

The U.S. Office of Research Integrity

FY 2020 Annual Report



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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



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



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.

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

E-Blasts

18,644
Subscribers

4
Distribution Lists

15
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.

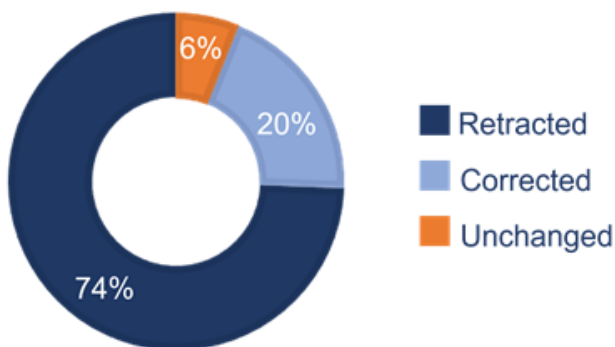
This work identified a gap in available resources related to detrimental research practices and a need for new resources (e.g., scenarios, case studies, role playing, video clips, and interactive videos) to cover these areas. This work also highlighted the need to optimize existing resources (scenarios, 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

Correcting the Scientific Record

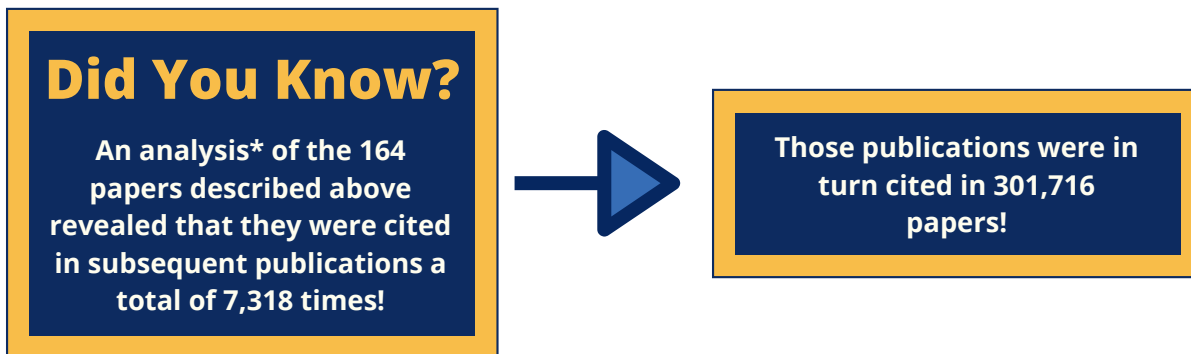
Retractions/corrections are a means of maintaining the integrity of the scientific literature and are necessary to alert the scientific community to serious problems identified within a published article. Thus, they help ensure that future research is not built upon problematic research. ORI has begun 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.

Status of Publications Found to Contain Research Misconduct (n=164) in ORI Findings of Research Misconduct (2015-2019)



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.



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.

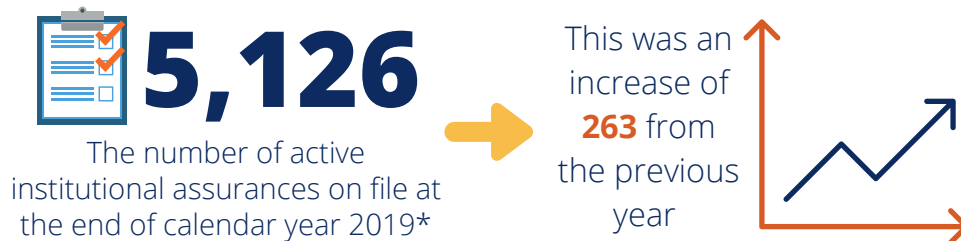
Click [here](#) for more information on ORI's FY 2020 grantees.

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](#)).



*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



15

New in FY 2020



17

Closed in FY 2020



12

Continued into FY 2021



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

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