Report on
RESEARCH COMPLIANCE

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News and Analysis for Colleges, Universities, AMCs and Other Non-Federal Entities

Contents

NIH Warns Institutions to be Vigilant Against Threats to U.S. Research From 'Foreign Entities'

NIH Director Francis Collins is urging institutions to take seriously "threats to the integrity of U.S. biomedical research" through "inappropriate influence," which could result in theft of intellectual property and acquisition of confidential study information by foreign governments and entities.

Testifying before the Senate Health, Education, Labor and Pensions (HELP) Committee on Aug. 23, Collins announced that, the day before the hearing, NIH had distributed to "representatives of more than 10,000 grantee institutions" a letter asking for their help and explaining specific "concerns."

Collins told the HELP committee that the letter, a copy of which *RRC* obtained, requests that institutions "review their records for evidence of malfeasance" in three areas of concern. However, the language in the letter itself is somewhat more passive and makes no mention of a "review" for "malfeasance," or any other new requirements or reporting—though these could certainly come in the future.

As Collins explained to the committee, the areas of concern are:

◆ "failure by some researchers at NIH-funded institutions to disclose substantial contributions of resources from other organizations, including foreign governments, which threatens to distort decisions about the appropriate use of NIH funds;

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Citing Process Issues, Researcher in Precedent-Setting 'Reckless' Case Appeals Debarment

A former investigator from Wayne State University (WSU) recently debarred by HHS for five years following a precedent-setting ruling that his misconduct was "reckless" has filed an appeal.

Christian Kreipke contends his governmentwide sanction is excessive and that he was not afforded the right to contest the debarment, according to the appeal letter his attorney provided to *RRC*. The move continues a process begun nearly a decade ago when he was first accused of fabrications.

Whether Kreipke will be successful in reversing the debarment or in receiving a lesser sanction remains to be seen. But regardless of the outcome, the recent historic ruling in his case may yet stand—namely that misconduct can be based solely on the finding that the action or actions at issue were committed "recklessly."

Secondarily, the case may also give rise to future findings of misconduct against individuals who may have perpetrated the misconduct but weren't actually proven to have done so. Further implications also flow from the complicated case, which saw an HHS administrative law judge make his own findings after essentially throwing out the arguments mounted by the HHS Office of General Counsel (OGC) on behalf of the Office of Research Integrity (ORI).

continued

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The case wound its way to HHS administrative law judge Keith Sickendick seven years after WSU itself found research misconduct in Kreipke's work, five years after the Veterans Affairs (VA) Department (where he also worked) did and three years after ORI reached the same conclusion.

In between those events, Kreipke filed and lost on procedural grounds a suit against WSU that alleged the misconduct investigation was retaliation for his contention that WSU's effort reporting system resulted in grant fraud. He won an appeal of VA's 10-year debarment for misconduct, with a judge finding that it was not shown the sanctions were made irrespective of whistleblowing complaints that Kreipke had also brought against VA.

He was fired by WSU in 2012, and in 2013, VA allowed his contract to expire and imposed the debarment, which was later overturned. However, VA has not lifted the debarment order, Kreipke and his attorney told *RRC*. He remains out of science and is engaged in "manual labor," they said.

The issue before Sickendick was ORI's 2016 proposed finding that followed WSU's. ORI determined Kreipke committed 64 instances of misconduct on the more common basis of intentional and knowing, and recommended a 10-year debarment. Kreipke appealed and was granted a de novo hearing that was conducted by Sickendick—a step no previous misconduct case has ever reached.

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As research compliance officials well know, the federal misconduct definition states that, among other requirements, the fabrication, falsification or plagiarism must have been committed intentionally, or knowingly, or recklessly to be considered misconduct. All previous federal cases have been based on the "intentionally" and "knowingly" standards, even though the use of the word "or" between the words allows for a determination to be based on any of the three alone.

In a sometimes scathing 126-page opinion, Sickendick painstakingly went through all of the allegations presented at the hearing by the OGC on ORI's behalf, concluding that "ORI did not show that Respondent intentionally or knowingly committed research misconduct in this case. However, the record shows that Respondent acted recklessly and committed research misconduct," he said, referring to Kreipke.

Five Years Is 'Remedial'

Sickendick wrote that "research misconduct may occur if one recklessly: Used materials without exercising proper care or caution and disregarded or was indifferent to the risk that the materials were false, fabricated or plagiarized." He concluded that Kreipke had acted recklessly when he "includ[ed] data, images, and other materials without validation of the accuracy of the information [which] constitutes failure to exercise proper care or caution and disregard or indifference to the risk for potential false information."

The judge chose a five-year debarment over ORI's recommended decade. "[T]he remedial purpose of an administrative action may arguably be accomplished more expediently in the case of reckless behavior than in the case of knowing or intentional behavior," he wrote.

Kreipke made his case for an appeal to the five-year debarment in an Aug. 7 letter to Andrea Brandon, an HHS debarment official. "Based on the evidence in this case I believe you will find that I have already been punitively punished for something that I had no control over," Kreipke wrote. "Beyond all of this, you and your office have apparently not followed policy in your treatment of this case and you have denied my constitutional rights of due process in delivering this decision." Kreipke told *RRC* in an email that he learned about the debarment through someone who saw it on the internet after it was published.

Shereef Akeel, Kreipke's attorney, told *RRC* "it was clear that there was no intentional wrongdoing by our client. It was also clear that the judge had no confidence at all in HHS's investigator."

The ruling, he said, also establishes that "one can be tagged with a reckless wrongdoing although they were not involved with creating the actual questioned data," which Akeel called "frightening."

Continued Akeel: "There's also a [second] due process problem here. There was a recommendation for our client to be banned for 10 years. We had to wait for nearly five years, and we actually prevailed in reducing this recommendation to five years. Still, the net result is that he will be out for 10 years for a recklessness charge—totally devastating a young scientist's promising career to combat close[d] head injuries and assist our veterans who served our country nobly."

RRC also asked Akeel what Kreipke is doing now. "Working manual labor, unfortunately," he responded. "A movie can be written about this, as all this started after he blew the whistle regarding mismanagement of federal funds."

Kreipke and his attorney were not the only ones who found the resolution of the case less than satisfying.

John Dahlberg, the former ORI deputy director who was involved in Kreipke's case from the start but was not present at the hearing, criticized the outcome of the de novo review (see story, p. 3). He was especially dismayed that the judge discounted testimony offered by ORI investigator Alex Runko, and called the implications of the ruling "troubling."

ORI: 'We Won'

In response to questions from *RRC*, an HHS spokesperson stood behind its handling of the hearing. "We believe this case was well-litigated by an experienced attorney, and we are pleased with the outcome," the spokesperson said. "ORI won the case."

The HHS spokesperson acknowledged that, in future de novo hearings, it would "provide more information to the judge on the background and experience of both fact and expert witnesses to assist the judge in weighing the witnesses' testimony."

The ruling is "thorough and careful," and ORI is "pleased with the judge's thoughtful decision and believes the research community is likely to find it useful and educational," the spokesperson said. The decision "assists us in understanding the lessons learned from this case."

It is not clear whether ORI will use the judge's ruling to begin to make findings, when justified, based on a reckless standard or against investigators who are not proven to have committed misconduct themselves.

Noting that the ruling "provides an example of reckless research misconduct and a judge's thoughts on how to define the terms," the HHS spokesperson said the decision "will be helpful to ORI in deciding how to approach future cases. Each case is unique and should not be generalized."

Link to ORI case summary, ruling:
https://tinyurl.com/y7ornrzd ✧

Former ORI Deputy: 'Reckless' Ruling Disappointing, Troubling; Impact Unclear

Before he retired in 2015 as deputy director, John Dahlberg was one of the longest serving members of the HHS Office of Research Integrity (ORI), which makes findings of misconduct in Public Health Service-funded research. In 2006, Dahlberg was named director of ORI's Division of Investigative Oversight (DIO), capping 14 years since he first began conducting research misconduct investigations. He became the deputy director of ORI in 2013.

Research misconduct findings ORI makes against investigators generally carry sanctions ranging from required supervision of several years to governmentwide debarment of up to 10 years. Until last month, findings have been made on the collective basis of three criteria that the fabrication, falsification or plagiarism was "committed intentionally, or knowingly, or recklessly." (Other specifications also apply.)

In a decision announced in July, an administrative law judge (ALJ) found Christian Kreipke, formerly with Wayne State University, guilty of 23 instances of misconduct and imposed a five-year debarment. The case is precedent-setting because the judge made misconduct findings based solely on the grounds the actions were committed recklessly, forgoing the intentional and knowing aspects of the definition.

In 2016, ORI had sought a 10-year debarment based on what it said were 64 instances of misconduct. Kreipke appealed and the case proceeded to an in-person hearing, called a de novo review. ORI announced Judge Keith Sickendick's ruling on July 31 (*RRC 8/2/18*). Kreipke has appealed the debarment.

RRC spoke to Dahlberg for a better understanding of the case and possible implications of the ruling. He said ORI had been pondering how to make a reckless-only finding, and he discussed the role of the HHS Office of General Counsel (OGC), which functions as in-house attorneys to ORI. Dahlberg offered his support for Alex Runko, the former DIO investigator who handled the case and testified during the appeal hearing, but was less than complimentary of how the HHS attorney from OGC handled the case. HHS stood behind the attorney and the outcome of the case (see story, p. 1).

Although you did not attend the hearing, you were involved in this case from the beginning and have watched it proceed to this stage with the ALJ decision. Is this the outcome you were expecting?

I was expecting that there would be a finding of misconduct. The surprising part was hearing how short the questioning was of the witnesses by the attorney for OGC at the hearing. It wasn't clear what was going to happen. And what did happen is regrettable.

What is the role of OGC in making misconduct findings?

The way this is supposed to work is that DIO conducts oversight review of institutional investigations, including additional analyses and possibly identifying additional concerns and possible new findings. DIO has a pre-decisional document called the ISR—investigational summary report. In that, the investigator for DIO puts the whole case together for DIO purposes.

DIO staff then meet together to discuss the findings proposed by the scientist/investigator and usually reach a consensus on whether the evidence warrants findings and what administrative actions seem most appropriate. These recommendations are sent to the ORI director who can concur or reject some or all recommendations. If the ORI director makes findings of research misconduct, these findings are sent to OGC for a review for legal sufficiency. This can be a lengthy process and can lead to increased emphasis on certain findings and the dropping of other findings. It can be a highly collaborative process, but that is not always the case.

And in a de novo hearing? What do you think went wrong in this case?

As judge Sickendick pointed out on multiple occasions, the hearing is a de novo process and requires that the factual findings must be established by direct testimony of witnesses where each can be cross-examined. For example, the ISR has no weight under a de novo hearing. Everything that's presented is the basis on which the findings are made, so the presentation has to be very detailed. It was clear that Sickendick was very unhappy with what happened. His excoriation of Alex in particular is regrettable. The OGC attorney didn't establish his credentials, among other issues.

Alex had prepared all the information in spreadsheets that the judge claimed weren't available to him. The attorney didn't point them out, describe them, didn't present them.

No one involved from either DIO or OGC had ever participated in such a hearing. Both OGC and ORI are lacking relevant experience in the courtroom, and it certainly showed in this case.

Do you think the ALJ was hesitant to throw out the government's whole case so he saved it based on the reckless finding?

Yes, I think that's exactly right.

How did the judge arrive at the reckless finding?

If you think of what he made findings on, it was as a first author or corresponding author, not as the perpetrator of the falsifications. If there are falsified figures and fabrications, Kreipke had responsibility for reviewing the original data and ensuring the accuracy of what was in the paper… and that's why he was found guilty. It seems reasonable to me that those are reckless acts and not knowing or intentional acts of misconduct. Reckless is more than negligence.

Why hadn't ORI, on its own, made a finding based solely on reckless criteria?

It's tricky business. DIO struggled with whether and how to invoke the recklessness standard for years. There were a number of cases in which the institution's findings were limited to the reckless standard and we were unable to make findings. For most of those cases, the respondent[s] fled to another country and we could no longer locate them.

OGC was, for a long time, unwilling to take a case to a hearing unless the intentional or knowing standard could be shown, so during my last year at ORI, we had discussion sessions at our training boot camps along with several talented outside attorneys to try to develop a sense of how to implement the reckless standard in a way that would be acceptable to the research community. At that time, institutions were starting to make findings based solely on recklessness, but ORI was reluctant to concur unless we could strengthen the findings.

What do you think of the decision?

I found the discussion on this issue by judge Sickendick helpful, and precedent-setting. The decision was rigorously argued. I had a sense that judge Sickendick was looking down the road to a likely appeal in federal court given the litigious tendencies Kreipke demonstrated prior to this hearing. I am not surprised by the efforts made by judge Sickendick to fully explain the legal framework available to him, the definitions he relied on, and the distaste expressed at the inept prosecution of the case.

There's now a ruling that establishes some sort of basis for recklessness, which is a good thing. The bad thing is it was a stronger case than that.

Did the sanctions seem appropriate based on what Sickendick found?

Yes. I think five years is a perfectly reasonable debarment. It's in excess of a standard, which is three years. Ten years would have been more appropriate for the scope of what Kreipke did.

What impact do you think this ruling will have on ORI or those accused of misconduct?

It is difficult to read the future. This finding, which did involve having well over half of the charges dismissed, nevertheless led to Kreipke being debarred for five years. It might lead to more requests for ALJ hearings.

I am hopeful that ORI and OGC can learn from this and continue to be successful in pursuing findings of research misconduct.

The apparent failures during the hearing to establish a chain of custody for the computer hard drives, and to explain how EnCase, software used to forensically examine digital media such as hard drives, works clearly played a

major role in the judge's determination that much of the evidence was of little probative value. The lack of acceptance of much of the evidence is very disappointing to DIO, and ought to be a wake-up call to OGC concerning the effort needed to prepare a de novo case acceptable to an ALJ.

Does the ruling mean that someone can be held accountable for misconduct in other collaborators' work?

I think so, and that's a little troubling. Recent rulings, including this one, make it clear that the first and corresponding authors have more overall responsibility, in a legal sense, than other co-authors for the contents of their papers. Even if such an accused investigator did not actually falsify or fabricate a figure, graph, or other data, it was reckless to include such material in a manuscript.

A lot of research now is international, multidisciplinary, etc. There may be situations in which the [principal investigator] or the first author is in another discipline and is not sufficiently expert in all the areas that are described or discussed in the paper. It may become necessary to obtain some expert opinion prior to publishing such a paper. But right now, I think it would be really hard to justify making findings of misconduct in such a situation.

Are there any lessons here for research integrity officials (RIOs) at institutions?

For difficult litigious respondents, it is essential that RIOs carefully document everything in the event that ORI ends up having to handle an appeal before an ALJ. Many institutions do not rely adequately on the advice of [their] general counsel in conducting interviews, or seeking advice on procedures, which can make it much more difficult for ORI to develop a legally sufficient case. ✧

Talladega to Pay $170K: Future NSF Proposals to Trigger Compliance Plan

Talladega College in Alabama is now among the few higher education institutions whose problems managing federal research awards have led to a financial settlement with the Department of Justice (DOJ) over allegations they violated the False Claims Act (FCA).

In March, Talladega agreed to pay a total of $169,647.41, of which $129,747.41 is restitution, to resolve allegations that it misspent part of a $2.5 million grant it received from the National Science Foundation (NSF) in 2008. At issue are what OIG said were "inappropriate charges, duplicate charges, and expenses for which the college had insufficient documentation."

Talladega also agreed to implement an extensive five-year "compliance program"—but this only comes into effect if it applies for or is awarded NSF funding within the next three years.

RRC learned that Talladega was the subject of the settlement and received a copy of the compliance plan by submitting a Freedom of Information Act (FOIA) request to the NSF Office of Inspector General (OIG).

Talladega's payment and compliance plan mark at least the second time an NSF awardee has agreed to an FCA settlement in the last two years. In 2017, Jackson State University (JSU) in Mississippi agreed to pay $1,170,120.37 and to implement a compliance program (*RRC 4/17, p. 1*).

The newest settlement concerns Talladega's handling of a $2.503 million award given in August 2008 for a program titled "Broadening Participation in Science and Mathematics: The Next Level." Problems with the grant, which expired in 2013, purportedly began two years into the award.

Closeout Memo Contains Few Details

Hints about the Talladega agreement were included in OIG's most recent semi-annual report to Congress, which was issued in late May. The report outlines OIG actions for the previous six months ending March 31. These reports include findings from audits and misconduct investigations (*RRC 7/18, p. 1*).

"A college agreed to settle allegations that it failed to maintain adequate records to support expenditures under an NSF award. Our investigation identified duplicate charges for equipment, an electronics purchase supported by an online shopping cart printout but never actually purchased, and lack of documentation for stipend payments to students. The settlement with DOJ required payment of more than $160,000 and required the college to implement a 5-year compliance plan to ensure proper oversight of NSF awards in the future," states the report.

Information about the genesis of the investigation that led to the settlement can be found in the closeout memorandum issued by OIG, which, like the semiannual report, does not identify the college. OIG referred *RRC* to a memorandum it said was about Talladega.

According to the memorandum, OIG received an "allegation of misuse of NSF funds by staff at a college." To conduct its investigation, OIG "interviewed" the principal investigator, "co-PI and other staff responsible for administering the NSF award. We obtained and reviewed relevant documents from the college."

OIG said the "interviews and review of the records" led it to identify the charges it questioned.

"[W]e identified inappropriate charges, duplicate charges, and expenses for which the college had insufficient documentation. We referred the matter to the U.S. Attorney's Office for possible civil action. The U.S. Attorney's Office and the college executed a civil settlement agreement," the closeout memorandum states.

The settlement document states:

> "The United States contends that it has certain civil claims against Talladega College arising from the management of the Grant. During the period of February 2010 to July 2013, Talladega College submitted claims and/or expended funds under the Grant and in so doing, expressly certified that every claim and/or expenditure was supported, allocable, and allowable and that Talladega College would maintain adequate records to support these claims and expenditures. An investigation into the administration of the Grant by the NSF Office of Inspector General identified expenditures of Grant funds that were not supported by adequate documentation."

The agreement was signed by both DOJ and the college to avoid "the delay, uncertainty, inconvenience, and expense of protracted litigation of the" claims outlined in the settlement.

RRC submitted a series of questions about the grant and settlement to Talladega, including whether any investigators or others faced sanctions as a result. No questions were answered. Instead, attorney Chad Woodruff, outside counsel for Talladega, emailed *RRC* a short statement that repeated the basic facts of the case. He said Talladega "was unable to provide adequate documentation based on obligations placed on the College as a grant recipient" and had "acknowledged the inability to do so."

Woodruff added that the agreement "further provided the College to adopt a compliance agreement to ensure compliance with laws, regulations and conditions concerning NSF awards. To date, the College is in compliance with the terms of the settlement agreement."

Final Payment Due in March

However, as noted earlier, the compliance program (described in the compliance agreement) is not required until Talladega submits or receives NSF funding.

The terms of the agreement call for Talladega to spread the $170,000 out over five payments of unequal amounts during a 12-month period that began on March 31 with $56,549.14. "The final payment will be composed of the remaining of $47,713.33 of the Settlement Amount and any outstanding interest accrued on the $169,647.41 Settlement Amount at a rate of 2.125 percent compounded annually, which is estimated as $3,605.01," the settlement states.

It is likely the payments will go to the U.S. Treasury, versus back to NSF, even though restitution is included. That's because the award appears to be fully expended. Typically, unspent funds are returned to an agency when improprieties are identified.

Based on a review of NSF's awards database, Talladega currently has no NSF awards. Whether the college has other NSF funds is among the questions posed by *RRC* that Talladega did not answer.

However, should Talladega anticipate being a recipient, it must implement the compliance program outlined in the settlement. The program "will commence upon submission of a proposal to NSF, being identified in an NSF proposal as a possible recipient of NSF funds, or upon receipt of NSF funds on any other basis (the Effective Date)," according to the settlement.

Once initiated, Talladega would be required to stick with the program until "NSF OIG receives and approves the fifth and final annual report."

Plan Requires Risk Assessment

The focus of the compliance program is to ensure Talladega's adherence to "all laws, regulations, terms, and conditions applicable to [NSF] awards, as now or hereafter amended, and to demonstrate Talladega College's commitment to the prevention of fraud, false statements, and misuse of funds related to NSF awards to Talladega College. The Compliance Program shall be based upon an assessment of the risk of such unlawful activities, have adequate financial and human resources, and be maintained to ensure that Talladega College and each of its relevant employees maintain the integrity required of a recipient of NSF funding."

Talladega would be required to identify a compliance officer and compliance committee and develop "policies regarding its commitment to ensure compliance with all laws, regulations, terms, and conditions related to the receipt of NSF awards."

It also would have to engage a "qualified external audit firm to conduct, on an annual basis, a comprehensive, independent audit of Talladega College's compliance with this agreement as well as all applicable laws, regulations, terms, and conditions regarding the use and expenditure of NSF award funds."

FCA settlements are not uncommon, but they are not usually accompanied by a separate compliance agreement. Such agreements are not typically released to the public.

In contrast to Talladega's agreement, JSU's compliance plan went into effect immediately and was not contingent on a new application for funding, likely because it had other NSF awards still in its portfolio. *RRC* also received a copy of the settlement through a FOIA request (*RRC 4/17, p. 1*).

The JSU settlement stemmed from an audit that OIG conducted in 2012.

Dated Feb. 5, 2013, the JSU audit reviewed $19.4 million in costs claimed on 31 NSF awards made from 2006 to 2011; no total was given for the awards.

Auditors questioned $943,475 among various groups of expenses, although Inspector General Allison Lerner said that amount was lowered to $625,000, which contrasts with the settlement amount of $1.17 million.

NSF OIG conducted an audit in 2012, identifying "salary charges to NSF grants that either lacked supporting documentation or had insufficient documentation to support the charges," as Lerner explained at a meeting of the National Science Board last year (*RRC 4/17, p. 3*).

Lerner said "a subsequent investigation found that in response to those preliminary findings, Jackson State employees altered labor effort reports using whiteout and fabricated entirely new documents. For some reports they made photocopies of old reports and changed dates, all to support effort that wasn't ultimately supportable."

According to the audit, which was publicly released, questioned costs included "fee charges, unallocable equipment costs and excess indirect costs," as well as "payroll charges and vendor purchases." The audit resolution report was not issued.

As with Talladega, the settlement required JSU to hire a compliance officer, establish a compliance committee, write policies and procedures, and conduct annual external compliance audits in accordance with the agreement.

In a statement to *RRC*, JSU denied wrongdoing and said that it had implemented a corrective action plan in 2013, prior to the settlement.

Another recent FCA settlement involved Columbia University, which paid $9.5 million to resolve allegations it claimed a higher on-campus indirect cost rate on more than 400 NIH grants for psychiatry and neuroscience research. The research was conducted in rent-free state-owned facilities (*RRC 8/16, p. 1*). ✧

Draft Guidance on New Common Rule Attracts Strong Responses From a Few

"We desperately need new forest management practices."

So begins a comment posted on regulations.gov in response to proposed guidance on scholarly activities deemed not to be research under the revised Common Rule, one of three recently released by the Office for Human Research Protections (OHRP). Of the 16 comments on the three, 11 are related to forest management practices, apparently assigned to the wrong document folder.

In addition to the scholarly activities draft guidance, OHRP addressed "When Continuing Review Is Not Required During the 6-Month Delay Period of July 19, 2018 through January 20, 2019: 2018 Requirements" and "Elimination of Institutional Review Board (IRB) Review of Research Applications and Proposals: 2018 Requirements." These are the three provisions in the rule that organizations are permitted to implement before the January general compliance date (*RRC 8/18, p. 1*).

The process of revising the Common Rule governing human research has taken seven years, with delays due in part to the required analysis of the thousands of comments OHRP received when it issued various iterations of the regulation. When the final rule was published in 2017 in PDF form, 459 of 543 pages were devoted to responses to comments (*RRC 2/17, p. 1*).

Journalist: Draft Guidance 'Confusing'

It may be welcome news to the agency that the three draft guidance documents OHRP issued in July have attracted so few comments, which should speed review and issuance of final documents.

The scholarly activities guidance drew three comments—one requested that it be withdrawn in its entirety. Two commenters on this draft guidance focused their attention on just the scholarly or just the journalistic provisions.

In his comments, Charles Seife, a journalist and professor of journalism at New York University, rejected the draft guidance as "confusing" and said it would "likely lead to the government imposing unconstitutional prior restraints upon journalists within academia." If adopted as drafted, the guidance would "do more harm than good," said Seife.

He noted that, although journalism "is specifically singled out as one of the categories that would often be exempt from these regulations," the draft guidance characterizes as exempt "scholarly and journalistic activities…conducted in various fields that focus directly on the specific individuals about whom information is collected and used, without extending that information to draw generalizations about other individuals or groups."

Much of journalism could be seen as "extending" and making conclusions that are not confined to an individual subject of reporting, said Seife.

For example, "the journalistic profile, a form that most directly can focus on a single individual, typically uses that individual as a means for understanding something beyond that individual: to help the public understand the pressures on and motivations of group[s] of people he/she belongs to" and "to get a better sense of a broader happening that the person is part of," Seife commented.

The draft guidance also poses a problem for oral history, as "academics" in this field "are also going to have difficulty calving off activities that fail to perform any generalization," he wrote.

But Seife isn't recommending revisions in the draft document. "It is better to leave the fine points of the distinction between regulated and unregulated activities unsaid," and simply withdraw the proposed guidance, he said.

In their comments, Christine Pierre and David Vulcano, president and chair of the Regulatory Affairs Committee, respectively, for the Society for Clinical Research Sites (SCRS), said OHRP needs to better differentiate what the Common Rule means by a scholarly activity from the scholarly activity required of medical residents by the Accreditation Council for Graduate Medical Education.

They suggested that, without clarification, "many research projects that should go further down the decision tree (i.e. for an exempt determination or require IRB oversight) to be discounted because it is done for purposes of meeting the 'Scholarly Activity' requirement" of the council.

"We ask that it be more clearly stated that it is *the activities* of the research, not *the purpose*, that are evaluated to make this exclusion determination," Pierre and Vulcano wrote.

Medical Case Reports Addressed

According to the draft guidance, "a medical case report could fall within this [exempt] category, if the point of the report were to describe an unusual and interesting case-specific medical complaint and its treatment," they said.

This mention is useful, the SCRS officials wrote, but they requested "elaboration" to indicate that, when the guidance is otherwise followed, "the exclusion [is] maintained regardless of the number of cases."

"It is our fear that, without specifically stating this in the guidance, these institutions," their comment continues, "and those who seek guidance from these institutions, will continue to set such arbitrary standards."

Perhaps the biggest reason the documents haven't drawn more comments is that they're fairly benign and don't get into the meat of the biggest compliance challenges facing institutions when the revised rule goes into effect Jan. 21.

In fact, organizations such as the Council on Governmental Relations (COGR), the Association of American Medical Colleges (AAMC) and the Association of American Universities (AAU)—reliable commenters all—have not submitted feedback on the draft guidances.

"The general consensus was that the guidance adhered fairly closely to the regulations and that there wasn't a lot of new information. We, therefore, had no questions or comments to submit," Lisa Nichols, COGR director of research and regulatory reform, told *RRC*.

But guidance on some provisions is definitely needed, and wanted. In May, COGR, AAMC, AAU and the Association of Public and Land-grant Universities commented that they supported moving the general compliance date of the revised rule from July to January "with the assumption that the delay period will in fact result in the timely availability of promised guidance."

The lack of guidance "this many months after the revised Common Rule was issued as a final rule has prevented institutions from making many policy and IT changes necessary to implement the rule," they said at the time.

OHRP should prioritize issuing guidance that addresses "the inclusion of key information in informed consent documents, posting of informed consent documents on a public website, benign behavioral interventions, and training resources," the organizations said.

Guidance Sought on Different Topics

The Secretary's Advisory Committee on Human Research Protections (SACHRP) has been working on guidance related to the revised Common Rule for many months and approved a series of recommendations for OHRP.

SACHRP itself does not issue guidance; this comes directly from OHRP, and it typically takes months for the committee's work to be reflected in output by the agency—if it chooses to act.

In the past 10 years or so, OHRP has not formalized dozens of SACHRP's recommendations, and they remain unofficial. Topics include minimal risk and informed consent, internet research, return of research results to subjects, and regulatory issues in cluster randomized trials.

The May comment letter from the organizations urged HHS to "leverage SACHRP's recommendations and resources to assist with the swift vetting and publication of guidance."

Regarding the revised Common Rule, SACHRP in 2017 completed a list of examples of research that, if deemed no more than minimal risk to subjects, could be considered for expedited review (see https://tinyurl.com/yad59gh5). SACHRP also finalized recommendations on broad consent and benign behavioral interventions.

At its upcoming meeting in October, SACHRP is expected to continue, and likely approve, its recommendations for guidance on the key information requirements in the revised Common Rule.

Link to draft guidance, comments:
https://tinyurl.com/y7of4yh7 ✧

NIH Warns Against 'Foreign' Influence

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◆ diversion of intellectual property in grant applications or produced by NIH-supported biomedical research to other entities, including other countries;

◆ failure by some peer reviewers to keep information on grant applications confidential, including in some instances disclosure to foreign entities, or other attempts to influence funding decisions."

In the letter, Collins told awardees that NIH officials "expect you to work with your faculty and with your administrative staff to make sure that…all applications and progress reports include all sources of research support, financial interests, and relevant affiliations" per NIH's policy.

"NIH is aware that some foreign entities have mounted systematic programs to influence NIH researchers and peer reviewers and to take advantage of the long tradition of trust, fairness, and excellence of NIH supported research activities," Collins wrote in the letter.

Collins added, "This kind of inappropriate influence is not limited to biomedical research; it has been a significant issue for defense and energy research for some time."

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ORI Director Still 'Detailed'; Division Director Jobs Posted

Although Kathryn Partin, director of the HHS Office of Research Integrity (ORI), is still working at an entirely different part of the government, HHS is making plans to hire directors of the two divisions that ostensibly report to Partin.

The HHS Assistant Secretary for Health (OASH) is hiring both the director of the Division of Investigative Oversight (DIO) and director of the Division of Education and Integrity (DEI).

But interested individuals had better move quickly: the positions were posted on usajobs.gov on Aug. 20, and the window for applications will close just 11 days later, on Aug. 31.

ORI is the only federal agency responsible for making findings of research misconduct that may occur in the billions of dollars of studies funded by NIH and other Public Health Service (PHS) agencies. Misconduct is defined as fabrication, falsification or plagiarism.

DIO investigates cases while DEI develops and sponsors training programs and maintains the assurances that organizations seeking PHS funding must submit.

In the recent past, ORI has suffered a number of vacancies and has been hobbled by a protracted hiring processes.

Partin, who joined ORI in December 2015, was transferred eight months ago to a position with the Uniformed Services University of Health Sciences (USUHS), part of the Department of Defense. At the time, the move was described as a three-month detail, but it was believed to have been precipitated by the resignation a few weeks earlier of DIO Director Susan Garfinkel (*RRC 12/17, p. 1*).

Garfinkel had been with ORI for 15 years and was seen as the glue that had held ORI together through years of staff turnover.

Former and current ORI staff members said Partin had pushed out both Zoe Hammatt, former director of DEI, and Garfinkel (*RRC 11/17, p. 1*).

Initially, Partin's arrival was welcomed as the agency had been without a director for more than two years, following the resignation of former director David Wright, who quit while blasting the OASH bureaucracy (*RRC 4/14, p. 1*).

But concerns arose within months. Approximately half of investigators also quit ORI while Partin was there, amid accusations that she didn't understand the misconduct regulations, was a "bully" and had created a toxic atmosphere (*RRC 10/16, p. 1*).

The new posting for the DEI director marks the second recent time OASH has listed the opening. A previous posting in October did not result in a candidate being hired.

An HHS spokeswoman confirmed Partin is still at the USUHS. Longtime OASH leader Wanda Jones remains the acting ORI director.

Link to DIO director job listing:
https://tinyurl.com/ybjbdj2w

Link to DEI director job listing:
https://tinyurl.com/yam7ja9u

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The letter also notifies institutions that, "in the weeks and months ahead you may be hearing from our Office of Extramural Research (OER) regarding grant administration or oversight questions or requests about specific applications, progress reports, policies, or personnel from, or affecting, your institution. We also expect and encourage your institution to notify us immediately upon identifying new information that affects your institution's applications or awards."

It closes by suggesting that institutions "reach out to an FBI field office to schedule a briefing on this matter," and thanking them "in advance for working with [OER] on this serious matter."

Although Collins did not mention any specific incidents that had sparked these developments, *Stat News* reported that NIH is "investigating roughly a half-dozen research institutions based on suspicions that researchers with federal grants failed to disclose significant financial contributions from foreign governments."

The news was attributed to Collins; he was not quoted directly.

Two days before the hearing, the Association of American Universities (AAU) alerted member presidents to the issue and gave word of Collins' upcoming testimony, which was part of a hearing called "Prioritizing Cures: Science and Stewardship at the National Institutes of Health."

"New information and concerns have come to light involving NIH research and the potential for breaches in the security, integrity, and confidentiality of grant information. We understand that some NIH-supported principal investigators (PIs) have been simultaneously receiving funding from foreign universities, labs, or other sources (e.g. foreign talent programs) without disclosing the foreign relationship and funding to their parent U.S. institutions," the AAU memorandum states. "Additionally, in some instances the PIs have also shared early results from the NIH-supported research with their foreign affiliates. We understand there may have also been specific breaches in the confidentiality of the NIH grant review process."

New Working Group Created

At the hearing, Collins announced the creation of the Foreign Influences on Research Integrity working group, which will be under NIH's Advisory Committee to the Director (ACD). The eight-member working group will include the presidents of Ohio State University, the University of Maryland, and Stony Brook University, among others.

The working group's task, according to Collins, will be to identify robust methods to:

- "Improve accurate reporting of all sources of research, support, financial interest and affiliations";
- "Mitigate the risk to intellectual property security";
- "Explore additional steps to protect the integrity of peer review"; and
- "Carry out [such] actions in a way that reflects the long tradition of partnership between NIH and grantee institutions that emphasizes the compelling value of ongoing honorable participation by foreign nationals in the American scientific enterprise."

In addition to working with "other government agencies and the broader biomedical research community, including NIH-funded institutions," NIH is joining with "U.S. university professional organizations to identify steps that can help mitigate these unacceptable breaches of trust and confidentiality that undermine the integrity of U.S. biomedical research," Collins testified.

America's "leadership position is made possible because the overwhelming majority of researchers participating on NIH grants, whether U.S. or foreign-born, are honest, hard-working contributors to the advancement of knowledge that benefits us all," Collins concluded. "We must move effectively to root out examples where our system is being exploited, but make sure to preserve the vibrancy of the diverse workforce that has played a major role in the American biomedical research success story."

At the hearing, Collins did not say when the working group might deliver a report or make recommendations, and it was not listed on the webpage for ACD working groups as of *RRC*'s deadline.

AAU told its presidents that it "will continue to closely monitor these new developments as part of our ongoing efforts to work with the federal government on security threats related to the conduct and outcomes of federally-funded research. We are working diligently with the FBI, Office of the Director of National Intelligence, Defense Security Services, and other federal security and science agencies to safeguard scientific information and intellectual property while preserving the openness and free flow of fundamental scientific information vital to scientific advancement."

NIH posted a version of Collins' testimony, titled "Statement on Protecting the Integrity of U.S. Biomedical Research."

Link to hearing: https://tinyurl.com/y8xqn9ho

Link to statement: https://tinyurl.com/yaft8ehe ✧

In This Month's E-News

The following are summaries of news transmitted to RRC *subscribers this month in email issues, the date of which is indicated in parentheses following each item. Weekly email and monthly print issues of* RRC *are archived on your subscriber-only website. Please call 888.580.8373 or email service@hcca-info.org if you require a password to access* RRC*'s subscriber-only website or are not receiving weekly email issues of the newsletter.*

◆ **"Effective immediately," investigators conducting human gene transfer protocols will no longer be required to register such trials,** seek approval from NIH's Recombinant DNA Advisory Committee, or submit previously mandatory reports, NIH and the Food and Drug Administration (FDA) announced Aug. 16. NIH has proposed a new oversight framework, which is open for comment until Oct. 16. "We hope this interim step will ease some of the burden for research that already falls under FDA oversight as NIH considers the proposed changes outlined in the *Federal Register*," Carrie Wolinetz, NIH deputy director for science policy, explained in a blog post. "These trials remain subject to FDA and other clinical trial regulations, and only after FDA, [institutional biosafety committee] and other relevant approvals are in place can these protocols proceed." In addition to the blog post and *Federal Register* notice, the announcement was accompanied by a statement from NIH Director Francis Collins, and an opinion article by Collins and FDA Commissioner Scott Gottlieb published in *The New England Journal of Medicine*. *(8/23/18)*

◆ **The HHS Office for Human Research Protections is "currently reviewing both studies and their impact on the community,"** an OHRP official recently wrote to the watchdog organization Public Citizen. OHRP was responding to Public Citizen's 14-page letter outlining concerns about now-suspended research involving ketamine use by the police on "agitated" individuals in emergency situations. After an investigation by the *Star Tribune*, an ongoing ketamine study was shuttered by Hennepin County Medical Center in Minneapolis; an earlier one it also sponsored concluded in 2016. The medical center's institutional review board deemed the studies minimal risk and waived informed consent—an "incorrect" determination, according to Public Citizen, which alleged the trials violated other OHRP and FDA regulations. *(8/23/18)*

◆ **The HHS Centers for Medicare & Medicaid Services should "take a number of practical steps to improve the accuracy, precision, and consistency of the data to better help consumers use the information" contained in CMS's Open Payments program, a new review shows.** Issued on Aug. 8 by the agency's Office of Inspector General (OIG), the review encompassed certain payments and "transfers of value" between drug manufacturers and teaching hospitals and physicians that occurred in 2015, the first year of the program. OIG found that, overall, less than 1% of 11.9 million records posted on the Open Payments website for that year "were missing elements, or were inaccurate or inconsistent." CMS agreed with OIG's recommendations, which include that it work to "ensure that records contain all required data" and "strengthen validation rules and revise data-element definitions so that actual drug and device names must be reported." *(8/16/18)*

◆ **In a request for information posted Aug. 10, NIH is asking "stakeholders throughout the scientific research community and the general public"** to help it figure out "how best to implement the NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information for prospective basic science studies involving human participants." NIH is seeking "examples of [these studies] that pose the greatest challenges in meeting the registration and results information submission requirements at ClinicalTrials.gov, including specific reasons for these challenges (e.g., specific data elements)." It is also asking for suggestions for alternatives to NIH's reporting standards that "would fulfill the aims described in the NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information." *(8/16/18)*

◆ **OHRP has posted guidance documents developed by European Union countries** regarding compliance with the EU's General Data Protection Regulation (GDPR). "For each country, the compilation also provides the links to any general GDPR guidances, as well as specific guidances on the topics of Research, Legal Basis, Consent, and International Data Transfer," OHRP announced in an email message. *(8/9/18)*

◆ **A recently issued memorandum spelling out the Trump administration's fiscal year 2020 "research and development (R&D) budget priorities"** contains a section on "partnering with industry and academia," and does not mention

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that funding should be based on "sound science," which was part of the FY 2019 document. Agencies use the memo as they "formulate" their "budget submissions," and it "details priority practices to effectively leverage R&D resources, including R&D workforce and infrastructure," the memo explains. The Association of American Universities drew attention to the changes in the memo, issued by the Office of Management and Budget. *(8/9/18)*

◆ **Federal agencies have done little, at least publicly, to alleviate regulatory burdens on research institutions, despite "an administration that has eagerly expressed intent to reduce regulations and associated costs,"** wrote Lisa Nichols and David Wynes in the July 20 issue of *Science*. Nichols is the director of research and regulatory reform for the Council on Governmental Relations, while Wynes is vice president for research administration at Emory University. They noted that it has been more than 18 months since enactment of the 21st Century Cures Act and the American Innovation and Competitiveness Act, which both contain provisions intended to "increase the efficiency of the federal investment in research and development and to reduce administrative burden on federally funded scientists." Yet, there is little evidence of progress implementing these provisions, and the research community is not adequately being consulted or participating in the efforts, Nichols and Wynes argued. *(8/2/18)*

◆ **Responding to congressional direction and backlash from investigators and institutions, NIH will delay until Sept. 25, 2019, "enforcement of registration and reporting policies for prospective basic science studies involving human participants,"** the agency announced in a notice on July 20. The delay is not applicable to studies "for which there are specific applications towards products or processes in mind, such as phase 0 or phase 1 studies of candidate interventions," it said. NIH adopted an expanded clinical or human subjects research trials policy effective Jan. 25 that calls for new application forms, an increase in elements to be reported on ClinicalTrials.gov, specialized training of investigators and other requirements (*RRC 10/16, p. 1*). When NIH offered examples of the types of trials that had to comply, complaints arose that basic research as well as social science and behavioral studies were being included inappropriately (*RRC 3/18, p. 1*). *(7/26/18)*

◆ **Alba Chavez-Dozal, a former post-doctoral researcher who held an unpaid appointment at the Veterans Affairs Health Care System in Albuquerque, New Mexico, has been banned from conducting VA research for four years** following a misconduct finding. According to an announcement in the July 24 *Federal Register*, Chavez-Dozal committed more than a half-dozen instances of research misconduct, including presenting fabricated data "at two lab meetings," fabricating a Southern blot image, and falsifying research results in published papers. Three papers have been retracted, according to the finding by the VA Office of Research Oversight. The announcement does not say whether Chavez-Dozal agreed to the ban or if it was imposed on her. The finding is rare for VA, and carries no other sanctions besides the four-year research ban. In contrast, both the National Science Foundation (NSF), as recommended by its Office of Inspector General (OIG), and the HHS Office of Research Integrity (ORI) annually make a dozen or more findings of fabrication, falsification and plagiarism. Sanctions in these cases typically include a prohibition against serving as an advisor to federal agencies, as well as debarment or supervision. Unlike ORI and VA, NSF does not reveal the name of investigators in misconduct cases. *(7/26/18)*

◆ **NSF has allowed all but $218,349 out of a total of $2,710,238 in costs claimed by the University of Michigan and questioned in a 2016 OIG audit,** according to one of three resolutions recently posted on its website. The period covered in the audit was from Oct. 1, 2011, to Sept. 30, 2014. As in many previous resolutions, NSF allowed salaries that OIG said exceeded allowable limits (*RRC 1/17, p. 8*). In this case, it allowed $2,242,477 for salaries. NSF disallowed $135,884 it said the university spent after the "expiration of the appropriation" and $33,355 for equipment. Salaries were not the issue in an audit of University of California, San Diego. The 2017 audit questioned $283,801 in costs claimed from April 1, 2012, to March 31, 2015 (*RRC 4/6/17*). Of this amount, NSF disallowed $187,089 in costs, the majority of which were claimed for equipment, materials and supplies. NSF allowed $96,712 for items in this same category, and for travel. *(7/26/18)*