Report on
RESEARCH COMPLIANCE

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

Contents

Taking Cue from Its Board, NSF Offers No Changes in RCR Mandate Despite Critiques

In the face of arguably unfavorable reviews by both the agency's Office of Inspector General (OIG) and academic researchers, the National Science Foundation (NSF) is allowing universities and other recipients of its funding to carry on with their own choice of training on responsible conduct of research (RCR)—at least for now.

That means institutions don't need to add an in-person component to online-only RCR training nor extend it beyond students to include principal investigators (PIs), two of the primary recommendations and "best practices" to emerge from both the OIG's review and the independent study. Regarding the mode of training, NIH, in contrast to OIG, does not allow awardees to offer online-only RCR programs under its training mandate. An author of the study told *RRC* NSF passed up a chance to hold institutions accountable and provide the push they need to improve education in the ethics of conducting research.

NSF's RCR training requirement has been in effect since 2010. The 2007 America Creating Opportunities to Meaningfully Promote Excellence in Technology, Education, and Science (COMPETES) Act required that the authorized organizational representative from any NSF funding applicant "certify that the institution has a plan to provide appropriate training and oversight in the responsible and ethical conduct of research to undergraduates, graduate students, and postdoctoral researchers who will be supported by NSF to conduct research."

Applicants may provide a copy of the RCR plan to NSF upon request; otherwise, submitting one is not required.

On Aug. 17, NSF Director France Cordova issued an "Important Notice #140," titled "Training in Responsible Conduct of Research—A Reminder of the NSF Requirement."

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'The Key to Not Getting Sued' and Other Tales from a Foremost Misconduct Attorney

Sometimes they weep. They curse. They can't pay. They fear for their futures. The wailing and woe-ing is all in a day's work when you're an attorney defending individuals accused of committing research misconduct or other misdeeds.

Clients who hire Paul Thaler, managing partner in the Washington, D.C.-office of Cohen Seglias Pallas Greenhall & Furman PC, get someone with 25 years' experience in ensuring universities "honor" the process that could lead to a finding or exoneration. For the hundreds of accused investigators he has represented, there's a lot at stake.

But the same is true for universities and other institutions that have to, first, try to prevent misconduct and, second, manage investigations into accusations of wrong-doing. They, too, don't want the adverse publicity of a "bad scientist" or a lawsuit for how they responded to allegations.

continued

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Speaking at the recent Quest for Excellence research integrity conference at George Washington University, Thaler provided rare insights into the views of accused scientists and the role of an attorney in a misconduct proceeding. His goal is to achieve as "pristine" a process as possible, "and then hopefully have a resolution that everyone can live with," said Thaler, who also gave an interview to *RRC* after the meeting.

"I think [research misconduct officials] are savvy enough to understand that many scientists are represented, but my experience is it is a smaller segment that fully appreciate what the scientist is going through emotionally" and otherwise, Thaler told *RRC*.

Mark Barnes, a partner in the Boston office of Ropes & Gray LLP, spoke during the same session as Thaler. Most of Barnes' statements concerned how institutions may make a finding that an investigator's actions were reckless—a topic that will be addressed in a subsequent issue of *RRC*.

"We know that it is possible that there will be people who will be falsely accused," Barnes said, "and so…lawyers like Paul perform a valuable service, of keeping the whole system honest."

Barnes frequently assists universities in research integrity issues but has also represented physicians accused of violating practice standards, he said.

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Thaler decided to specialize in representing accused investigators after winning some early cases, including one he's never forgotten, perhaps because of the sheer terror the researcher expressed to him.

"The very first three words—I'm going to use a curse word—the very first three words this client said to me, in broken English, were, 'I scared shitless.' He hadn't even said hello. He was just so afraid of what he was up against," Thaler recalled. At the end of what he called "a long story," the man is "still a professor conducting research."

The decision to hire him isn't an easy one, said Thaler. "Very rarely are these guys wealthy."

"I've had so many conversations where everyone's crying because they can't pay me," Thaler told conference attendees. "They've run out of money, they don't have a job and so sometimes I just have to wait until they get employed again or [until] they can pay us." Thaler may also have to reduce his bill "by a great amount. It's tough and it's not something anyone wants to go through."

Thaler declined to share his hourly rate with *RRC*, which he said is "hundreds of dollars" per hour and less than "four figures." Thaler said he also assigns work to lower-paid associates whenever possible to keep costs down for his clients.

While he referred during his presentation to investigators and researchers he represents as "guys," Thaler told *RRC* he uses the word broadly and that his cases include women in numbers equal to the percentage of female researchers working today.

Attorney: Litigation Not Inevitable

Thaler acknowledged he isn't always greeted warmly by universities. Officials who don't know him may immediately assume his presence means the researcher is guilty. Their second reaction may be "they're going to sue us." But that is a last resort, Thaler said.

He urged universities to have greater empathy for accused researchers and to not "begrudge them protecting their own careers or reputations."

This sensitivity is one of the keys to not being sued. "If there's a perception of an erroneous outcome by a professor," Thaler warned, "then he's likely to continue to seek some sort of remedy. And if he's treated fairly, is my point, and you adhere to your policies and procedures, then you're likely to have a better process yourself."

Thaler referred to a quote from Justice Oliver Wendell Holmes, who said, "even a dog can tell the difference between being stumbled over and being kicked."

He drew a contrast from the classic role of a litigator. "So much of what I do is trying to act especially as a referee," versus as "an advocate in litigation."

Misconduct investigations are "a different animal. I think what happens many times and why you might have had bad experiences with counsel who come in as litigators is that they don't understand the nuances of this type of process and attack it as if it was litigation right off the bat," Thaler told the audience. "Very early on, I realized that it doesn't make much sense for me to treat the [inquiry or investigative] committee as the opposing side. The committee is actually my judge and jury and when I litigate, I would never attack the judge or jury the way that some litigators might feel that they have to when they advocate in a misconduct proceeding." Such attorneys, he said, "don't have any idea of how things are supposed to work."

Thaler said he views his job "mostly as helping to ensure the process, as set forth in the [regulations] and the policies and procedures of universities are adhered to."

As an employer, a university has a "duty to maintain its reputation, maintain the integrity of the university," Thaler said. It also "has a responsibility to students to provide dependable, quality professors, to make sure that the people who are educating the students are good scientists."

He asked the attendees to consider "what happens if you have, and I put it in quotes, because one person's image of a bad scientist is another person's vision of someone who made a mistake—a 'bad scientist.' What [are] the repercussions? What is the obligation, rather, of the university as an employer? Well, as an employer, keep in mind the university hired this guy in the first place and there was a vetting process that happened and it really doesn't do a lot of good for the university to have a bad scientist."

A university's reputation "is not enhanced by identifying 'Hey, we have a bad scientist, we're going to kick him out the door,' because this is one of your people," Thaler said.

A 'Collaborative' Process

Thaler added that "it is the responsibility of all the stakeholders involved to figure out what happened and to deal with it."

"If it means that the scientist needs to be rehabilitated in some fashion, then that's the purpose of the process," Thaler said. "It's not to punish; it's to make science better and so that's what our goal should be collectively."

Thaler said "many" of his clients "are essentially exonerated, even as early as the inquiry stage. Sometimes there are allegations that are not accurate…they are not fruitful in the sense that they don't end up with a research misconduct finding, a negative one."

Often accusations are "motivated by bad intentions," said Thaler. There may be "a competing scientist at the university who makes an allegation because there's some jealousy, there's some competition for research money that they're both up against."

Thaler's representation may not involve attending inquiry or investigative committee meetings. He is currently involved in a case where procedures aren't being followed. While Thaler attended by phone, he realized that an external counsel was interviewing his client—no committee members were present. Thaler said he considered this improper.

He also contended that his clients want the process to be "timely" and have no desire to prolong investigations. "I promise in 90%-plus…of hundreds of scientists I've represented, their interest was to speed it up, not to drag it out. I guarantee you. They want this resolved. They want it over with, as you can imagine you would if you were up against a similar set of allegations."

Terminations Can't be Automatic

Another problem can arise when institutions try to fire the accused researcher before all the appropriate processes have been followed.

"One of the reactions the university can have, aside from trying to rehabilitate the scientist, is to terminate" him or her, Thaler said. If this action is "premature," the institution is going to face an objection from the investigator's attorney for not following appropriate processes.

A misconduct finding doesn't "relieve you of the obligation to maintain the other policies and procedures that dictate your relationship as employer," Thaler warned. "So, if you have a tenured professor, and you say, 'This guy is a bad actor, we're going to fire him,' don't forget your processes in your universities. You'd be surprised at some of the deans [whom] I've dealt with who sent my client a letter, 'You're hereby terminated.' Well, you can't do that. We have to go through a whole process."

Another task is ensuring that confidentiality is maintained; Thaler said he has to remain "vigilant about how things are being handled." He noted that federal misconduct regulations "provide for restoration of reputation."

A breach of privacy is "one of the most common complaints we have, that [a case] ends up in the newspaper or ends up [with] people…talking about it all over campus," Thaler said. He told *RRC* that

institutions need to make efforts to share information with only those who need to know, and remind everyone involved—even witnesses—that they are not to speak about what is going on, and tamp down on rumors that start.

Confidentiality "is [a] very important piece of this process that we have found is frequently not strictly adhered to and causes quite a bit of damage to the scientist," Thaler told *RRC*. Loss of privacy can become the basis for a suit, he added.

"I sincerely view us all as collaborators in this effort to make sure that the scientific process, the science itself, is protected, and also the rights of all the stakeholders are maintained and the process is true, the way it's supposed to be handled," Thaler said.✧

Group Floats Nine Recommendations for Handling Integrity Issues in Papers

When allegations of possible mistakes or wrongdoing are made against authors for papers submitted or already published, their affiliated universities or other institutions should have a quick way of addressing concerns short of launching a full-scale misconduct investigation.

Having "mechanisms for assessing the validity of reported research" focused "solely on determining the trustworthiness of the research itself, and its reporting, rather than on the behaviour or intentions of the researchers," is one of nine recommendations a group of publishers, research integrity scholars and other individuals recently drafted.

The goal of this "CLUE" working group is to improve the handling of misconduct cases particularly with regard to making corrections and retractions. "Cooperation & Liaison between Universities & Editors (CLUE): Recommendations on Best Practice" is the title of the working group's draft paper, posted online as a "pre-print" this spring (*RRC 8/10/17*).

Members include Liz Wager, former chair of the international Committee on Publication Ethics (COPE), which published guidelines for how the two groups could manage research integrity cases in 2012, and Zoe Hammatt, former director of Division of Integrity and Education for HHS Office for Research Integrity (ORI).

The proposed recommendations, which are open for comment, build on those guidelines. Some relate only to institutions that conduct research, others just to publishers and editors, while some refer to actions that can be taken jointly.

The paper is published on the pre-print website bioRxiv.org, described as the "pre-print server for biology, and pronounced bio-archive. Papers posted have not been peer-reviewed.

Wager told *RRC* that, in this case, the group posted the paper "for consultation," or comments and feedback, before formal recommendations are released.

Recommendations Include Data Archives

Probing the "trustworthiness" of a research product would "permit institutions to respond more rapidly to journal enquiries and without concerns about breaching confidentiality related to institutional policies or employment processes," the group said in its paper. But "such assessments would not prevent further investigation through the institution's established processes for handling misconduct allegations."

"We tried to draft the recommendations so it's clear which part applies to journals and which to institutions [and] universities," Wager told *RRC*.

The following are recommendations contained in the CLUE pre-print:

◆ Institutions should have a research integrity officer (or office) and publish their contact details. National research integrity bodies (or other appropriate organizations, e.g., major funders) should keep a register of people responsible for research integrity at their country's institutions, to enable journal editors (and others) to contact them. Where such lists are not available, journals should request corresponding authors to provide the name and contact details of their institution's research integrity officer (or of an individual with responsibility for handling research integrity cases).

◆ Research institutions and major funders should have systems to ensure that essential research data are retained for at least 10 years, and ideally permanently. Responsibility for data storage (e.g., for multicentre studies) should be defined in funding agreements.

◆ Institutions should develop mechanisms for assessing the validity of research reports that are submitted to, or published by, academic journals; these processes should be independent from systems to determine whether misconduct has occurred.

◆ Institutions should publish their processes for conducting inquiries and investigating misconduct and should share information about such processes with journals, on request.

◆ Anonymous or pseudonymous allegations to institutions should be judged on their merit and not dismissed automatically.

◆ Institutions should notify journals directly and release relevant sections of reports of misconduct investigations to all journals that have published research that was the subject of the investigation. The report should clearly indicate which articles or manuscripts are affected. Names may be redacted to ensure privacy. Institutions should allow journals to quote from misconduct investigation reports or cite them in retraction statements and related publications (e.g., explanatory editorials or commentaries).

◆ Institutions and funders should respond to journal requests for information to ensure that peer reviewers' and authors' competing interests are properly disclosed.

◆ Journals should develop criteria for determining whether, and what type of, information relating to the validity or reliability of research reports should be passed on to institutions. In addition to sharing any direct evidence of plagiarism, fabrication or falsification with institutions, journals should share reviewer or editor suspicions that work is "too good to be true" or of something being "not right." Journals should not reveal the identity of peer reviewers or other people raising concerns (unless this is already published or the individuals have given permission for this disclosure). Anonymous or pseudonymous allegations to journals should be judged on their merit and not dismissed automatically.

◆ While journals should normally raise concerns with authors in the first instance, they should also have criteria to determine when the authors' institution(s) should be contacted immediately without (or at the same time as) alerting the author(s).This would normally occur only in exceptional cases when journals have strong suspicions or clear evidence of substantive or significant falsification or fabrication of data.

◆ Journals and publishers should retain peer review records for at least 10 years to enable the investigation of peer review manipulation or other inappropriate behaviour by authors or reviewers.

More Work To Be Done

Wager said institutional feedback to the paper thus far has been "mixed."

"To some, and in some countries, what we are proposing is quite radical," she said. "So people aren't sure how practicable the recommendations are, but to others, many things," such as identifying a person to serve as a research integrity official, "are their current, normal practice."

Some of the recommendations are repeats from the COPE guidelines, such as publishing the research integrity contacts at universities. That's because they haven't been universally adopted.

The current COPE guidelines "are not that widely known," Wager said. "Although we developed them in consultation with several institutions, one problem may be that institutions don't look to COPE for guidance as much as journals do."

This makes sense because "COPE is primarily an organization for editors and publishers. But," she added, "we also know that many journals don't follow these principles, either."

Attendees at the Fifth World Conference on Research Integrity in Amsterdam in May talked about the pre-print but the proposed guidelines haven't yet been formally presented in public, Wager said.

"We had an excellent discussion…in Amsterdam with contributions from different types of journals and institutions from around the world. That meeting also stimulated people to send comments directly to us," she told *RRC*.

So far, no cut-off-date has been established to accept feedback. "We haven't fixed a date as we want to ensure everybody has a chance to respond," Wager said, adding the group members realize "it's now the summer vacation in Europe, so universities may need more time.

Differing Laws Pose Challenge

RRC asked Wager about next steps following the publication of the pre-print.

"We do hope to publish a final version but the discussions in Amsterdam made us realise we still have some work to do," she said. "One problem in drafting international guidance such as this is taking account of the different [laws] which affect how misconduct cases are handled and how information can be released. Even in the U.S. as you know, there isn't a uniform process, with ORI and NSF [National Science Foundation] having different policies. But in most other countries [for example, in the United Kingdom], there aren't even national bodies giving guidance, so universities are largely self-governing and autonomous."

She noted that ORI "names individuals found to have committed misconduct" while the NSF Office of Inspector General "issues anonymous reports."

Universities and funders can make efforts now to address these issues.

"Many of the recommendations are simple to implement, like listing a research integrity contact

person on a university website. We hope some could be addressed straight away," Wager said.

Wager added that she hoped the posting of the pre-print paper itself would help to spur discussions and changes.

"One thing we've realised is that journals and universities don't always understand how each other works and therefore don't understand why they behave in the way they do," Wager said. "Also, sadly, we know that journals don't always respond appropriately when contacted by universities and universities don't always conduct proper investigations."

Problems, she said, exist "on both sides."

The CLUE group won't try to insist that the recommendations be adopted as mandatory requirements, although publishers and funders certainly could impose them as such.

"These will always be voluntary, best practice guidance," Wager said, "but we very much hope that both journals—probably via publishers and editors—and institutions, by which we mean all research institutions but of course this includes universities, would try to apply them and build them into their policies and practices."

Link: http://tinyurl.com/y9wronws.✧

NSF OIG Shares Best Practices For Preventing, Investigating Misconduct

Allison Lerner is on a mission.

The inspector general (IG) for the National Science Foundation (NSF) wants to stop researchers before they "take that step that sets them down the wrong path," as she puts it, toward committing fraud and research misconduct.

Lerner and others say people caught in a "fraud triangle" might be tempted to do wrong; the sides of the triangle are perceived pressure, a perceived opportunity and a rationalization that enables the person to commit the act.

"What we really want to do in our office is try to reach out," she said, referring of her colleagues at the Office of Inspector General (OIG). "We want to make it difficult for people to make that leap."

Lerner spoke at last month's Quest for Excellence Conference cosponsored by the HHS Office of Research Integrity (ORI), George Washington University and the organization Public Responsibility in Medicine and Research.

Lerner said OIG wants to encourage universities and other research institutions to create the conditions that will help thwart wrong-doing. She also discussed methods for conducting misconduct inquiries and investigations that will result in the best outcomes.

In another session at the conference, Paul Thaler, a D.C.-based attorney who represents researchers accused of misconduct, addressed the role that attorneys play in an investigation and how institutions can avoid being sued (see story, p. 1).

"There's going to be a small number of folks who are just wired to do things wrong," Lerner said. "There are [a] small number of people who never, under any circumstances, would do anything wrong and then there's the big unwashed masses in the middle who probably won't [commit misconduct or fraud], but if the circumstances were right, could find themselves on the wrong side."

IG: Facilitate 'Empowerment'

According to Lerner, training, mentorship and having a good system of checks and balances are ways to prevent fraud, as well as fabrication, falsification, plagiarism and other misdeeds in the conduct of research and the administration of funds.

Further, institutions should create "an environment where people feel empowered [so that when] they see something that looks wrong, they feel like they can say something and they know" where to bring their concerns, she said.

Lerner addressed specifics of training NFS requires on responsible conduct of research (RCR) during a recent National Science Board meeting. OIG recently completed a review of RCR programs that are required under the America COMPETES Act (see story, p. 1).

At the ORI meeting, she emphasized that OIG believes using a "blend" of online and interactive training that permits personal discussions is a more effective form of training than online-only.

She added that "RCR is not just for students." In fact, training might go far toward tamping down plagiarism, which may not stem from students.

Ninety-six percent of plagiarism findings OIG made from 2012-2016 involved principal investigators (PIs) or faculty.

"We also note that a significant number of [individuals] in research misconduct cases have been educated in other countries and may not have all of the sensitivity or understanding of how research is conducted in the United States," Lerner said. "That's

another reason to include faculty in RCR training. And finally, mentorship and mentoring."

Among the questions institutional research officials need to ask themselves are how often do "your PIs regularly discuss research ethics with their students? Do they review data collected by their students? Do you have mentorship training for faculty? And do you have mentors for new faculty that can help them figure out how best to mentor students?"

Ensuring good mentorship "is a critical responsibility," and "based on what we're seeing [is] an area where renewed attention and focus needs to be applied," Lerner said.

She added that "students should be able to talk to their mentors if they see an issue, but as we've seen, sometimes those relationships break down. Do they know that there is another place that they can go to raise issues and bring concerns? That is something for you all to think about."

Lerner Shares What Not to Do

Moving to discuss investigations, Lerner reminded audience members that "the institution bears the responsibility for preventing and detecting research misconduct." OIG will then review their reports and make recommendations to NSF on responses, which can range from letters of reprimand to debarment. She also offered some thoughts on how investigations can go awry. Her suggestions for what not to do in investigations are applicable to projects funded by all federal agencies, not just NSF.

◆ ***Leaving the office of general counsel out of the process.*** "One of the key issues that has to be addressed in a research misconduct report is intent," Lerner said. "And lawyers have a lot of training in figuring out and grappling with intent and they can help you on that. So take advantage" of the institution's office of general counsel, she suggested.

◆ ***Being unnecessarily slow.*** "Timeliness is a real issue. Obviously, whenever an allegation of fabrication, falsification or plagiarism arises it's in everyone's interest to resolve that issue as quickly as possible. But sometimes these cases, especially when you're talking about fabrication and falsification, are complex. We understand that…we are always willing to give extensions to get things done," Lerner said. If the institution—particularly a small one—cannot complete the investigation, OIG can step in and do so, Lerner said.

Lerner's talk was accompanied by slides; the one relevant to investigations contained the sentence: "It should not take a year and a half to resolve a plagiarism case."

◆ ***Losing focus.*** "Sometimes universities don't get their committees focused," Lerner said. "We've had situations where it's day 175 and the university decides, 'Oh, we need get a committee together.' Then

'Our Favorite Plagiarism Excuses'

At a recent conference on research misconduct, Allison Lerner, inspector general for the National Science Foundation (NSF), described best practices in preventing and managing allegations of fraud, fabrication and other wrong-doing (see story, p. 6).

Lerner also shared real-life examples of excuses NSF officials have heard while conducting investigations into plagiarism.

◆ I was distracted by bird vocalizations outside my thatched roof hut, grabbed my digital camera to get pictures of the pair of woodpeckers, and when I returned to my computer where I thought I had saved my changes to the material, it had crashed with the wrong draft saved. (a/k/a the Woodpecker Defense)

◆ I guess my thinking was this person is just trying to understand what my research is about and what I'm proposing to do. And so how is letting him or her know that I got this text from this other paper, how is that going to help him understand better my project or what I'm trying to say?

◆ I did not copy from the suggested source. We just both paraphrased from the cited author in exactly the same way.

◆ As engineers, we do not use quotation marks around copied text.

◆ Quotation marks are only needed for the copied words of "famous people."

◆ A rogue British secretary did it.

◆ It's only a proposal. It's not like it's a publication.

◆ The reviewers are smart enough to know what is my work and what is someone else's.

◆ My English teacher told me it's not plagiarism if I change every seventh word.

you've got five days. That's not really going to work. So ensuring that you do your best to get a committee established early and to make it move efficiently is in everyone's interest."

◆ ***Failing to hear directly from accused individuals.*** "Some committees don't even interview the subject. That raises real due process questions and certainly once a report like that comes to us we're going to have to go forward and ensure that the subject has the opportunity to provide his or her view of events," Lerner said.

◆ ***Letting explanations go unchallenged.*** Institutions need to follow up with key witnesses "once an explanation has been given" by the accused person, Lerner advised.

◆ ***Obtaining a vague admission.*** "Another problem that we've seen is sometimes you'll have an admission from the person who is alleged to [have] falsified or fabricated data," Lerner said, but the person doesn't "specify actually what they did. That prevents us—and the university—from understanding the cause of the problem. And in a situation like that, we're going to have to go back and talk and try and get to that root cause."

Therefore, "If you have an admission from a subject, get detailed, written documentation that speaks to the specific research misconduct acts," Lerner added. "How did you do it, why did you do it, what did you do" are questions to ask. "All of those things you want to have articulated and that will make the admission meaningful and help you in determining whether you have research misconduct and the extent of it."

◆ ***Treating accusations against students as academic issues only.*** An accusation of misconduct may inappropriately go "to the academic side and not to the research side," Lerner said. "So people deal with it by having a student leave the school, but there's not a recognition that there's a research issue that needs to be dealt with as well. Ensuring that there's good communication between folks on the research [integrity and oversight] end and the academic end helps [keep] something like that from happening."

◆ ***Relying on memory.*** When conducting interviews, make a recording. "That's what we do and that will make it really easy to get transcripts," said Lerner. This also provides "a nice clear record moving forward of what was said. You're not relying on memory or other people's notes."

◆ ***Leaving out data and other evidence held externally to the institution in cloud and email servers, such as Gmail and Dropbox.*** "Down the road if you have a research misconduct issue arise, there can be evidence that's not contained in your university systems… how do you get access to that information?" Lerner asked. "That's one conversation I suggest that you have with your folks. Yes, it may be convenient to utilize those external sources and mechanisms for communication, but it can complicate your life down the road." One solution is to make it clear that the university "owns" the data, no matter where they are.

◆ ***Lacking the appropriate expertise.*** "If you don't have anyone on the committee who has expertise in the discipline that's at issue, see if you can grab someone from another school. Because it's really important—having someone with the knowledge of the specific issues that you're dealing with," Lerner said.

◆ ***Submitting incomplete reports.*** Once an investigation is concluded, the report needs to "effectively address all of the elements of a potential case of research misconduct. If you skip over an issue and it comes to us, we're going to have to resolve that," Lerner said.

Reports must "effectively address the elements" of a research misconduct finding. These include addressing whether the act or acts meet the definition of misconduct; ensuring that the accused individual acted "with the prerequisite intent," including whether the behaviors were "reckless, knowing or purposeful;" whether the act or acts were "a significant departure from accepted practice;" and whether a "preponderance of the evidence" supports the conclusions.

◆ ***Forgetting OIG can be a resource.*** According to Lerner, "anytime you are dealing with a research misconduct case involving NSF funds, we are always willing to brief the committee that you have on process or procedural issues early on." Doing so can provide assistance and clarity, especially to research integrity officers, Lerner said, and can help "in ensuring the committee stays focused and does work in a way that gives you a strong end product that is a fine basis for action at the university level—and then something that we at NSF can rely upon without having to go out and do a lot of additional extra work."

On a related note, Lerner pointed out that OIG has "the ability to subpoena documents if they're not available to the university. So if you have a situation where you believe these documents are necessary and we think they would be necessary for us, we could go out an issue a subpoena."✧

NSF Stays Course on RCR Training

continued from p. 1

True to the title, the notice describes awardees' RCR training requirements under the act and does not impose any new ones.

"It is the responsibility of each institution to determine both the focus and the delivery method for appropriate training," Cordova wrote.

The notice followed a National Science Board meeting two days earlier during which Inspector General Allison Lerner explained the results of the OIG review to NSB's Committee on Oversight, chaired by John Anderson, professor of chemical engineering at the Illinois Institute of Technology.

Members took no action on the topic, even though Cordova asked the NSB for direction on how NSF should respond to the OIG report. Only one member argued that training should be mandatory for faculty and PIs, and there did not appear to be a consensus on the issues raised.

Required Risk Assessments Not Done

OIG's review, issued July 25, consisted of a survey of 48 institutions; of these, 11 lacked an RCR program at the time OIG contacted them *(RRC 7/27/17).* Ultimately, eight did put a plan in place. Much of the RCR training was provided online, was not required for PIs and didn't always have to be completed prior to the start of a research project, OIG discovered.

NSF's guidance to institutions on RCR training included that they conduct a risk assessment to determine who would benefit from such programs. None of the 48 had done so, Lerner said. In addition, 64% offered online-only training.

Although she did not stress this at the NSB meeting, Lerner told participants at a recent research misconduct conference cosponsored by the HHS Office of Research Integrity that the use of "computer-based training" leads to "missing out on some opportunities. We think that a blend, that relies on computerized training but also some interaction with professors, is really the best way to go."

NSF OIG has been "recommending that in situations where we have research misconduct findings. We've been recommending interactive-based RCR training for several years now," Lerner said. (See related story, p. 6.)

OIG's findings echo those published earlier this year in *Science and Engineering Ethics (RRC 7/17, p. 4)*. In that study, Trisha Phillips, an associate professor of political science at West Virginia University; Elizabeth Heitman, professor in the Program in Ethics in Science and Medicine at the University of Texas (UT) Southwestern Medical Center; and their colleagues; concluded institutions are failing to provide "meaningful" RCR training.

Those authors reviewed the RCR programs for twice as many universities as did OIG, and noted that 87% use only CITI training (Collaborative Institutional Training Initiative) online training.

OIG said NSF should "consider encouraging…plagiarism training, for all new faculty or faculty who have not submitted an NSF proposal" for funding.

Overall, "NSF's awardees could benefit from NSF providing written guidelines or templates for universities to follow, as requested by the Act's report language, and from the sharing of best practices with the broader community," OIG added.

Lerner said some of the best practices OIG observed were:

- "Adding stress management to RCR training"
- "Requiring RCR training for *all* graduate students (even if they are not funded by NSF)"
- "Involving faculty in RCR training (only 15% currently do)"
- "Requiring periodic RCR refresher training—every 3+ years"
- "Requiring participants to take training *before beginning* NSF research."

With Cordova and Lerner also commenting, NSB committee members spent 15 minutes talking about the topic after Lerner's presentation. "I'm sure we will be continuing the discussion," chair Anderson said, before moving on to the next agenda item.

Some NSB members spoke of not wanting to increase universities' compliance burdens and commented that perhaps two related issues were being inappropriately combined, namely RCR training issues and a broader topic of mentorship.

Referring to the language in the COMPETES Act, Sethuraman Panchanathan, executive vice president and chief research and innovation officer at the Arizona State University Center for Cognitive Ubiquitous Computing, said the OIG's observations "clearly call for" NSF to state that "training is for faculty, undergraduates, graduates and post-docs. We somehow left the faculty out in that, or the PIs."

NSB member Roger Beachy, professor emeritus of biology at Washington University in St Louis, asked Lerner whether NSF had considered "engaging" with the Association of American Universities and the Association of Public and Land-grant Universities "on the importance of this."

Lerner responded that OIG was "willing to talk to anyone and share our findings" but that NSF is the more appropriate body for "taking a conversation and moving it to the next level for some sort of action."

At that point in the meeting, Cordova said Congress, in drafting the COMPETES Act, was clear that it wanted NSF to have "maximum flexibility" in how it implemented the training requirement. Noting that the process of awarding grants was a "partnership" with universities, she asked NSB members to identify "the roles and responsibilities" and "how far" NSF should go.

Cordova also noted that the OIG report, which she called "really helpful," was "very careful in its conclusion." OIG "didn't even use the word 'recommendation.' It used the word 'suggestion' about sharing some kind of guidance or templates and best practices," she said.

To NSB member Vinton Cerf, vice president and chief internet evangelist for Google, the responsibility lies with universities. He questioned why NSF would want to be "the point of the spear" and said it should be up to the universities to be "getting together to sort out how to assure academic credibility." They should be working to "fight against this problem," he said.

Cerf said he liked "the idea of the NSB saying 'This is bad stuff and we should fix it' but somebody else ought to pick up some of the burden."

NSF: Check Out NAS Integrity Study

To date, the only action NSF appears to be taking in response to the OIG report is the reminder notice. At the NSB meeting, Cordova said she had previously circulated it for input. No NSB member addressed the notice or followed up on her mention of it.

Essentially, the notice repeats the training requirement and recommends that institutions review the OIG report and another federal study conducted by the National Academy of Sciences (NAS) that is not specific to the topic of RCR training.

In the notice, Cordova said RCR training "should be effective and appropriately tailored to the specific needs and circumstances at each university."

"The NSF recognizes the importance of research integrity and the responsible and ethical conduct of research," she added in the notice. "The scientific research enterprise is critical to our nation, and its progress depends on maintaining integrity in the process of conducting research."

Cordova referred to findings in the NAS report, *Fostering Integrity in Research (RRC 5/17, p. 1.)* The report "notes that the core values and guiding norms underpinning research integrity are crucial to assure that new generations of researchers are able to meet the challenges of a dynamic research environment," she wrote in the notice.

The OIG report "suggests that universities could benefit from best practices. I would like to draw your attention to Chapters 9 and 10 in the *Fostering Integrity in Research* report to learn more about some best practices and the many resources available for RCR educational materials and strategies," Cordova said.

In closing out the notice, the NSF director expressed her belief that "we can all do more to achieve and demonstrate the effectiveness of RCR training and improve strategies for fostering research integrity," and she promised more discussions would be forthcoming.

"This will continue to be a topic of discussion at NSF, including the [NSB], and among the scientific societies, universities, colleges, and other institutions involved in the research enterprise. Thank you for your continued commitment and dedication to this important endeavor," she said in the notice.

Universities Aren't 'Acountable'

Heitman, the co-author of the study who is with UT Southwestern, said NSF hasn't used its influence to improve RCR training.

"It's not that NSF needs to be the point of the spear," Heitman said, in reference to Cerf's comment, "but rather that NSF needs to hold the universities accountable for what they are teaching as good research practices." Today NSF only imposes a "minimal standard" when it could make the requirements "more substantive," she said.

NSF "could have made that change fairly easily" in terms of prohibiting online-only training as does NIH," Heitman told *RRC.* NIH also requests to see RCR plans "and you can be scored as unacceptable if you don't have an adequate plan. NSF is not doing that, and that was something they chose not to do early on."

At the NSB meeting, NSF officials could have said, "Yes, we're going to start reviewing these plans, we want to see your plan as part of your grant proposal. And they didn't do that," Heitman said.

"I think that NSF's main challenge is in getting universities to recognize that [agency officials] are not just talking about compliance; they're talking about education," she added. "Universities are thinking about RCR training as a compliance standard rather than something that they might incorporate into their traditional established educational activity."

Link to notice: http://tinyurl.com/y7hvflrp

Link to NSB meeting webcast: http://tinyurl.com/ybnvjg47

Link to NSF OIG report: http://tinyurl.com/y7v3aamc.✧

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.*

The federal government is sponsoring a stakeholder workshop, Sept. 25-26 in Chicago, to hear from "boots-on-the-ground implementers" of the federal institutional policy for dual use research of concern (DURC). Speakers will address "challenges encountered and strategies devised and, perhaps most importantly, facilitate the sharing of best practices among research institutions and investigators in order to make compliance with the policy easier," according to Carrie Wolinetz, NIH associate director for science policy. NIH's National Science Advisory Board for Biosecurity defines DURC as "life sciences research that, based on current understanding, can be reasonably anticipated to provide knowledge, information, products, or technologies that could be directly misapplied to pose a significant threat with broad potential consequences to public health and safety, agricultural crops and other plants, animals, the environment, materiel, or national security." The institutional policy requirements went into effect in September 2015.

In announcing the workshop on her blog, Under the Poliscope, on Aug. 18, Wolinetz said it is of "vital importance [to check] in on how the policies we craft are being implemented by our stakeholders. Policies should not be set in stone, especially when they apply to fast moving areas of science, and we need to hear from the affected community what is or is not working." *(8/24/17)*

◆ **While stating that non-human primates (NHPs) are "critical for biomedical research because of their close physiological similarities to humans, which allows them to serve as models for human disease,"** the NIH Office of Research Infrastructure Programs (ORIP) is conducting a study to "assess the demand for and use of NHPs in biomedical research." The purpose is to "provide critical information on current and future NHP needs and how those needs are being met. The study findings and aggregate data will be useful in guiding the NIH and the biomedical research community regarding meeting future national resource needs," NIH said in an Aug. 14 notice. NIH has been phasing out invasive research on NHPs over the past several years and has pledged to retire several hundred chimpanzees that it owns when space becomes available at a federal sanctuary.

ORIP is asking for "information on capabilities from U.S. organizations that breed NHPs and/or provide NHP research services and either (1) provide NHP-related services on a fee-for-service basis, or (2) engage in active outreach to establish collaborations with external investigators who require access to NHP resources that can be provided by the organization. Information is sought from organizations that have a holding capacity of 100 or more animals with a typical annual throughput of 400 or more animals." The agency plans to "develop an inventory of sources capable of providing a wide range of professional, technical, and support services to the biomedical research community to enable projects that require studies in various NHP species, across the full spectrum of biomedical research," NIH announced. *(8/24/17)*

◆ **The CEO of Xigen, LLC, a private research firm that was awarded $1.8 million from NIH and NASA, is facing charges of wire fraud and "aggravated identity theft" for which he could face a 20-year prison sentence and fine of $250,000.** The indictment against Zheng "Jason" Geng, unsealed on Aug. 10, was announced by Stephen Schenning, acting U.S. Attorney for the District of Maryland and officials from the FBI, Inspectors General offices at NASA, HHS and the National Science Foundation.

The awards were part of the Small Business Innovation Research Program (SIBIR). "To support the applications, Geng submitted endorsements for his grant applications using the identities of people without their permission, or misrepresenting their positions within Xigen," the government said in a statement. "In addition, he submitted endorsements that misrepresented active affiliations with various universities including, Harvard University Medical School and Johns Hopkins University School of Medicine, and budgeted funds for subcontractors without their knowledge and without providing

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them with budgeted funds." The fraudulent activities spanned from 2005 to 2016, according to the indictment. *(8/17/17)*

◆ **With the "final phase of implementation" looming for new mandates related to NIH-supported clinical trials, Michael Lauer, the agency's deputy director, has explained how investigators will know whether the requirements apply to their research.** In his Aug. 11 post on the "Open Mike" blog, Lauer stated that the initiatives are "aimed at improving the quality and transparency" of clinical trials. The definition of such "encompasses a wide variety of study types," he wrote. "These range from mechanistic studies to behavioral studies, to pilot/feasibility studies, all the way to large-scale efficacy and effectiveness trials." The requirements include the use of single institutional review boards for trials with more than one site, registration on clinicaltrials.gov and specialized training for investigators. NIH is also making available resources to aid compliance, available on a single website. *(8/17/17)*

◆ **The HHS Office for Human Research Protections (OHRP) "appeared to carry out its compliance activities for protecting human subjects while maintaining its independence from the HHS agencies that fund the research and the institutions conducting the research,"** the agency's Office of Inspector General (OIG) concluded in a long-awaited report issued July 31. However, OIG said HHS should address factors that "limit" the autonomy of OHRP, which enforces compliance with federal regulations known as the Common Rule that govern human subjects research conducted with Public Health Service (PHS) support. Congress requested the report several years ago after a public tiff between OHRP and NIH. In 2013, OHRP determined that the lead center in an NIH-funded study of different oxygen saturation levels provided to extremely premature infants had violated informed consent requirements, a finding it later held in abeyance following unprecedented criticism spearheaded by NIH. HHS officials reportedly also got involved and told OHRP and NIH to "align" their views. OIG has been planning to conduct the report since 2015 but its timetable slipped. *(8/3/17)*

◆ **When Iowa State University licenses technology or intellectual property (IP), it works to assure that "the patent will be beneficially used."** Louisiana State University "does not permit brokerage" of its IP and its licensees "are expected to be directly active in developing and commercializing" any resulting products. In addition, only the highest-level university officials can grant exceptions to such policies. How these universities and two others have addressed technology transfer and protection from so-called "patent trolls" is described in a new survey released by the Association of American Universities and the Association of Public and Land-grant Universities. Conducted jointly, the survey was designed to assess how institutions responded to recommendations the organizations issued in 2015. "A key finding of the survey shows that 87 percent of institutions employ practices, are developing, or have already developed written policies to ensure their technology transfer practices are consistent with advancing the public good, the university's core missions," the associations said. Eight-nine institutions responded to the survey, which also lays out "next steps for campus technology transfer offices." *(8/10/17)*

◆ **In an unusual move, the HHS Office of Research Integrity (ORI) announced a settlement with a former University of Florida (UF) researcher regarding a single finding of research misconduct in one published paper**—although he previously had at least eight other papers retracted. On July 31, ORI announced that Nasser Chegini, who retired in 2012 as a professor in UF's Department of Obstetrics and Gynecology, falsified data in 13 figures in a 2007 paper published in the Journal of Reproductive Endocrinology. "ORI acknowledges that the following papers were retracted as a result of the institution's investigation," the agency said, and listed eight papers for which Chegini was an author or coauthor. Typically ORI validates misconduct findings regardless of whether a paper has already been retracted. For, example, in 2016, ORI debarred Zhiyu Li, a former researcher from Mount Sinai Medical Center, for five years. ORI found that Li had included 57 falsifications in images in grant applications and published papers, of which two had already been retracted at the time of ORI's announcement. Findings of this sort also back up the work of institutions, which are required to pursue all leads to determine the scope of the misconduct. *(8/3/17)*