

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



## Annual Report FY 2022



Office of the  
Assistant Secretary  
for Health



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# INVESTIGATIVE OVERSIGHT

## Fiscal Year 2022

### Cases Continued from Previous Years



33

### Allegations Received



269

### Cases Opened



38

### Total Closures



78

The ORI File Transfer System (FTS) was used by **93** institutions to upload approximately **20,600** files related to **172** unique cases.

Note: Fiscal Year (FY) 2022 is October 1, 2021-September 30, 2022. Some of the cases and allegations that were closed in FY 2022 were opened in previous years. "Total Closures" represents the total number of closed cases (42) and administrative closures (36) for FY 2022.

## 707 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 [42 C.F.R. Part 93](#) 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





**FALSIFIED**

**FALSIFIED**

+



# COMMUNICATIONS

Website	
	<b>3,032,663</b> Page Views
	<b>1,390,275</b> Visitors
	<b>234</b> Locales*

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









Email Updates		
<b>19,468</b> Subscribers	<b>4</b> Distribution Lists	<b>5</b> Email Updates Sent

**20** ORI Updates

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

**11**  
The number of blog posts on ORI's website



Social Media	
	<b>5,275</b> ENGAGEMENTS
	<b>59,048</b> IMPRESSIONS
	<b>100</b> LIKES
	<b>12</b> REPLIES
	<b>95</b> RETWEETS
	<b>138</b> HASHTAG CLICKS
	<b>2369</b> URL CLICKS
	<b>263</b> PROFILE CLICKS

**3,034**  
SOCIAL MEDIA POSTS\*

**5,851**  
  
FOLLOWERS\*

\*As of September 30, 2022.

# INTRAMURAL PROJECTS

## Website Analysis and Redesign

As part of ORI's continued commitment to improving its outreach, education, and research community support programs, ORI began the multi-year process of updating its website. In this initial phase, ORI sought to understand how the website could better serve the stakeholder community, improve outreach and engagement, make information more accessible to target audiences, enhance the visitor experience, and improve readability, navigation, and ease of use.

The project began with a needs assessment, which included both focus groups and an assessment of current efforts. Focus groups included institutional Research Integrity Officers (RIOs) with differing levels of experience and individuals involved in fostering the responsible conduct of research. The groups addressed questions about specific needs, challenges, and engagement strategies as well as the support and resources that would be most helpful to ORI's stakeholders in the research integrity community. The rich discussions yielded important insights about stakeholder experience and engagement with the website and current resources and information.

ORI has examined website analytics data, feedback from focus groups, and input from ORI staff as it considers optimizing its communication channels. Standard metrics such as audience analysis, audience behavior, and usability metrics are used across industry to improve website features and user experience.



# INTRAMURAL PROJECTS

## Revision to ORI's Regulation

ORI's regulation, the Public Health Service (PHS) Policies on Research Misconduct (42 C.F.R. Part 93), was promulgated in 2005. It establishes several requirements for institutions applying for or receiving funding for biomedical or behavioral research, research training, or activities related to that research or research training from any of the PHS funding components regarding the handling of allegations of possible research misconduct and fostering an environment that promotes research integrity and discourages research misconduct.

In FY 2021, ORI began to lay the groundwork for a revision of the 2005 ORI regulation at 42 C.F.R. Part 93. In FY 2022, ORI received authorization to begin the process and will undertake notice-and-comment rule-making as called for under the Administrative Procedure Act.

To begin to understand stakeholder concerns about the regulation, ORI released a Request for Information on September 1, 2022. During the response period, ORI received comments by email from a combined total of 31 individuals, institutions, and organizations. Comments ranged in nature and length from short emails to multi-page letters. ORI will use these comments to develop a notice for public comment.



# ENSURING RESEARCH INTEGRITY GRANTS PROGRAM

## Research, Development, and Demonstration, FY 2022

- Supports projects that undertake research, development, and demonstration activities to advance the evolving field of research integrity as well as to develop innovative practical approaches, tools, and/or resources and produce tangible outcomes related to ensuring research integrity and compliance with 42 C.F.R. Part 93. ([42 C.F.R. Part 93](#))
- FY 2022 focus areas included: (a) transparency in the conduct or reporting of research; (b) effective communication between authors and/or collaborators for the purpose of avoiding, mitigating, and resolving authorship/collaborator disputes and/or issues related to the integrity of the research (e.g., conflicts of interest, research integrity, rigor, reproducibility, transparency, reliability); (c) handling allegations of research misconduct under [42 C.F.R. Part 93](#); and (d) interventions to address issues related to research culture and climate (e.g., overly-competitive environments, toxic workplaces, bullying, harassment, etc.) that can negatively impact the integrity, conduct, quality, and reliability of research.
- Recipients in the FY 2022 cohort are eligible to submit non-competing continuation applications for a second year of funding.

**3**  
Grants  
**\$448,299**  
Awarded

**4**  
Publications cited  
support from the  
ORI extramural  
research program  
during FY 2022

### FY2022 Grant Awards

Ensuring Research Integrity-Research, Development, and Demonstration (IR-ORI-22-001)

Project Title	Grantee	Principal Investigator	Institution
Natural Language Processing to Assess and Improve Citation Integrity in Biomedical Publications	Board of Trustees of the University of Illinois	Halil Kilicoglu, PhD	University of Illinois at Urbana-Champaign
Treating DNA sequence data as first-class research objects for greater research transparency and credit	Regents of the University of Michigan	Patrick D. Schloss, PhD	University of Michigan
Education and Assessment to Improve Research Misconduct Proceedings	The Pennsylvania State University - University Park	PI: Courtney Karmelita, BS, M.Ed., D.Ed. Co-PI: Bridget Carruthers, Ph.D., RBP	PI: The Pennsylvania State University - University Park Co-PI: The Ohio State University

Click [here](#) for more information on ORI's FY 2022 grantees.



# ENSURING RESEARCH INTEGRITY GRANTS PROGRAM

## FY 2023 Grant Opportunity Forecasts

### Research, Development, and Demonstration ([Opportunity Number: IR-ORI-23-001](#))

- This opportunity supports projects that: (a) conduct research on one of the four focus areas identified below, related to ensuring research integrity and compliance with [42 C.F.R. Part 93](#); (b) develop innovative approaches/tools/resources based on the results of this research; and (c) demonstrate the impact and/or effectiveness of these approaches/tools/resources.
- FY 2023 focus areas include: (a) transparency in the reporting of research; (b) effective communication between authors/collaborators for the purpose of avoiding, mitigating, and resolving authorship/collaborator disputes and/or issues related to the integrity of the research (e.g. conflicts of interest, research integrity, rigor, reproducibility, transparency, reliability); (c) handling allegations of research misconduct under [42 C.F.R. Part 93](#); or (d) interventions to address issues related to research culture and climate (e.g., ultra-competitive environments, toxic workplaces, bullying, harassment, etc.) that can negatively impact the integrity, conduct, quality, and reliability of research.
- ORI anticipates making new awards (FY 2023 cohort) of between \$75,000 and \$150,000 in total costs (direct plus indirect) per year, for a project period not to exceed two years (two 12-month budget periods). Estimated Total Program Funding: \$450,000.

### Conferences ([Opportunity Number: IR-ORI-23-002](#))

- This opportunity supports projects to plan and implement conferences or workshops related to ensuring research integrity and compliance with [42 C.F.R. Part 93](#). 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: \$100,000.

# 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

**24** Compliance review cases handled in FY 2022

Closed in  
FY 2022



**17**

Continued  
into FY 2023



**7**

## 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, 2022.

### 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

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## **Wanda K. 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 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.

\*In April 2022 OASH/ORI initiated the search for a permanent ORI Director. On February 10, 2023, the Assistant Secretary for Health announced the selection of Sheila Garrity, JD, MPH, MBA, who is expected to start the week of March 26, 2023.

# **CONTACT US**

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