

Report on Research Compliance Volume 17, Number 6. May 21, 2020 Leadership Jobs Finally Filled, ORI Seeks Input on Sequestering Digital Evidence

By Theresa Defino

With the recent appointment of an HHS leader as its permanent director and a former Johns Hopkins misconduct official to another key post, the HHS Office of Research Integrity (ORI) has a full complement of permanent leaders for the first time since 2016.

ORI, which provides education and enforces research misconduct regulations, is responsible for ensuring that the billions of dollars in research funded by the Public Health Service (PHS), including that supported by NIH, is free of fabrication, falsification and plagiarism. ORI has two divisions: the Division of Investigative Oversight (DIO) and the Division of Education and Integrity (DEI). The leadership level is rounded out by a deputy director.

In addition to the recent appointments, ORI has seen a slight uptick in activity of late, releasing its second misconduct finding of the year on May 11, but this pace still puts it far behind its historical output. Additionally, ORI published a request for information (RFI) in April in preparation for guidance it intends to issue within a few months.^[1]

The new appointments may bring stability to a pivotal agency that has been wracked by internal discord and personnel departures beginning nearly a decade ago, with the director and education division posts particularly difficult to keep filled. In January 2019, all four of the leadership positions were either vacant or being held by officials in acting or interim capacities.^[2]

Discord Preceded Departures

When former director Kathryn Partin assumed the job in December 2015, she inherited a spot that had been open nearly two years, following the high-profile resignation of David Wright, who cited dysfunction at HHS for the end to his two-year tenure. But Partin's management style proved controversial almost immediately, leading first to the departure of former DEI Director Zoë Hammatt in December 2016, and DIO Director Susan Garfinkel 11 months later—both reportedly pushed out by Partin.^[3]

Research misconduct investigators began to resign under Partin and closure rates also suffered. In 2016 and 2017, ORI issued seven misconduct findings each year, a low not seen in the previous 16 years and less than half the typical number in preceding years. It issued no findings from August 2016 to June 2017.

HHS took action after Garfinkel left, moving Partin in December 2017 to a “temporary” detail at the Uniformed Services University of the Health Sciences, but she never returned to ORI. Partin was ultimately appointed to an NIH intramural research integrity leadership post.^[4]

Instead, longtime HHS leader Wanda Jones stepped in as the interim ORI director. In the meantime, the deputy director that Partin hired also left, leaving Jones doing double duty for extended periods of time.

The first vacant leadership position HHS filled on a permanent basis was the deputy director job, which HHS gave

to Jones in June 2019. Next was the DIO job, which went to Alexander Runko a month later.^[5] A scientist-investigator at ORI from 2010–2016, Runko returned following a post as director of the extramural genomic program at the National Heart, Lung, and Blood Institute.

Also in July of last year, HHS named Elisabeth Handley, previously with the Centers for Medicare & Medicaid Services (CMS), interim ORI director, and in March of this year she was given the position on a permanent basis. Also in March, Karen Wehner joined ORI as DEI director from her former post as associate director of the Division of Research Integrity at the Johns Hopkins University School of Medicine, although her appointment wasn't announced until April.^[6]

New Leaders Enthusiastic About Posts

To learn more about staffing issues at ORI and gain information about what drew Handley and Wehner to ORI, RRC submitted a series of queries to HHS. Some of the emailed responses were attributed to an HHS spokesperson on behalf of ORI and others to Handley and Wehner themselves.

At CMS, Handley was the director of the Office of Human Capital and, “in the integrity arena,” had been the deputy center director and acting director of the Center for Program Integrity at CMS during a period when there was a “decrease in the time to hire and new developmental and training programs for staff,” the post about her hiring as interim director states. Handley’s previous duties include conducting “evaluation and inspections” for the Office of Inspector General and “running the National Cancer Institute’s Office of Liaison Activities,” HHS said at the time.

Handley told RRC she was “delighted” to be named to the post permanently. “Our health is our biggest asset,” she said, noting the important “link between research integrity and human health and safety.”

“Patients’ lives depend upon the results of scientific research being true, but unfortunately sometimes researchers falsify, fabricate, or plagiarize research results. Doing so threatens patient health, impedes scientific progress and wastes money,” she said. “I am passionate about making sure we protect patients’ health by reviewing institutions’ research misconduct cases, taking action against cheaters, and educating researchers about how to responsibly conduct research. The COVID-19 pandemic demonstrates how critical it is that research be done with integrity since so much is riding on the results.”

While at Johns Hopkins, Wehner’s duties included providing responsible conduct of research training. She also was the assistant research integrity official, offering “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,” ORI said in announcing her appointment.

Wehner said she applied to the DEI post to be able to “contribute more broadly to efforts aimed at ensuring the integrity and reliability of biomedical research.”

“I am looking forward to working with the DEI team, colleagues across the office, other federal partners, and stakeholders in the research community on resources, projects, and initiatives to further our common goal of promoting and ensuring research integrity,” Wehner said.

HHS: ORI ‘Moving Integrity Agenda’

RRC asked ORI to comment on the fact that all the top slots had been filled on a permanent basis, why the process took so long, and whether the lack of permanent leaders hampered the functioning of ORI, both in terms of investigations and educational events.

Addressing only the current staffing of leadership positions, the spokesperson said ORI staff collectively “bring rich experience as bench scientists who know what it is like to work in a lab, a former institutional research integrity reviewer and trainer on the responsible conduct of research who has experienced promoting research integrity in a large institution, and as executives with track records of producing key results in program integrity and science.”

The spokesperson added that, “Together, they are moving the research integrity agenda forward.”

RRC also asked about any possible impact of the pandemic, noting that few misconduct cases have been closed this year. “The pandemic is not interfering with ORI’s investigative work,” the spokesperson said. “Institutions are continuing their research and we are receiving the same level of allegations, investigation reports, and requests for technical assistance and guidance as before. ORI is continuing to follow up on institutions’ inquiries, investigations, and allegations from whistleblowers as we did before the pandemic.”

The spokesperson noted that ORI’s oversight review times vary depending on “the complexity of the research misconduct, and the number of allegations, published papers, grants, respondents, and institutions involved.”

Deadline Approaching for Sequestration RFI

However, there can also be problems with collecting evidence—as ORI itself recently recognized in the RFI. Published in the April 29 *Federal Register* under the misleading title “Findings of Research Misconduct,” the RFI does not describe a closed case, as is usually the situation with this wording.

“To better support institutions in carrying out their responsibility for maintenance and custody of research records and evidence, ORI intends to publish guidelines that will inform interested parties of best practices for sequestering evidence during a research misconduct proceeding,” the notice states. “Failing to properly sequester data can have a significant detrimental impact on the outcome of a research misconduct proceeding.”

The deadline for comments is June 15, according to the *Federal Register* notice. ORI “is working towards” issuing the guidance this summer, the HHS spokesperson said.

The RFI was “not prompted by a specific case,” but of a desire to offer institutions assistance that is current, according to the spokesperson.

“As the use of technology and laboratory record keeping evolves, ORI seeks to update the guidance, training, and technical assistance that we provide to institutions for handling allegations of research misconduct,” the spokesperson said. For example, the spokesperson noted that ORI has resources on its website under a page titled “Rapid Response for Technical Assistance,” which has links to tools that assist with forensic analysis of images.^[7]

RRC asked ORI what percentage or number of cases do not lead to a misconduct finding because of problems with evidence, digital or otherwise.

“ORI believes the proportion of cases closed without a finding specifically due to issues with sequestration is a minority of cases,” the spokesperson said. “There are several reasons why a case may not result in a finding by ORI, such as when the alleged misconduct has been found to be the result of honest error, the laboratory’s records were insufficient to determine who was responsible for the alleged misconduct or when the alleged misconduct did not involve PHS funds.”

Indiana U. Paper Offers Strategies

The agency is “interested in learning what major challenges exist in the sequestration process and approaches to overcome them. Although ORI will accept comments on physical evidence, ORI is particularly interested in best practices in the sequestering of digital evidence,” the spokesperson said. “Digital evidence presents specific challenges that may not exist with physical research records. Many of these challenges are described in the RFI, including data storage, making forensic copies, or identifying sources for digital data.”

In 2016, ORI provided a \$50,000 award to Indiana University to fund a three-day conference, “Sequestration Analysis: Collaborative Institutional Approaches & White Collar Concerns.” ORI has not issued any materials resulting from this conference.

However, Indiana University produced an 11-page report that it submitted to ORI. The paper “highlights items to consider when discussing the sequestration process using three categories: Pre-Sequestration, During Sequestration, and Post Sequestration,” and the document “is intended to be living and breathing and revised as standards, regulations and technologies change.”

For a copy of the paper, email John Baumann, Indiana University associate vice president for research compliance, at baumannj@iu.edu.

1 Findings of Research Misconduct, 85 Fed. Reg. 23,834 (April 29, 2020) , <https://bit.ly/2zOif72>.

2 Theresa Defino, “Four New Hires Will Be Needed to Lead Misconduct Oversight Agency,” *Report on Research Compliance* 16, no. 3 (March 2019), <https://bit.ly/366p7ZA>.

3 Theresa Defino, “Pivotal ORI Misconduct Investigative Chief Resigns; Both Divisions Now Lack Leaders,” *Report on Research Compliance* 14, no. 11 (November 2017), <https://bit.ly/3bFa4HD>.

4 Theresa Defino, “RRC E-Alerts: November 2018,” *Report on Research Compliance* 15, no. 11 (November 2018), <https://bit.ly/2LEkQU2>.

5 Theresa Defino, “RRC E-Alerts: July 18, 2019,” *Report on Research Compliance* 16, no. 8 (August 2019), <https://bit.ly/2LEFD9U>.

6 Theresa Defino, “In This Month’s E-News: May 2020,” *Report on Research Compliance* 17, no. 5 (May 2020), <https://bit.ly/369SzoW>.

7 “Rapid Response for Technical Assistance,” ORI, last viewed May 18, 2020, <https://bit.ly/3cJEI8o>.

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