

The U.S. Department of Health and Human Services, Office of Research Integrity

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FY 2021 Annual Report



Office of the
Assistant Secretary
for Health



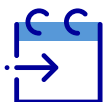
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ORI INVESTIGATIVE OVERSIGHT

Fiscal Year 2021

Cases
Continued



24

Allegations
Received



230

Cases
Opened



55

Total
Closures



95

**The ORI File Transfer
System (FTS) launched
in May 2021!**

41 institutions
uploaded
5,341 files
related to
47 unique cases

Note: Fiscal Year (FY) 2021 is October 1, 2020 - September 30, 2021. Some of the cases and allegations that were closed in FY 2021 were opened in previous years. "Total Closures" represents the total number of closed cases (44) and administrative closures (51) for FY 2021.

448 Technical Assistance sessions provided by ORI

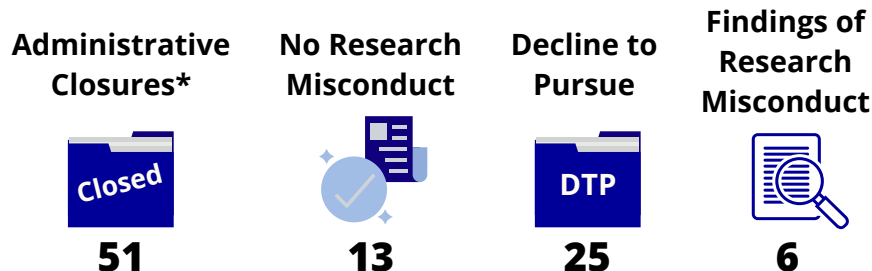
ORI's Rapid Response for Technical Assistance (RRTA) program provides technical assistance to institutions responding to allegations of research misconduct that involve Public Health Service (PHS)-funded research. The goals of the RRTA program are to facilitate high-quality and well-documented investigations and to help resolve research misconduct cases promptly. Examples of technical assistance available from ORI are:

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



ORI INVESTIGATIVE OVERSIGHT

Outcomes in FY 2021 Closed Cases

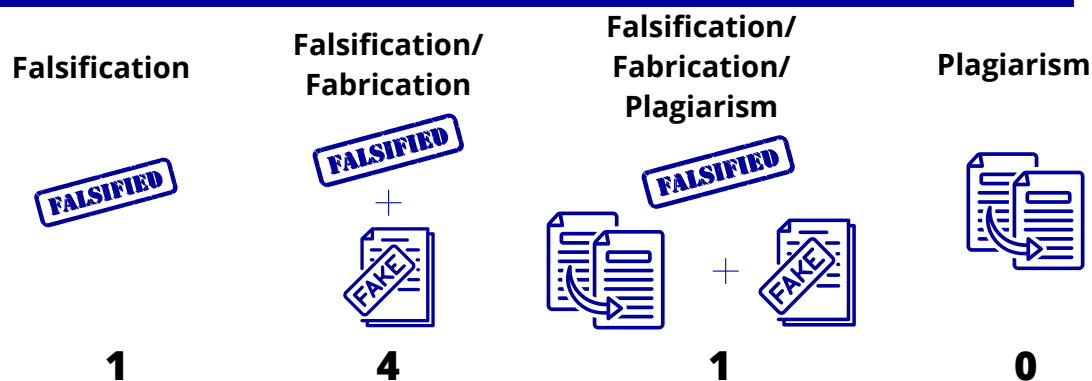


See the research misconduct case summaries!

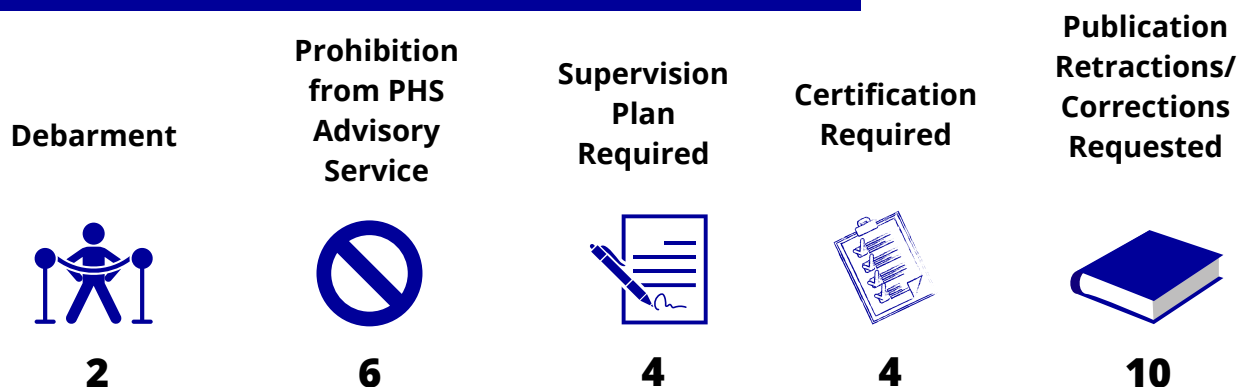
[Click Here](https://ori.hhs.gov/case_summary)

ori.hhs.gov/case_summary

Number of PHS Findings of Research Misconduct by Allegation Type



Administrative Actions in PHS Findings

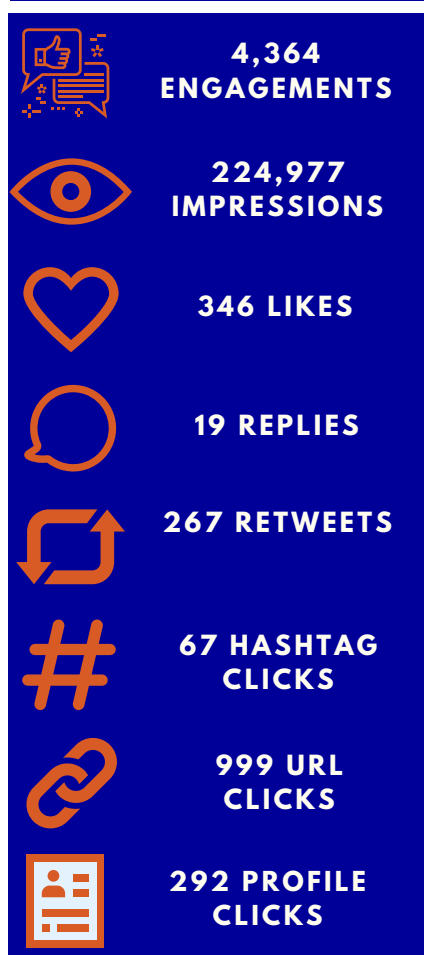


Notes: Some cases had multiple administrative actions. Some of the cases closed in FY 2021 had been opened in previous years. Debarments are government-wide. Supervision plans are for PHS-funded research.

*Generally, an administrative closure involves a case that resolved during the assessment or inquiry stage of the institutional proceeding, and ORI concurred with the institution's determination that there was insufficient evidence to warrant further investigation.

COMMUNICATIONS

Twitter



ORI posts regular updates for stakeholders via its Twitter account, website, and email lists.



*This includes countries, territories, and geographic regions identified by Google Analytics.



INTRAMURAL PROJECTS

Fostering Research Integrity and the Responsible Conduct of Research: Practices, Challenges, and Needs

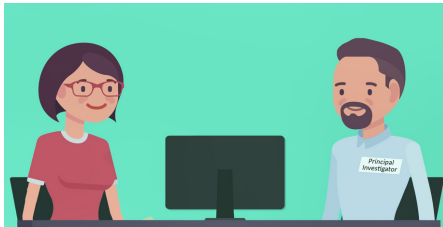
Research institutions receiving funding for research from any of the PHS funding components have long been expected to “[f]oster a research environment that promotes the responsible conduct of research, research training, and activities related to that research or research training, discourages research misconduct, and deals promptly with allegations or evidence of possible research misconduct.” [42 C.F.R. § 93.300\(c\)](#). An environment that promotes the responsible conduct of research and fosters research integrity benefits not only the quality of research funded by PHS but all of science.

ORI is committed to conducting outreach and developing educational resources that best support PHS-funded research institutions in their efforts. ORI published a Request for Information in the *Federal Register* to ask members of the biomedical research community about their needs, best practices, and challenges related to: using training and education to foster research integrity; research integrity/responsible conduct of research (RI/RCR) program administration and facilitation of training; and RI/RCR training sessions. ORI received thoughtful comments from individuals, organizations, and research institutions that will be used to inform the development of future educational resources and outreach activities.



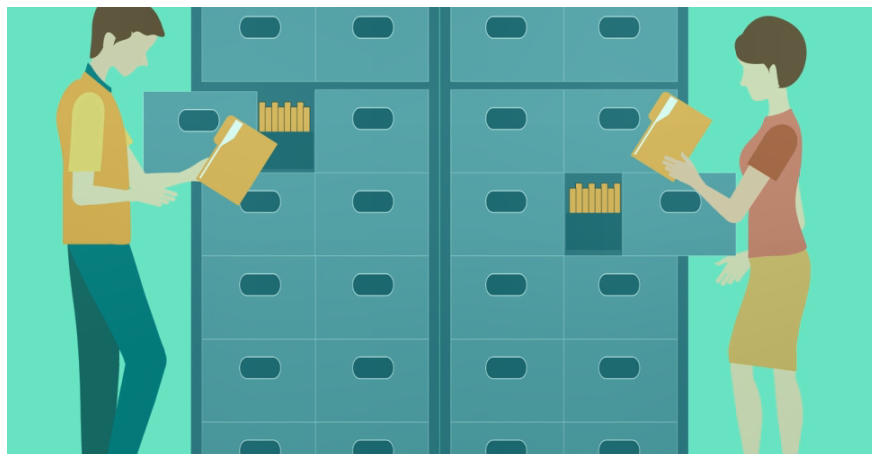
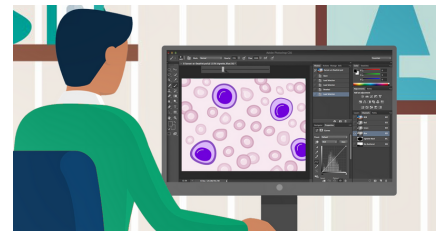
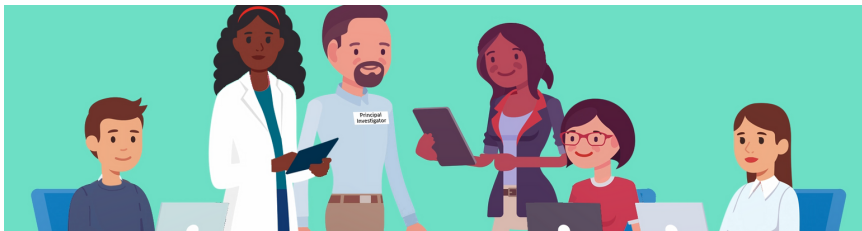
INTRAMURAL PROJECTS

Resource Development



ORI has observed that there is a need for, and the research community has expressed interest in, resources related to certain topics such as authorship, publishing, data management, recordkeeping, research misconduct, and mentoring. ORI began the development of new resources related to these topics that can be used by institutions and researchers to stimulate discussion and as sources of information. Resources include both traditional infographics as well as short, animated videos. The animated videos were purposefully kept short (approximately 1.5 minutes) so that they can be used as conversation starters in courses and the research environment as well as in outreach efforts focused on raising awareness about responsible research practices and research integrity. ORI will begin releasing the new resources in CY 2022* via the ORI website and in conjunction with communications campaigns focused on specific topics.

*Note: Calendar Year (CY) 2022 is January 1, 2022 - December 31, 2022.

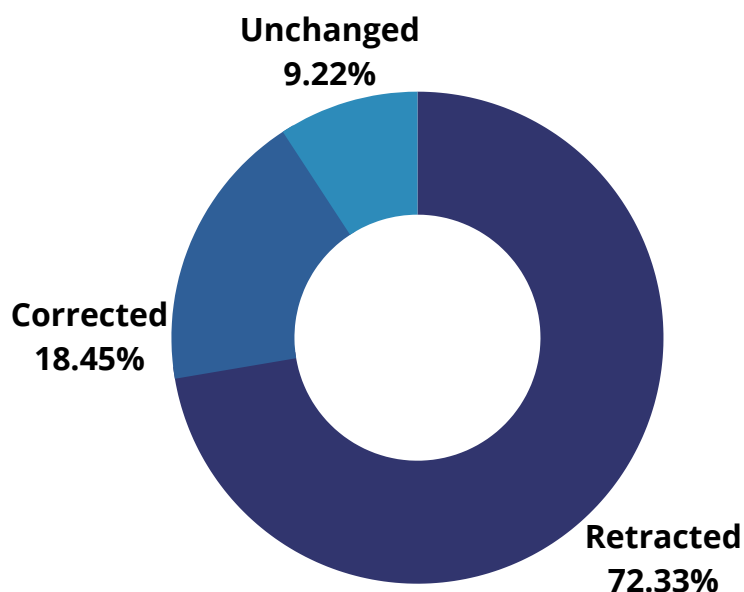


INTRAMURAL PROJECTS

Correcting the Scientific Record

Retraction or correction of research publications that contain research misconduct is an important step toward restoring the scientific record and ensuring that future research and healthcare decisions are not built upon fabricated, falsified, and/or plagiarized research. In FY 2021, ORI continued studying trends and outcomes associated with publications* reported by ORI as containing research misconduct.

Status of Publications Reported in ORI's FY 1993 - 2021 Federal Register Notices as Containing Research Misconduct



Of the 477 publications found by ORI to contain instances of research misconduct and reported in notices in the *Federal Register* (FRNs), from June 21, 1993, to September 20, 2021, over 90 percent were retracted (345, 72.33%) or corrected (88, 18.45%) by the end of FY 2021. By the end of FY 2021, fewer than 10 percent of all publications in this study remained unchanged in the scientific record. Of the 44 publications that were not corrected or retracted by the end of FY 2021, all were published before 2017.

To protect the scientific literature and public health from fabricated, falsified, and/or plagiarized research, ORI will continue to monitor and work on new ways to ensure that the scientific record is restored.

*Note: Publications included in this study are those abstracts and papers that were: (1) found by ORI to contain instances of research misconduct; (2) included in ORI Findings of Research Misconduct, published as notices in the *Federal Register* (FRNs) from June 21, 1993-September 20, 2021. Of the 316 FRNs published during this timeframe, 152 of the FRNs contained publications (477) that fit these criteria. This study did not include abstracts of conference presentations that were found by ORI to contain research misconduct and were included in FRNs during the same timeframe.

ORI GRANTS PROGRAM

Conferences on Research Integrity

- Funds projects that plan and implement conferences or workshops that provide a forum for discussion, production of tangible outcomes, and broad dissemination of knowledge and materials related to research integrity and compliance with the PHS Policies on Research Misconduct ([42 C.F.R. Part 93](#))
- FY 2021 focus areas included: (a) responsible conduct of research training; (b) fostering an environment that promotes research integrity; (c) prevention of research misconduct; (d) effective handling of research misconduct allegations; (e) whistleblowing and protection of whistleblowers; and (f) other topics linked to research integrity and compliance with [42 C.F.R. Part 93](#).



\$146,282 Awarded

**3
Grants**

Considerations, Options, and Resources for Data Management in PHS Funded Research

- Supports research and development related to data management and stewardship, to help ensure the integrity, reliability, and availability of data acquired in connection with PHS-funded research
- Work conducted under this cooperative agreement will focus on the development of practical approaches, considerations, and resources related to: data provenance, recordkeeping, organization and storage of data, data sharing and access, institutional policies, and standard operating procedures

\$643,249 Awarded

**1 Cooperative
Agreement**

Research Integrity Program Development and Evaluation

- Funds innovative projects that aim to develop and evaluate programs and resources related to: (a) fostering research integrity; (b) preventing or detecting research misconduct; (c) protecting whistleblowers, respondents, and other vulnerable individuals; and (d) enabling the proper handling of allegations of research misconduct
- Supports the creation of materials, resources, tools, and expertise to support a variety of new or existing programs

\$190,001 Awarded

**2
Grants**

Click [here](#) for more information on ORI's FY 2021 grantees.

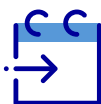
COMPLIANCE

Compliance Review Program

- Ensures that institutions comply with their policies and the PHS Policies on Research Misconduct ([42 C.F.R. Part 93](#)) when responding to allegations of research misconduct
- Monitors the implementation of PHS administrative actions
- Responds to retaliation complaints from whistleblowers
- Responds to instances of noncompliance by requiring specified corrective actions be taken

38 Compliance review cases handled in FY 2021

From Previous
Years



20

New in
FY 2021



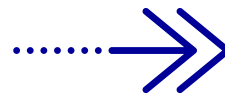
18

Closed in
FY 2021



15

Continued
into FY 2022



23

Assurance Program

The Assurance Program is responsible for ensuring that PHS research funds are awarded only to eligible institutions.

An institution is eligible when it has an active assurance on file with ORI stating that it has developed research misconduct policies and will comply with the PHS Policies on Research Misconduct ([42 C.F.R. Part 93](#)).



5,137

The number of active institutional
assurances on file at the end of
CY 2020*

*CY 2020 assurances were filed from January 1, 2021 through April 30, 2021.

COMPLIANCE

Assurance Program - Policy Review Project

Institutions that apply for or receive PHS [1] support for research are required to establish and maintain an active assurance pertaining to research misconduct with ORI. As part of that assurance, institutions are required to develop, implement, and comply with institutional policies and procedures for responding to allegations of research misconduct that are consistent with the PHS Policies on Research Misconduct ([42 C.F.R. Part 93](#))[2]. ORI is responsible for reviewing these policies and procedures to determine whether they comply with the PHS Policies on Research Misconduct. When policies are found to be non-compliant, ORI works to ensure appropriate corrective actions are taken.

In FY 2021, ORI established the Assurance Program Institutional Policy Review Project to undertake a comprehensive review of policies submitted by institutions as part of their assurance with ORI.

Through the end of FY 2021, the project had initiated the review of over 1,000 domestic and international institutional assurances for compliance with PHS Policies on Research Misconduct ([42 C.F.R. Part 93](#)). Beginning in FY 2022, ORI will contact institutions with non-compliant policies and procedures and offer assistance in establishing acceptable policies and procedures.



[1] PHS funding components are "any organizational unit of the PHS authorized to award grants, contracts, or cooperative agreements for any activity that involves the conduct of biomedical or behavioral research, research training or activities related to that research or research training, e.g., agencies, bureaus, centers, institutes, divisions, or offices and other awarding units within the PHS." [42 C.F.R. § 93.209](#). This includes the: National Institutes of Health (NIH), Centers for Disease Control and Prevention (CDC), Food and Drug Administration (FDA), Substance Abuse and Mental Health Services Administration (SAMHSA), Health Resources and Services Administration (HRSA), Indian Health Service (IHS), Agency for Healthcare Research and Quality (AHRQ), Agency for Toxic Substances and Disease Registry (ATSDR), Office of the Assistant Secretary for Health (OASH), Office of the Assistant Secretary for Preparedness and Response (ASPR), and the Offices (10) of the Regional Health Administrator.

[2] See the PHS Policies on Research Misconduct ([42 C.F.R. § 93.300 – § 93.304](#)) at https://ori.hhs.gov/sites/default/files/42_cfr_parts_50_and_93_2005.pdf

MEET THE DIRECTORS



Wanda Jones, Dr.P.H., Acting Director

Dr. Jones has served as the Associate Director of Research and Scientific Integrity and Deputy Director since February 2020. Prior to joining ORI in December 2017, Dr. Jones was in the Office of the Assistant Secretary for Preparedness and Response, where she led development of the HHS 2017 update to the Pandemic Influenza Plan. From 2009 to 2016, Dr. Jones was the HHS Principal Deputy Assistant Secretary for Health (PDASH), where she oversaw ORI operations and was the signing official on voluntary settlement agreements on research misconduct findings. Dr. Jones joined the Centers for Disease Control and Prevention (CDC) in 1987, where she led laboratory training efforts in HIV/AIDS testing, and then moved to a science advisory role in HIV/AIDS policy at CDC, focusing on policies related to neonatal screening, women and HIV/AIDS, vaccine development, and HIV reporting. In 1994, she established CDC's Office of Women's Health and was selected to lead the HHS Office on Women's Health in 1998.



Alexander Runko, Ph.D., Director of the Division of Investigative Oversight (DIO)

Dr. Runko worked at ORI as a Scientist-Investigator from 2010-2016, where he was involved in handling and assessing allegations and reports of inquiries and investigations of research misconduct that involve PHS funding. In that role, he also trained and provided guidance to research institutions, federal agencies, and journal editors on forensic and analytical tools to examine and uncover the falsification and fabrication of scientific data. Dr. Runko has a Ph.D. in biochemistry and molecular pharmacology from the University of Massachusetts Memorial Medical Center, where his research focused on neurogenesis, embryology, developmental biology, and genetics. He completed his postdoctoral training at NIH's National Institute of Neurological Disorders and Stroke, where he analyzed the genetic and molecular mechanisms underlying neurodegenerative diseases.



Karen Wehner, Ph.D., Director of the Division of Education and Integrity (DEI)

Prior to joining ORI, Dr. Wehner served as the Associate Director of the Division of Research Integrity at the Johns Hopkins University School of Medicine (JHU SOM). In this role, she was responsible for overseeing, developing, and delivering Responsible Conduct of Research training for faculty, postdocs, and staff at JHU SOM as well as consulting on and supporting RCR training for graduate students. Dr. Wehner also functioned as Assistant Research Integrity Officer, providing comprehensive support for the institution's response to allegations of research misconduct. Dr. Wehner earned her Ph.D. in Genetics at Yale University, completed postdoctoral work at Stanford University School of Medicine, and conducted basic biomedical research at JHU SOM.

CONTACT US

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