice**
- Proposed approach: Training that is stakeholder focused and needs based
- Goal: Efforts aimed at fostering and promoting research integrity and the responsible conduct of research are viewed as beneficial research resources

Research Integrity and the Responsible Conduct of Research: Training as a Beneficial Research Resource (1 of 6)

- A solid foundation
 - “In-person”
 - Variety of formats
 - Opportunity for researchers from across the spectrum to hear *and* learn from one another and their peers
 - Ability to evaluate and adjust the program

“Will you change your practice as a result of having attending today’s session? Please explain.”

Research Integrity and the Responsible Conduct of Research: Training as a Beneficial Research Resource (2 of 6)

- A solid foundation
- Think beyond just compliance
- Think about needs
- Think about the practical
 - **What will help address the issues and challenges that impact research?**
 - **What can learners immediately apply in their work?**
 - **What will make it easier to conduct research responsibly?**

Research Integrity and the Responsible Conduct of Research: Training as a Beneficial Research Resource (3 of 6)

- A solid foundation
- Think beyond just compliance
- Think about needs
- Think about the practical
- Develop programming that addresses needs and practical considerations

Research Integrity and the Responsible Conduct of Research: Training as a Beneficial Research Resource (4 of 6)

- Tools – policies, procedures, plug-and-play
- Training – communication (issues, norms, tools, expectations)
- Resources – support for responsible research practices

Example #1: Data Ownership

Research Integrity and the Responsible Conduct of Research: Training as a Beneficial Research Resource (5 of 6)

- Tools – policies, procedures, plug-and-play
- Training – communication (issues, norms, tools, expectations)
- Resources – support for responsible research practices

Example #2: Authorship/Collaborator Disputes

Research Integrity and the Responsible Conduct of Research: Training as a Beneficial Research Resource (6 of 6)

- Everyone plays a role in fostering research integrity and the responsible conduct of research, and improving the quality and impact of the research that is conducted.

- Institutional leadership
- Research integrity staff
- Research integrity/RCR educators and trainers
- Researchers
- Mentors
- Principal investigators
- Faculty
- Trainees (students and postdocs)
- Research staff
- Funding/oversight agencies

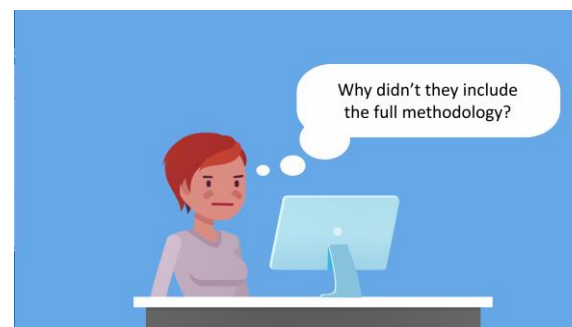
Division of Education and Integrity: Recent Education and Outreach Activities

- New short animated videos related to fostering research integrity and the responsible conduct of research
 - Authorship and Publishing
 - Data Management
 - Recordkeeping
 - Mentoring

Talking With Your Research Group About a Data Management Plan



Transparency in the Reporting of Research (Part 1)



Mentoring: Ways to Promote Research Integrity



Looking Ahead

- New Resources – Visit our YouTube Channel (@HHS_ORI)
- Support for Implementation of and Compliance with 42 CFR Part 93
- 2024 Grant Opportunities
- Develop and Launch New ORI Website
- Notice of Proposed Rule Making – Open for Public Comment
- Job Opportunities



ORI News (Blog)

<https://ori.hhs.gov/blog>



Thank you!

Website, Social Media, and Email

- www.ori.hhs.gov
- [@hhs_ori](https://twitter.com/hhs_ori)
- AskORI@hhs.gov

Got Questions? Ask ORI.

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

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

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

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

*How do I use ORI's
forensic image tools?*

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

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

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.

Office of Research Integrity: Contact Information

Office Mailing Address:

U.S. Department of Health and Human Services
Office of Research Integrity
1101 Wootton Parkway, Suite 240
Rockville, Maryland 20852

Email: AskORI@hhs.gov

Website: <https://ori.hhs.gov/>

Phone Numbers:

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DEI	240-453-8400
Assurance Program	240-453-8407