# The U.S. Office of Research Integrity

## FY 2020 Annual Report

OASH | Office of Research Integrity

# TABLE OF CONTENTS

# ORI INVESTIGATIVE OVERSIGHT

## Fiscal Year 2020

**Cases Continued**

**35**

**Allegations Received**

**204**

**Cases Opened**

**34**

**Total Closures**

**72**


Note: Fiscal Year 2020 is October 1, 2019 - September 30, 2020. Some of the cases and allegations that were closed in FY 2020 were opened in previous years. Closures represents the total number of closed cases (45) and closed allegations (27).

## 361 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 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 2020 Closed Cases

**No Research Misconduct**

**8**

**Decline to Pursue**

**26**

**Findings of Research Misconduct**

**11**

See the research misconduct case summaries! **Click Here**

**Over $75 Million**

The amount of federal funds* impacted by research misconduct in ORI's FY 2020 findings of research misconduct

*This is a preliminary estimate of direct or collaborative funding. ORI has begun to conduct additional assessments based on these preliminary estimates.

## Number of PHS Findings of Research Misconduct by Allegation Type

**Falsification**


**2**

**Fabrication**


**1**

**Falsification/ Fabrication**


**7**

**Falsification/ Fabrication/ Plagiarism**


**1**

## Administrative Actions in PHS Findings

**Debarment/ Voluntary Exclusion**

**5**

**Prohibition from PHS Advisory Service**

**11**

**Supervision Plan Required**

**5**

**Certification Required**

**5**

**Publication Retractions/ Corrections Requested**

**21**

**Voluntary Exclusion and Supervision**

**1**

Note: Some cases had multiple administrative actions. Some of the cases closed in FY 2020 had been opened in previous years. Debarments are federal-wide. Supervision plans are for PHS-funded research. Multiple research misconduct findings were made in each of the 11 cases closed with findings.

# COMMUNICATIONS

## Twitter

- 22,258 ENGAGEMENTS
- 939,822 IMPRESSIONS
- 1,165 LIKES
- 158 REPLIES
- 1,060 RETWEETS
- 261 HASHTAG CLICKS
- 5,701 URL CLICKS
- 1,326 PROFILE CLICKS

**564** TWEETS

**5,224** FOLLOWERS

**ORI posts regular updates for stakeholders via its Twitter account, website, and listserv.**

## Website

**2,104,980** Page Views

**947,250** Visits

**223** Locales*

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

## Did You Know?

**ORI offers a variety of RCR resources, such as videos, infographics, and modules, that can be downloaded or streamed directly from our website.**

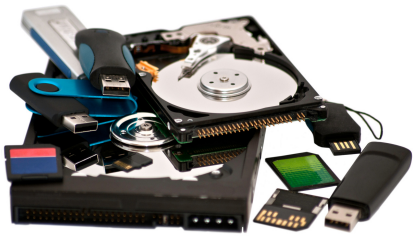
## E-Blasts

| 18,644 | 4 | 15 |
|---|---|---|
| Subscribers | Distribution Lists | Email Updates Sent |

# RESEARCH

## Challenges and Approaches to Sequestration of Evidence

As the use of technology and laboratory record keeping evolve, ORI is interested in continuing to update the guidance, training, and technical assistance that we provide to institutions for handling allegations of research misconduct.



Sequestration is a key aspect of handling allegations of research misconduct and is heavily impacted by evolving technologies and laboratory record keeping practices. For this reason, ORI sought to learn from the research integrity community about challenges and solutions in sequestering digital evidence. Examples include data stored in cloud environments and on personal electronic equipment or storage devices.

ORI published a Request for Information to ask members of the research integrity field about major challenges that exist in the sequestration process and approaches to overcome them, especially regarding digital evidence. ORI received thoughtful comments from the research integrity community and is considering this information as it develops resources on this topic.

## Needs Assessment: Promoting Research Integrity

ORI conducted an assessment of the resources currently available for use in research integrity (RI) and responsible conduct research (RCR) educational and training activities. The goal of the assessment was to identify gaps and unmet needs, in both format and content, that should be addressed in the future development of new RI/RCR related resources.

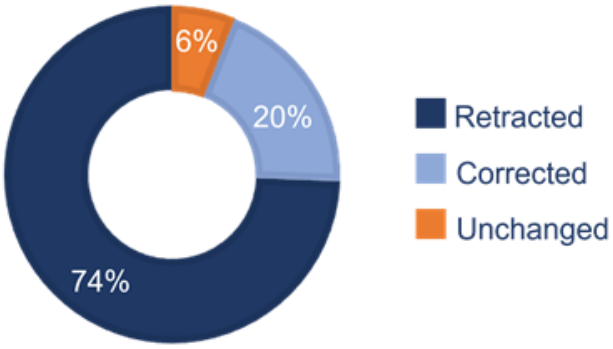
This work identified a gap in available resources related to detrimental research practices and a need for new resources (e.g., scenarios, case studies, role playing, video clips, and interactive videos) to cover these areas. This work also highlighted the need to optimize existing resources (scenarios, case studies, and video clips) for more effective use, by RCR educators and research integrity professionals, through the development of accompanying facilitator and discussion guides. ORI is exploring how to best address the needs and opportunities identified by this assessment and plans to develop resources that address them by 2022.

# RESEARCH

## Outcomes of Retractions and Corrections Requested by ORI

Retractions/corrections are a means of maintaining the integrity of the scientific literature and are necessary to alert the scientific community to serious problems identified within a published article. Thus, they help ensure that future research is not built upon problematic research. ORI has begun to monitor each of its requested corrections and/or retractions. Early results from this work highlight the value of ORI's investigative work and the importance of capturing the results through this process.

**Outcomes from Retractions/Corrections Recommended by ORI (2015-2019), n = 164**




An initial review of misconduct cases closed by ORI from 2015 to 2019 revealed that 40 of the 50 respondents had a total of 164 publications involving research misconduct. For 154 publications (94%), the journals had corrected the record in some manner. Retractions accounted for most corrections (122, 74%), while the remainder included other less serious journal actions such as editorial expressions of concern, corrections, and errata. Of the original 164 publications, 6% remained in the literature, unchanged, as of July 1, 2020.

**Did You Know?**

**An analysis* of the 164 papers described above revealed that they were cited in subsequent publications a total of 7,318 times!**

**Those publications were in turn cited in 301,716 papers!**

**To protect the scientific literature and public health from flawed research, ORI will continue to monitor and report on retractions as it studies new ways to decrease the time to retraction and mitigate the number of citations after retraction.**

*Note: analysis done on articles that appeared in PubMed through 9/24/2020

# ORI GRANTS PROGRAM

## Research on Research Integrity (RRI) Grant Awards

- Seeks to develop an evidence base for creation or enhancement of educational and interventional programs that promote research integrity and prevent research misconduct
- Funds innovative original research related to the: (a) prevention of research misconduct; (b) facilitation of whistleblowing and the protection of whistleblowers; and (c) promotion of the responsible conduct of research and the furtherance of research integrity

**RRI** **$420,235** Awarded in FY 2020

**3** Grants

## Conferences on Research Integrity (CRI)

- Seeks to provide a forum for discussion, production of tangible outcomes, and broad dissemination of generalizable knowledge on the topics related to: (a) Responsible Conduct of Research (RCR) training; (b) fostering an environment that promotes research integrity; (c) prevention of research misconduct; (d) effective handling of research misconduct allegations; and (e) whistleblowing and protection of whistleblowers
- Funds projects that plan and implement conferences or workshops on research integrity and compliance with the Public Health Service Policies on Research Misconduct (42 C.F.R. Part 93)

**CRI** **$43,769** Awarded in FY 2020

**1** Grant

## Research Integrity Program Development and Evaluation (PD&E)

- Seeks to support 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
- Funds the creation of materials, resources, tools, and expertise to support a variety of new or existing programs

**PD&E** **$188,173** Awarded in FY 2020

**2** Grants

**10** **The number of research publications citing support from the ORI Extramural Research Program during FY 2020.**

Click here for more information on ORI's FY 2020 grantees.

# COMPLIANCE

## 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).**

**5,126**

The number of active institutional assurances on file at the end of calendar year 2019*

This was an increase of **263** from the previous year

*Calendar year 2019 assurances were filed from January 1, 2020 through April 30, 2020.

In calendar year 2019, assurances on file increased from institutions of higher education, other health/ human resources/ environmental services organizations, and small businesses. In contrast, filings decreased from research organizations/ institutes/ foundations/ laboratories, independent hospitals, and educational organizations other than higher education.

## Compliance Review Program

- Ensures that institutions comply with their policy 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

**32 Compliance review cases handled in FY 2020**

| From Previous Years | New in FY 2020 | Closed in FY 2020 | Continued into FY 2021 |
|---|---|---|---|
| 15 | 17 | 12 | 20 |

# MEET THE DIRECTORS

**Elisabeth Handley, M.P.A., Director of the Office of Research Integrity (ORI)** Before joining ORI, Ms. Handley held multiple jobs in the Centers for Medicare and Medicaid Services (CMS), including Deputy Center Director and Acting Director of the Center for Program Integrity, and earlier conducted evaluation and inspections in the HHS Office of Inspector General. At the National Cancer Institute (NCI), the Office of the National Coordinator for Health Information Technology, and the Health Resources and Services Administration, Ms. Handley was responsible for grants and program integrity. Ms. Handley began her federal career as a Presidential Management Fellow at the Social Security Administration, after receiving a master's degree in public administration from Florida State University.

**Wanda Jones, Dr.P.H., Deputy Director, and Associate Director, Research and Scientific Integrity** Prior to joining ORI, 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, 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 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, embryology, developmental biology and genetics, and 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

## Postal Address

U.S. Department of Health and Human Services
Office of Research Integrity
1101 Wootton Parkway, Suite 240
Rockville, Maryland 20852

## Phone

240-453-8800

## Email

AskORI@hhs.gov

## Website

https://ori.hhs.gov

## Subscribe to our Email Updates

https://cloud.connect.hhs.gov/ORI

## Follow Us

@HHS_ORI