

#COGROct2023

Updates from the
Office of Research
Integrity (ORI) with
Director Sheila Garrity

October 26, 2023



COGR



www.cogr.edu

US Department of Health and Human Services Office of Research Integrity

Sheila R. Garrity, JD, MPH, MBA - Director

October 26, 2023



OASH

Office of the
Assistant Secretary
for Health



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

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 - **implement and/or comply with the requirements of 42 CFR Part 93**

Division of Education and Integrity: Overview

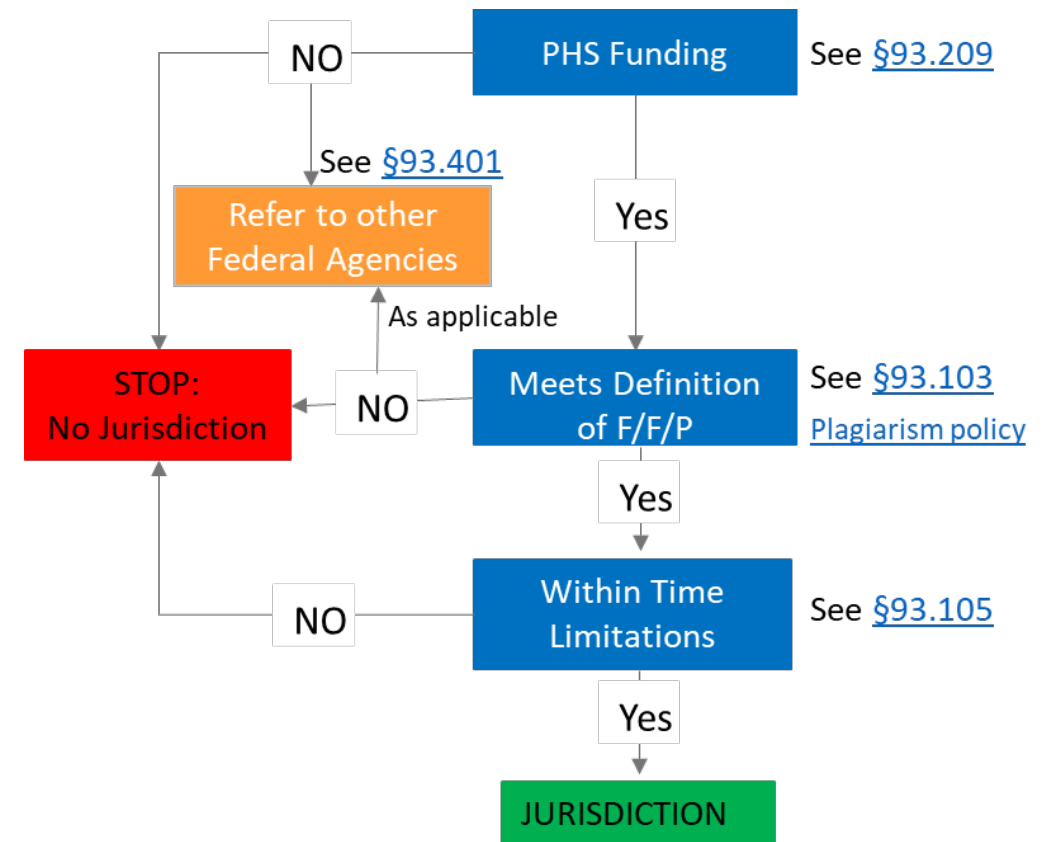
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- Administer the ORI Grants Program
- Respond to FOIA and Privacy Act requests

Division of Investigative Oversight (DIO) Functions

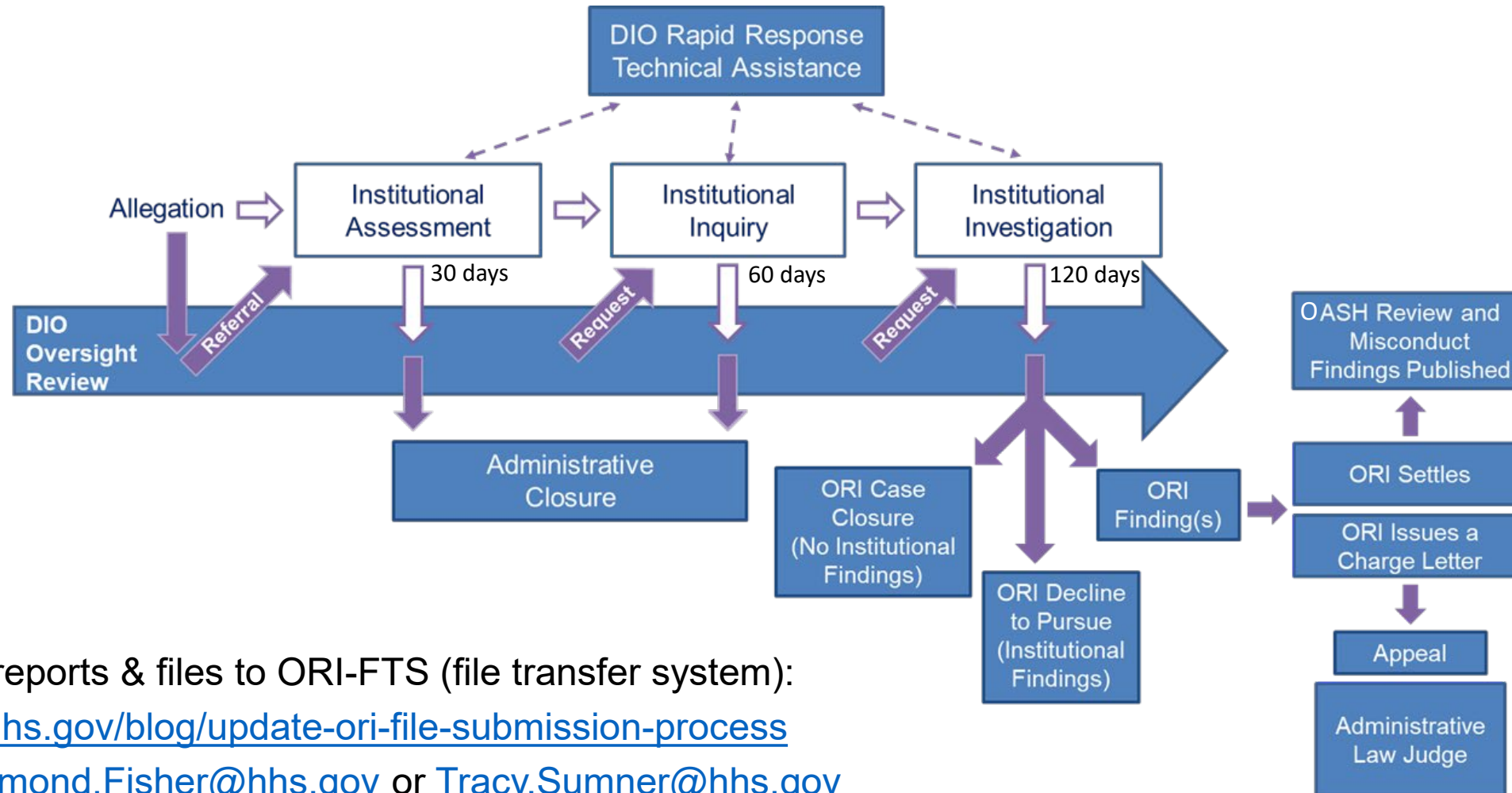
- Monitor, review and assess research misconduct allegations and investigations
- Provide information on Public Health Service (PHS) research misconduct policies and procedures
- Provide guidance and technical assistance
- Develop and recommend PHS findings of research misconduct and administrative actions



ORI's Jurisdiction



ORI Handling of Allegations and Oversight Review Process



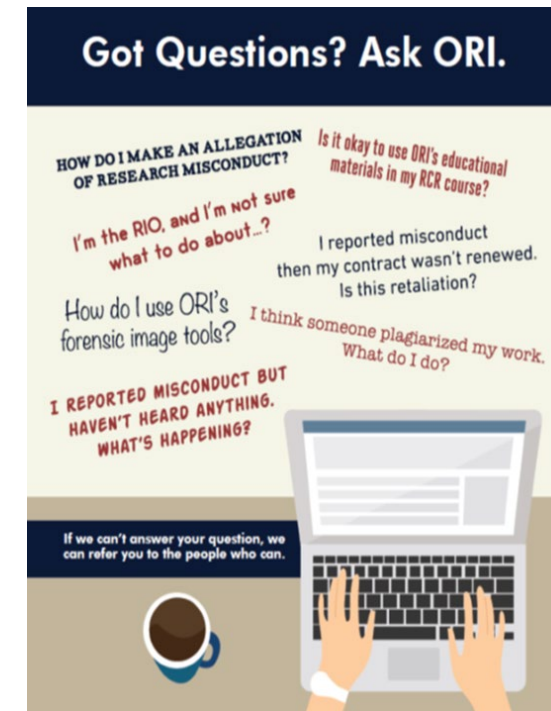
Submit all reports & files to ORI-FTS (file transfer system):

<https://ori.hhs.gov/blog/update-ori-file-submission-process>

Email: Raymond.Fisher@hhs.gov or Tracy.Sumner@hhs.gov

Rapid Response for Technical Assistance (RRTA)

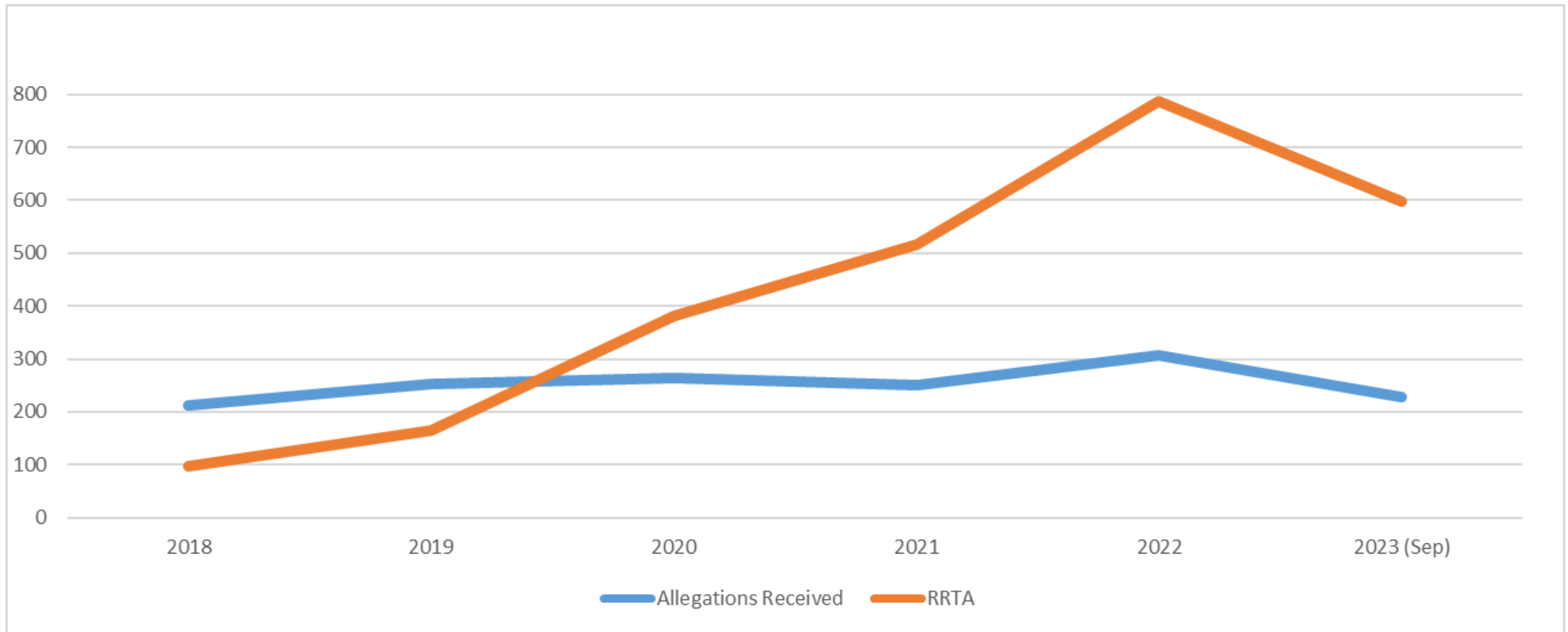
- Image enhancement and statistical analyses of data
- Forensic analyses
- Sequestration of records
- Handling allegations and preliminary assessment
- Handling complainants, respondents, and witnesses
- Referral / notification to other federal agencies or institutions
- Review of institutional research misconduct proceedings
- Voluntary admissions
- Legal, whistleblower, and retaliation issues



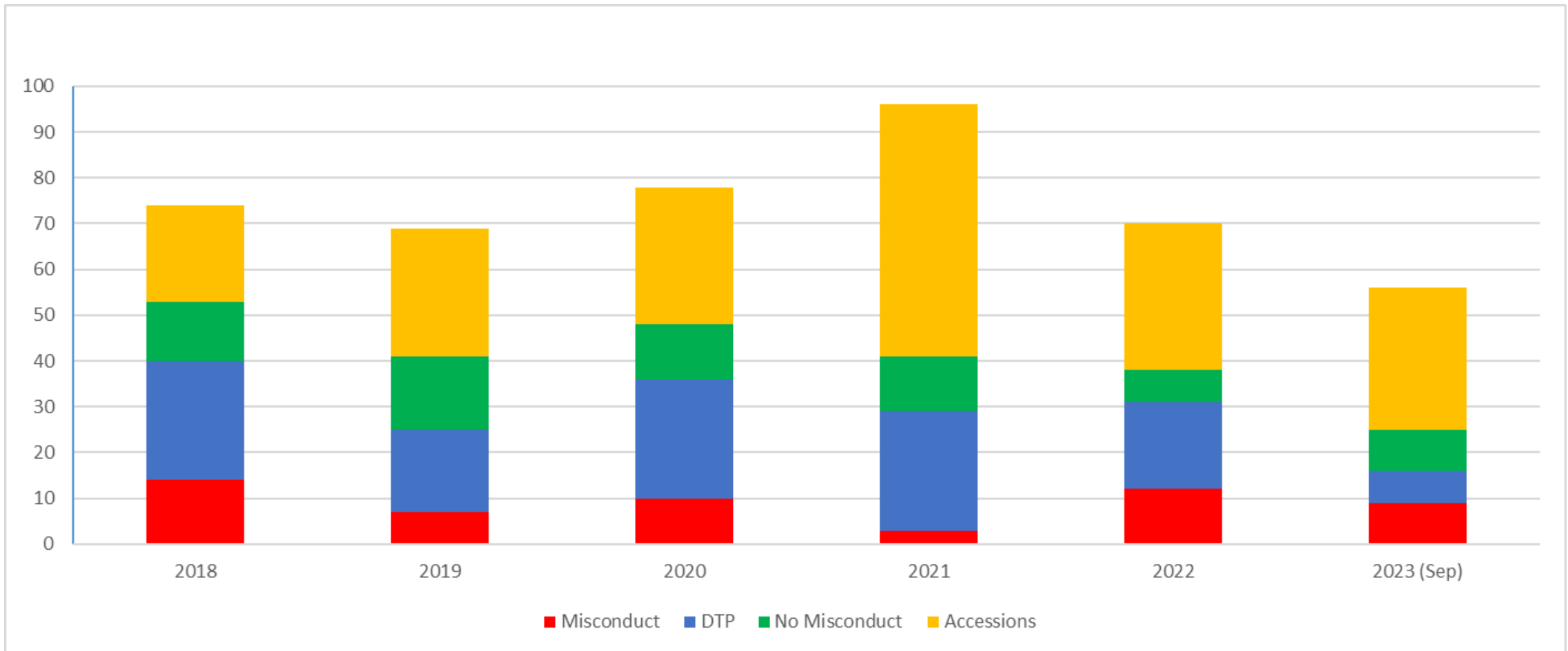
• Email: AskORI@hhs.gov DIO Phone #: 240-453-8800 Website: <https://ori.hhs.gov/>

 **Poll Everywhere** [Pollev.com/cogrstaff949](https://pollev.com/cogrstaff949) **Ask a question from your seat!**

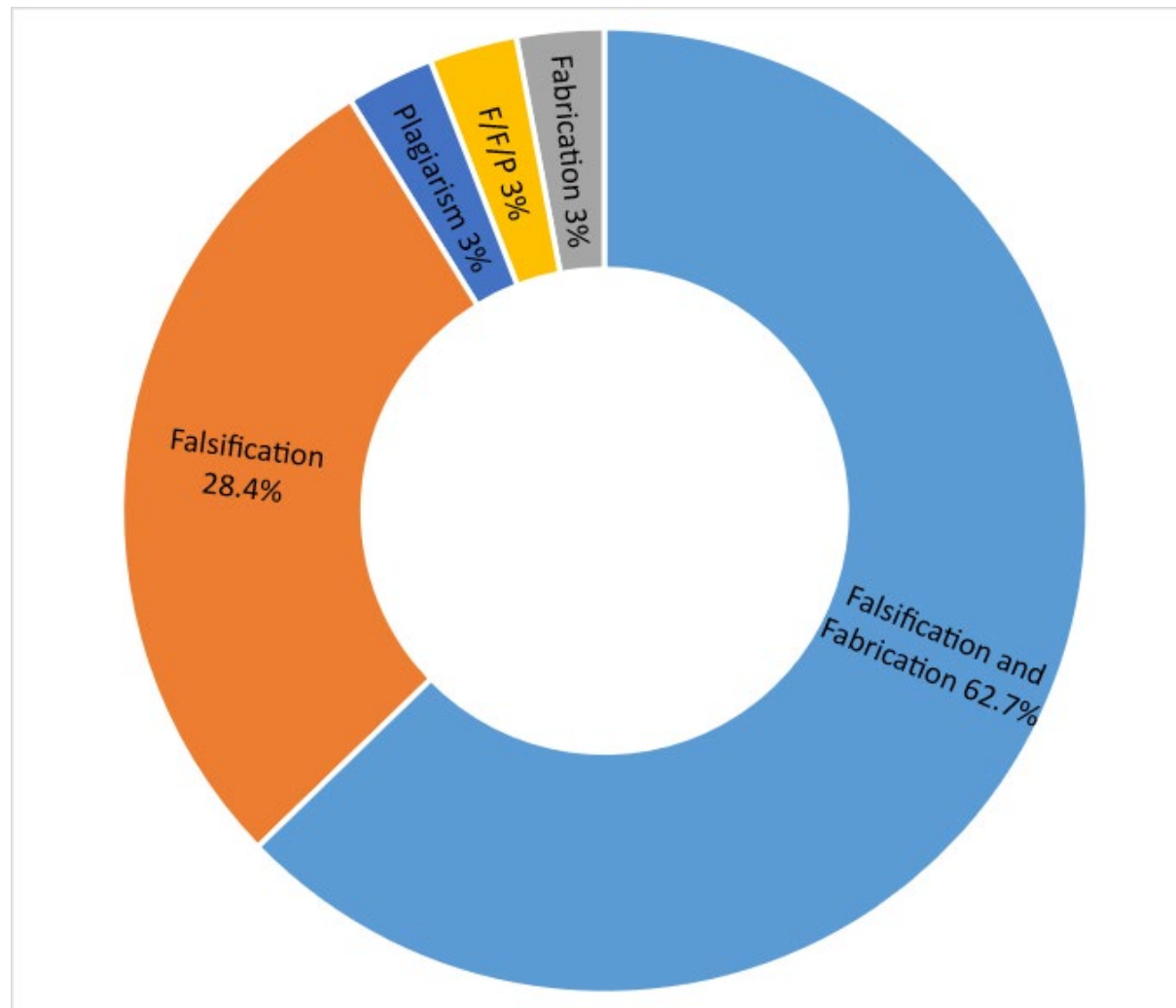
ORI - New Queries by Year



ORI Case Closures



Types of Research Misconduct in ORI Cases with Findings CY2013 – CY2022



2023 PHS Research Misconduct Findings

Type	Research Records	Position	Administrative Actions
Falsification, fabrication	51 figures in 5 papers, 1 manuscript, 1 review article, 3 posters, 3 grant applications & 4 progress reports	Research Associate Professor	7-year Debarment, Correction/retraction of 1 paper
Falsification, fabrication	8 figures in 3 papers	Assistant Professor	3-year Debarment, Correction/retraction of 1 paper
Falsification, fabrication, plagiarism	1 pre-print & 4 papers	Professor	3-year Supervision
Falsification, fabrication	12 figures in 4 grant applications	Assistant Professor	4-year Supervision
Falsification, fabrication	3 papers, 2 grant applications & 2 manuscripts	Postdoctoral Fellow	3-year Supervision
Falsification, fabrication	21 figures in 4 papers, 2 presentations & 3 grant applications	Assistant Professor	4-year Debarment, Correction/retraction of 3 papers
Falsification, fabrication	12 papers	Professor	7-year Debarment
Falsification, fabrication	12 papers	Professor	7-year Supervision
Falsification, fabrication	2 papers & 2 grant applications	Assistant Professor	4-year Supervision Correction/retraction of 1 paper

https://ori.hhs.gov/content/case_summary

Notice of Proposed Rulemaking (NPRM) 42 CFR 93

- Proposed revisions to the Public Health Service Policies on Research Misconduct
- Last Updated in 2005
- Request for Information (RFI) Released on September 1, 2022
- Received Over 30 Comments Informing the Proposed Revisions
- NPRM Released October 5, 2023

RFI Responses

- ORI Received Comments from Individuals and Institutions
- Comments were divided into 3 categories:
 - **Regulations to be Revised**
 - **Regulations to be Retained**
 - **Regulations to be Removed**

RFI Responses: ORI Regulations to be Revised

- Revise the investigation process
- Revise the inquiry and investigation deadlines
- Revise the internal appeals and review process
- Clarify rules for confidentiality
- Revise the six-year limitation and the subsequent use exception
- Revise the definition of research misconduct
- Increase penalties for research misconduct
- Increase transparency from ORI

RFI Responses: ORI Regulations to be Retained

- Retain the definition of research misconduct
- Retain the health or safety of the public exception to the six-year limitation
- Retain the requirement to sequester materials

RFI Responses: ORI Regulations to be Removed

- Remove the subsequent use exception
- Remove the term “reckless” from the required mental state
- Remove explicit investigation time limits in the regulation
- Remove the six-year limitation in the regulation
- Remove language allowing for institutional discretion

NPRM Updates to 42 CFR 93

- Gaps and Opportunities Revealed by RFI:
 - **Clarify complex processes**
 - **Define vague concepts**
 - **Explanations of undefined terms**



NPRM Updates to 42 CFR 93

- Subpart A
 - **Refining HHS, PHS, and ORI Responsibilities**
- Subpart B
 - **Revised & New Definitions**
- Subpart C
 - **Clarified Guidance for Institutions**

NPRM Updates to 42 CFR 93 (cont.)

- Subpart D
 - **Updates to ORI Processes & Disclosures**
- Subpart E
 - **Simplified Appeals Process**

NPRM Public Comment Period

- Federal regulations require a 60-day comment period
- All comments are submitted online at Regulations.gov
- ORI is especially interested in comments from:
 - Research Integrity Officers (RIOs)
 - Complainants
 - Investigation Committee Members
- We want detailed comments!
- **Comment period closes December 5, 2023**



Questions?

 **Poll Everywhere** [Pollev.com/cogrstaff949](https://pollev.com/cogrstaff949) *Ask a question from your seat!*



Thank you!

Contact Us:

- 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.