

US Department of Health and Human Services Office of Research Integrity

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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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- Develop resources and conduct outreach to support institutional efforts to:
 - **promote a research environment that fosters research integrity, discourages research misconduct, deals promptly with allegations of research misconduct; and**
 - **implement and/or comply with the requirements of 42 CFR Part 93**

Division of Education and Integrity: Overview

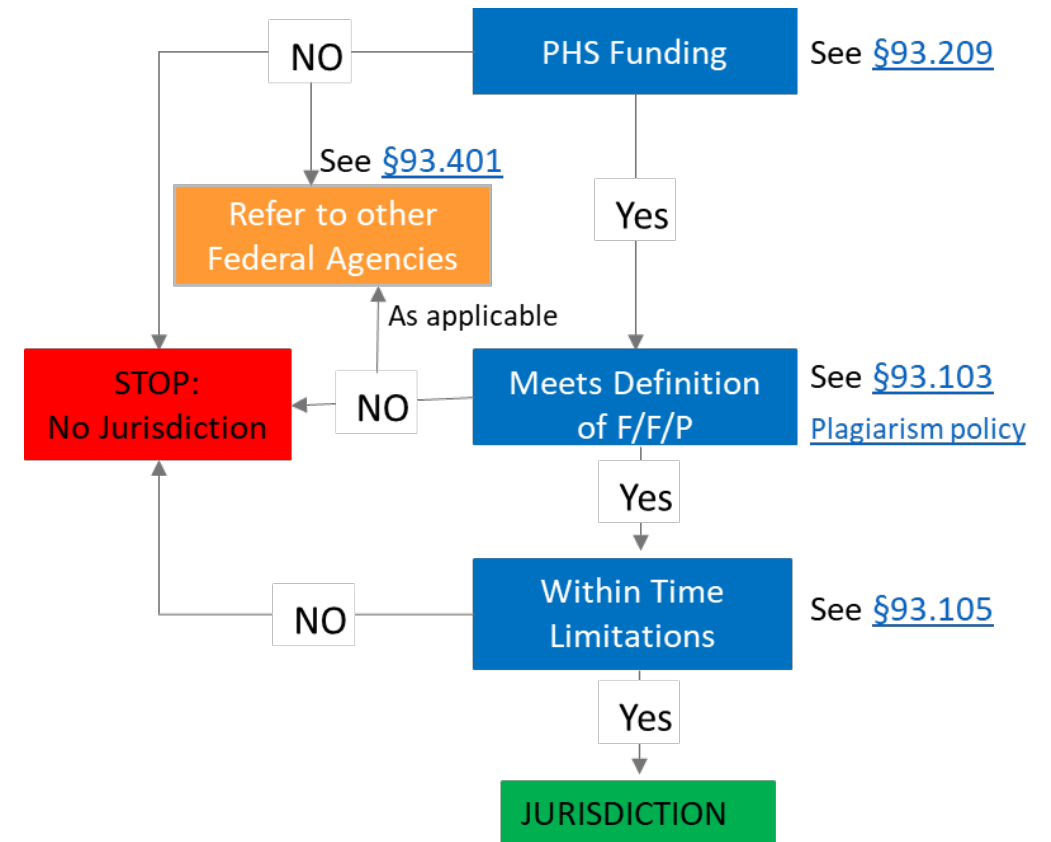
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- Administer the ORI Grants Program
- Respond to FOIA and Privacy Act requests

Division of Investigative Oversight (DIO) Functions

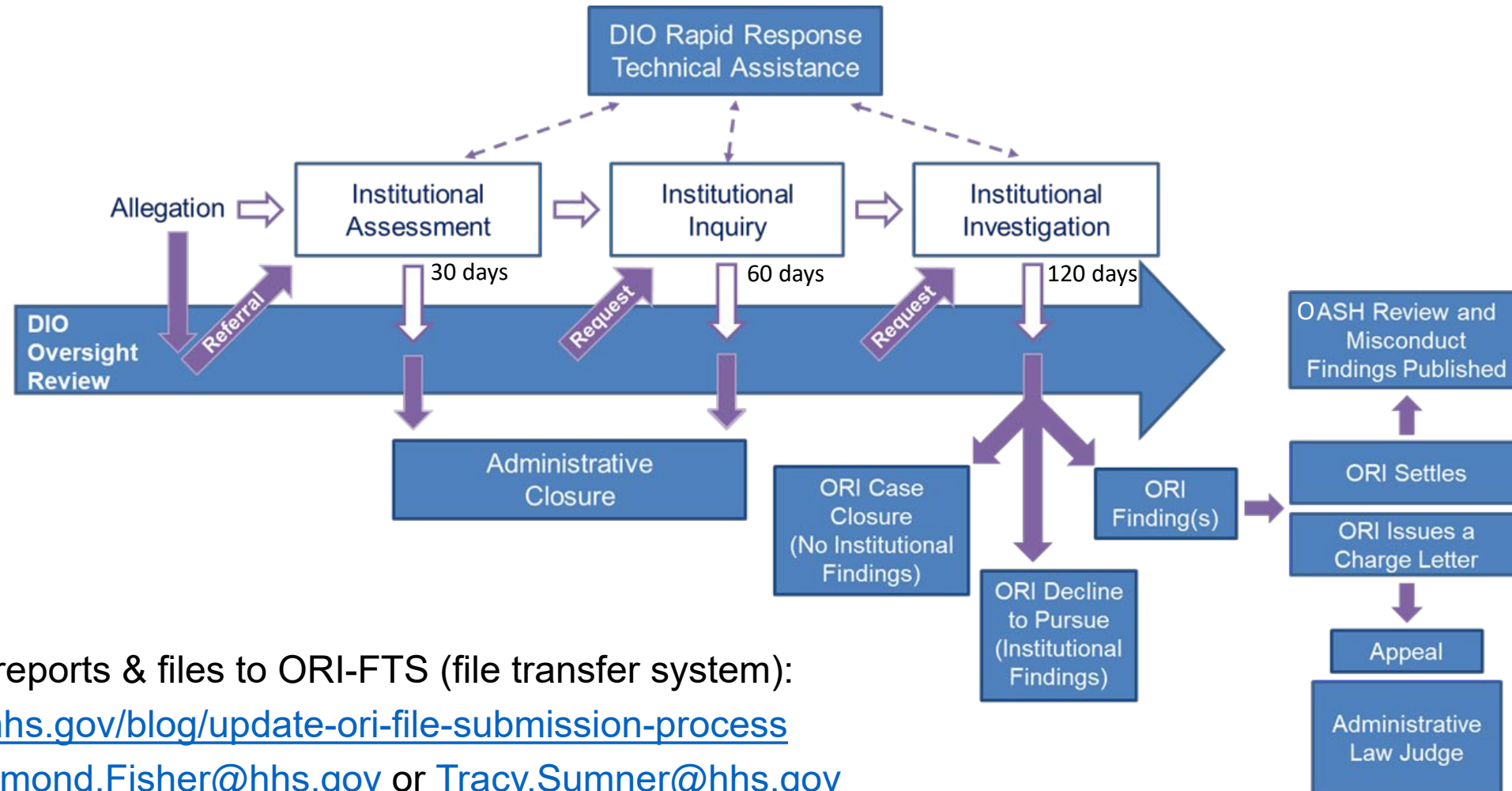
- Monitor, review and assess research misconduct allegations and investigations
- Provide information on Public Health Service (PHS) research misconduct policies and procedures
- Provide guidance and technical assistance
- Develop and recommend PHS findings of research misconduct and administrative actions



ORI's Jurisdiction



ORI Handling of Allegations and Oversight Review Process



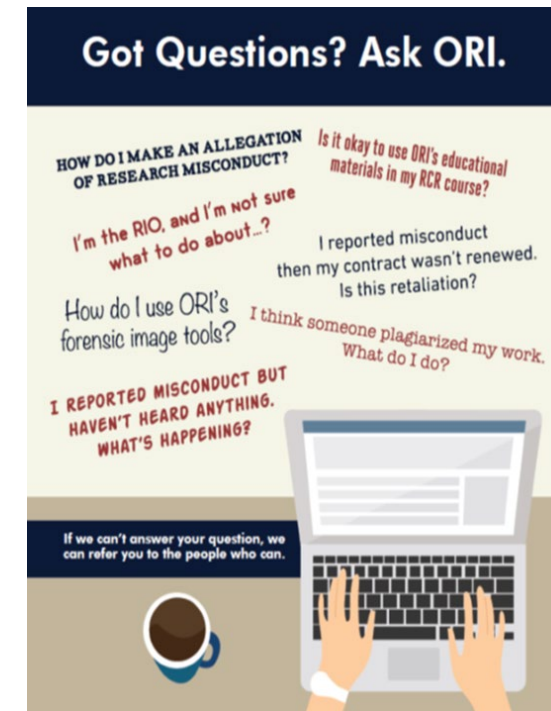
Submit all reports & files to ORI-FTS (file transfer system):

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

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

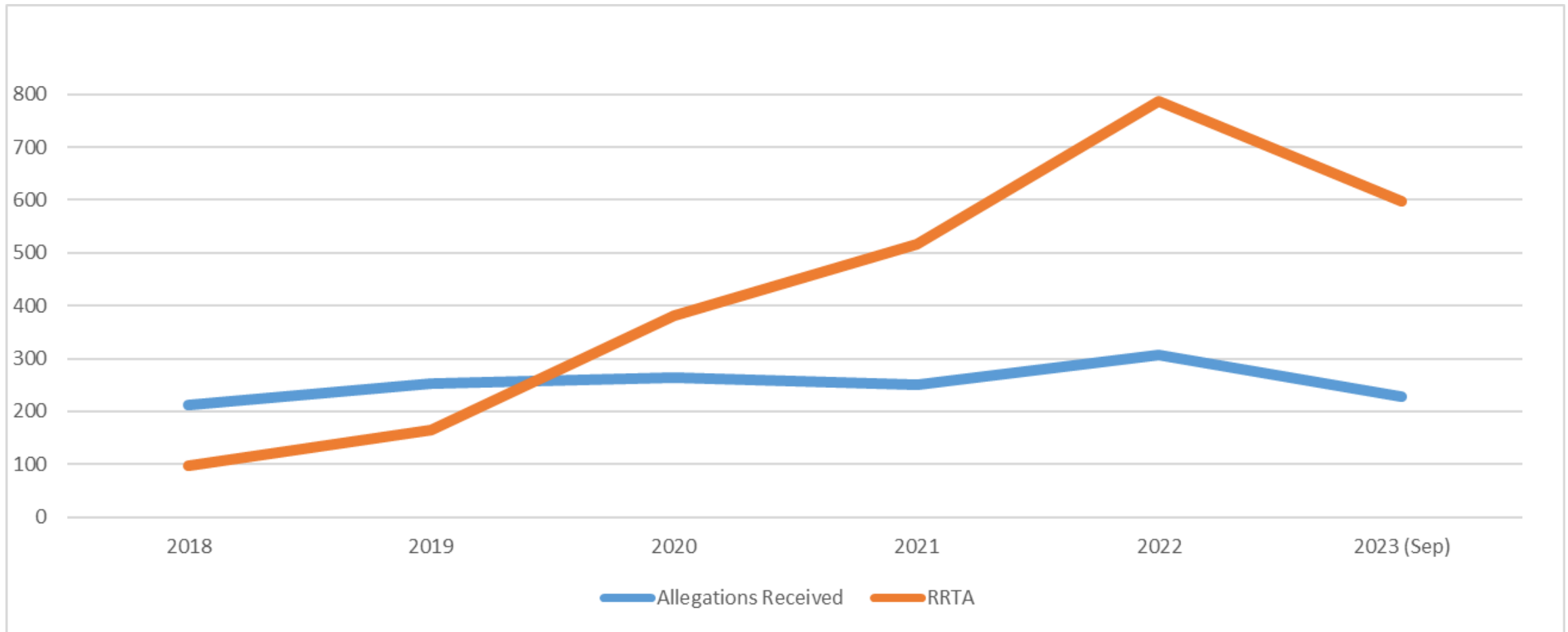
Rapid Response for Technical Assistance (RRTA)

- 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

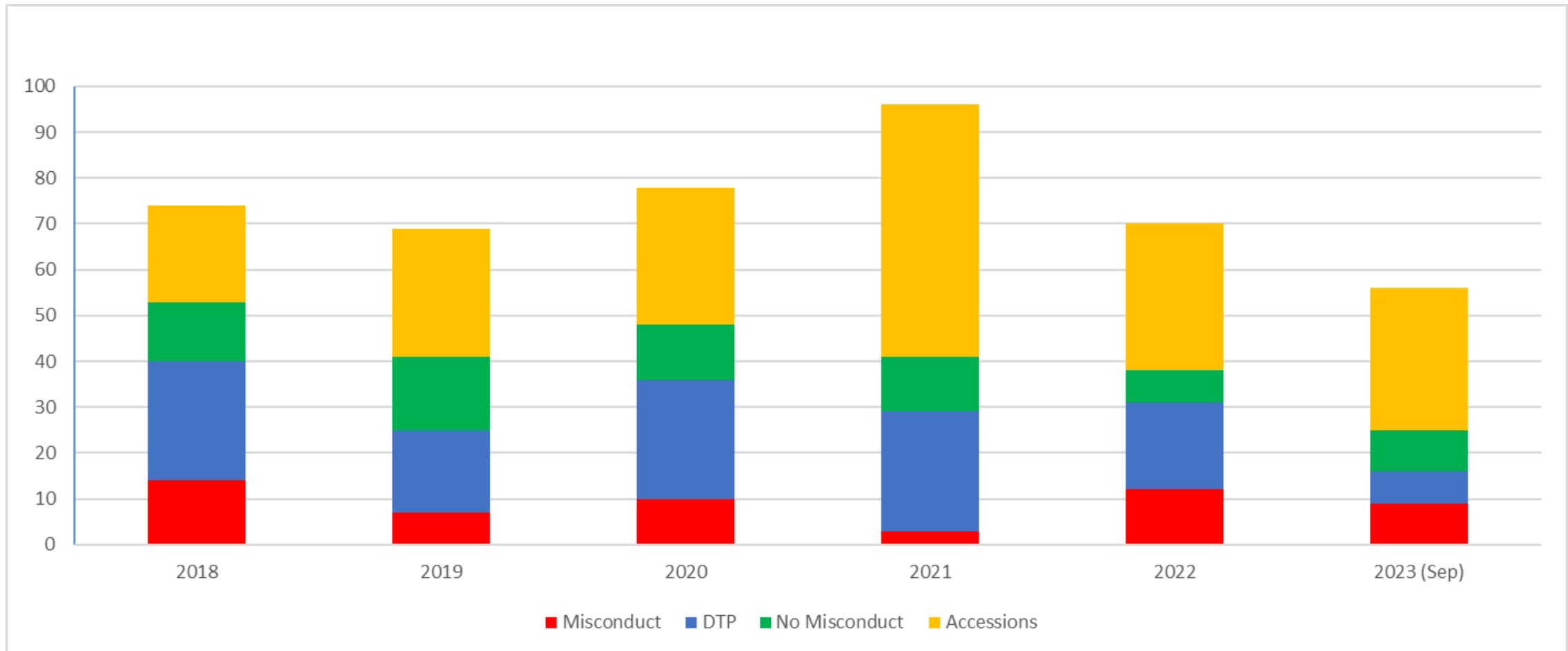


- Email: AskORI@hhs.gov DIO Phone #: 240-453-8800 Website: <https://ori.hhs.gov/>

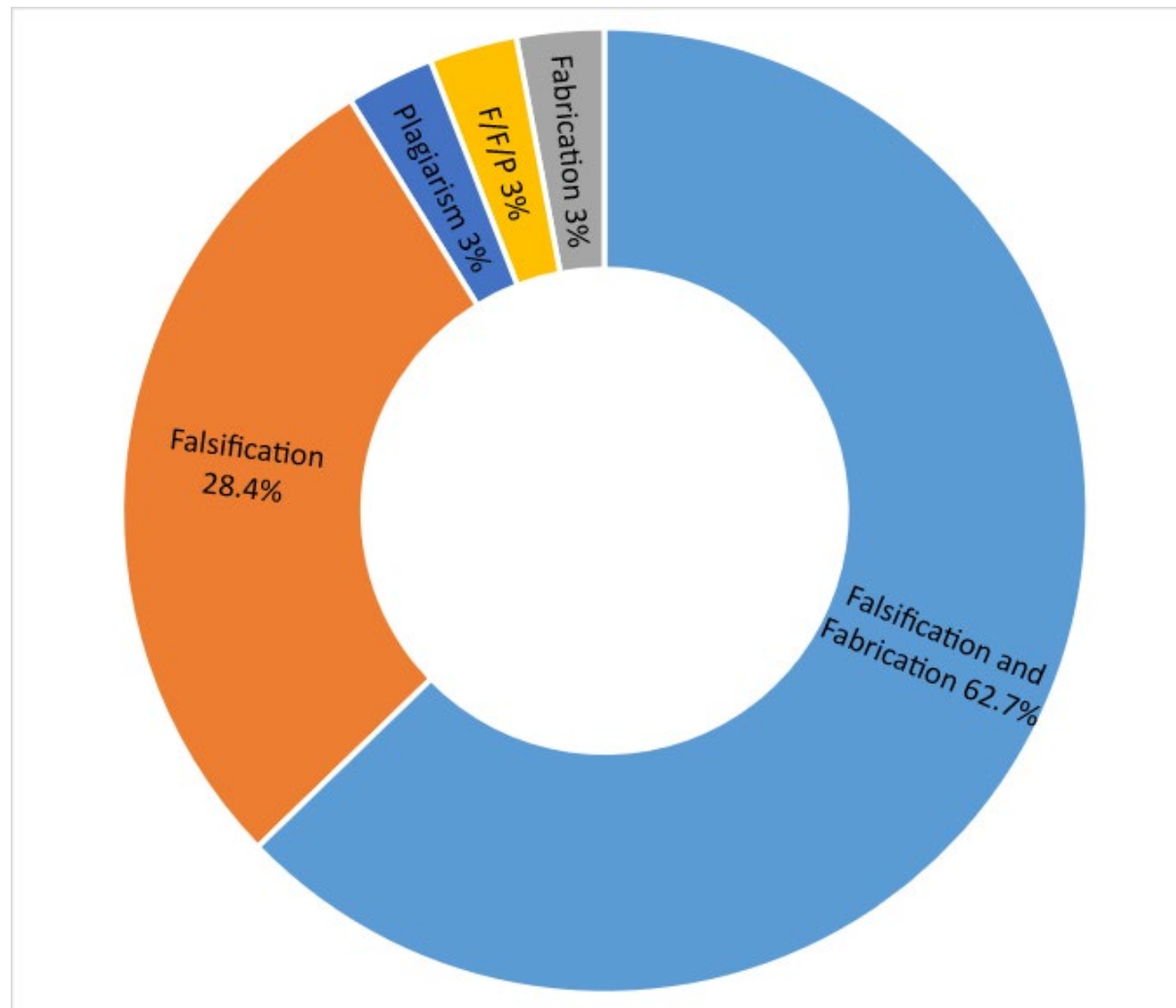
ORI - New Queries by Year



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 |

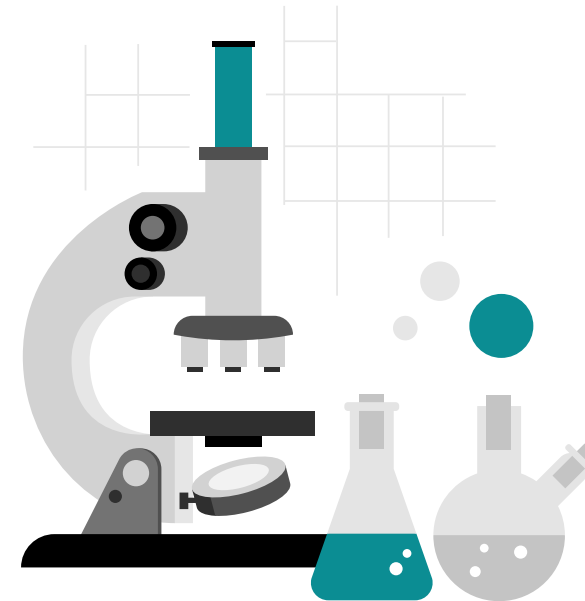
https://ori.hhs.gov/content/case_summary

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

NPRM Updates to 42 CFR 93

- Clarify complex processes
- Define vague concepts
- Explanations of undefined terms



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?



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.