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

Annual Report

FY 2023







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INVESTIGATIVE OVERSIGHT

Fiscal Year 2023

Cases Continued from Previous Years



Allegations Received



Cases Opened



Total Closures



The ORI File
Transfer System
(FTS) was used by
119 institutions to
upload approximately
116,126 files related
to 230 unique cases.

Note: Fiscal Year (FY) 2023 is October 1, 2022-September 30, 2023. Some of the cases and allegations that were closed in FY 2023 were opened in previous years. "Total Closures" represents the total number of closed cases (34) and administrative closures (47) for FY 2023.

886 Technical Assistance Sessions Provided by ORI

ORI's Rapid Response for Technical Assistance (RRTA) program provides technical assistance and procedural guidance 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, help resolve research misconduct cases promptly, and ensure that institutional proceedings meet the requirements under the federal regulation at <u>42 C.F.R. Part 93</u> for ORI's oversight review. ORI provides technical assistance on topics including:

- 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.



INVESTIGATIVE OVERSIGHT

Outcomes in FY 2023 Closed Cases

Administrative Closures*



No Research **Misconduct**



Decline to **Pursue**



13

Findings of Research **Misconduct**



See the research misconduct case summaries! **Click Here** ori.hhs.gov/ case summary

Number of PHS Findings of Research Misconduct by Allegation Type

Falsification

FALSIFIED

Fabrication



Falsification/



Falsification, Fabrication, & Plagiarism



Administrative Actions

Debarment

Advisory Service



Prohibition from PHS



Supervision Plan Required



Certification Required



Publication Retractions/ **Corrections** Requested



Notes: Some cases had multiple administrative actions. Some of the cases closed in FY 2023 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 in which ORI concurred with the institution's determination that there was insufficient evidence to warrant further investigation.

COMMUNICATIONS

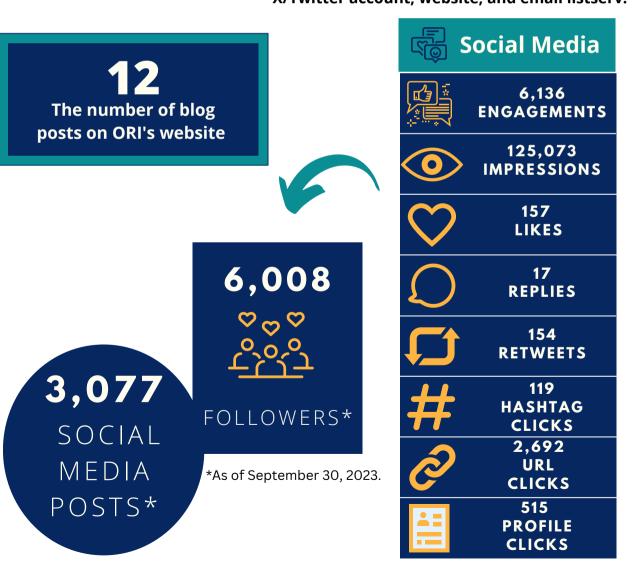


*This includes countries, territories, and geographic regions identified by the analytics provider.



22 ORI Updates

ORI posts updates for stakeholders via its X/Twitter account, website, and email listserv.



INTRAMURAL PROJECTS

ORI's YouTube Channel

In September of 2023, ORI launched its YouTube channel, making video resources more accessible, streamable, and easy to find. Since the launch, ORI has released a number of long and short animated videos, legacy content, and videos about ORI news and updates. Visit our YouTube channel here: https://www.youtube.com/@HHS_ORI.











































GRANTS PROGRAM

Ensuring Research Integrity - Conferences (IR-ORI-23-002)

This opportunity supported projects to plan and implement conferences or workshops related to ensuring research integrity and compliance with <u>42 C.F.R. Part 93</u>. Virtual conferences and workshops were eligible for funding.

FY 2023 Grant Awards

Title: The Future of Research Integrity

Grantee: University of South Alabama

Project Leaders: Dusty Layton, MPA, (Project Director); and Lynne Chronister, MPA,

(Co-Investigator)

Institution: University of South Alabama

Conference Website: https://www.southalabama.edu/departments/globalusa

/cce/research integrity conference/

Title: 8th World Conference on Research Integrity

Grantee: National Technical University of Athens/Research

Committee

Project Leader: Costas Charitidis, Ph.D., MSc Institution: National Technical University of Athens

Conference Website: https://wcri2024.org/

Click here for more information on ORI's FY 2023 grantees.

2 New Grants +
3 Continuations
\$496,653 Awarded

Publications cited support from the ORI extramural research program during FY 2023

GRANTS PROGRAM

Non-Competing Continuations of FY 2022 Research, Development, and Demonstration Awards, FY 2023

Title: Natural Language Processing to Assess and Improve Citation Integrity in Biomedical Publications

Grantee: Board of Trustees of the University of Illinois

Project Leader: Halil Kilicoglu, Ph.D.

Institution: University of Illinois at Urbana-Champaign

Title: Treating DNA Sequence Data as First-Class Research Objects for Greater Research Transparency and Credit

Grantee: Regents of the University of Michigan

Project Leader: Patrick D. Schloss, Ph.D.

Institution: University of Michigan

Title: Education and Assessment to Improve Research Misconduct Proceedings

Grantee: The Pennsylvania State University - University Park

Project Leaders: Courtney Karmelita, BS, M.Ed., D.Ed., (PI); and Bridget

Carruthers, Ph.D., RBP, (Co-PI)

Institution: The Pennsylvania State University - University Park (PI), and

The Ohio State University (Co-PI)

FY 2024 Grant Opportunity Forecasts

Conferences (Opportunity Number: IR-ORI-24-001)

- This opportunity supports projects to plan and implement conferences or workshops related to ensuring research integrity and compliance with <u>42 C.F.R. Part 93</u>. Virtual conferences and workshops will be eligible for funding.
- Conferences or workshops must be designed to provide a forum for discussion and produce tangible outcomes related to at least one of the following themes: (a) fostering an environment that promotes research integrity and the responsible conduct of research; (b) prevention of research misconduct; (c) effective handling of research misconduct allegations; (d) training in the responsible conduct of research; or (e) other topics linked to research integrity and compliance with 42 C.F.R. Part 93.
- ORI anticipates making awards of between \$25,000 and \$50,000 in total costs (direct plus indirect) for a project period not to exceed one year. Estimated Total Program Funding: \$200,000.

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



308 Institutional Policies Reviewed for Compliance in FY 2023

Assurance Program

The Assurance Program is responsible for ensuring that PHS biomedical and behavioral research funds are awarded only to institutions with active assurances.

An institution may only receive PHS biomedical or behavioral research funding 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).



*As of September 30, 2023.

Activities related to the management of these records include (but are not limited to):

- Reviewing annual institutional submissions (e.g., Annual Report on Possible Research Misconduct, small institution statements, foreign institution statements, etc.)
- Providing technical assistance to Annual Report System users (e.g., establishing new accounts, assisting with login username and password resets, etc.)
- Working with institutions and grant management specialists to resolve account holds that may impact the release of funding to an institution
- Establishing and reviewing institutional ORI Assurance Records
- Providing support to institutions as they prepare and submit their electronic Annual Report on Possible Research Misconduct

MEET THE DIRECTORS





Sheila Garrity became ORI Director in March 2023.

Before coming to ORI, Ms. Garrity served as Associate Vice President of Research Integrity at George Washington University (GW) from 2014 to 2023 where she oversaw operations of the Office of Laboratory and Radiation Safety, Office of Human Research, Office of Animal Research, Office of Research Integrity and Regulatory Affairs and served as the institutional Research Integrity Officer (RIO). At GW Ms. Garrity was responsible for policy development, informational sessions, and development of educational modules to assist investigators with understanding their ethical and fiduciary responsibilities regarding their research.

Prior to that, Ms. Garrity spent more than 20 years at Johns Hopkins University School of Medicine where she served as the director of the Division of Research Integrity and Research Integrity Officer (RIO). She is a founding member and first president of the Association for Research Integrity Officers (ARIO, founded 2013). Ms. Garrity was in the first group of teaching RIOs when ORI launched its first series of RIO Bootcamps in the early 2000's.

Ms. Garrity earned her JD from the University of Maryland School of Law and her MBA and MPH at Johns Hopkins where she also received a certificate in Health and Human Rights.

MEET THE DIRECTORS



Wanda K. Jones, Dr.P.H., Former Deputy Director

Dr. Jones served as the Associate Director of Research and Scientific Integrity and Deputy Director from February 2020 to January 2024, when she retired from federal service. Prior to joining ORI in December 2017 and serving as Interim and then Acting Director until August 2019, 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 of research misconduct proceedings. 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

Dr. Runko started at ORI in 2010 as a Scientist-Investigator, where he was involved in handling and assessing allegations and reports of inquiries and investigations of research misconduct that involve Public Health Service 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 and gene expression in the developing brain. He completed his postdoctoral training at the NIH's National Institute of Neurological Disorders and Stroke (NINDS), where he analyzed the genetic and molecular mechanisms underlying neurodegenerative diseases. Dr. Runko also worked at NINDS as a Health Program Specialist in the extramural research program where he managed portfolios of grant proposals and awards on neurological diseases, and at the NIH's National Heart, Lung, and Blood Institute (NHLBI), where he was the Extramural Genomic Program Administrator and Data Access Committee Chair that directed the management of genomic and phenotypic data submissions and the review of applications from researchers to access and utilize NHLBI datasets.



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

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 an Assistant Research Integrity Officer, providing comprehensive support for the institution's response to allegations of research misconduct, and she handled other research integrity matters, such as authorship disputes and professional misconduct occurring in the research space. 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. Dr. Wehner's research employed the use of molecular, genetic, and biochemical techniques and focused on the assembly, regulation, and activity of ribosomes.

CONTACT US

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