

Report on Research Compliance Volume 17, Number 7. June 25, 2020 Institutions Pushing Back Against Removing PIs From Awards, Despite Harassment Findings

By Theresa Defino

In the first six months of this year, NIH removed 24 individuals from its peer review panels, and at least 14 researchers lost their status as principal investigators (PIs) on awards, due to allegations or findings related to sexual harassment and other misconduct such as bullying and creating an unsafe research environment.

But the numbers could potentially be higher, because NIH is encountering resistance from institutions that insist a sanctioned investigator can still be a PI. In fact, some are essentially telling NIH their actions are sufficient and to “leave us alone,” according to Carrie Wolinetz, one of the top NIH officials charged with rooting out sexual and other types of harassment among NIH awardee institutions.

Wolinetz made her comments as part of an update from the Working Group on Changing the Culture to End Sexual Harassment, which she co-chairs, on NIH’s efforts since December to implement the groups’ recommendations.^[1] (See related story for working group member Angela Rasmussen’s reactions to NIH’s “slow” progress and her thoughts on other efforts it needs to undertake.)^[2]

Speaking during the Advisory Committee to the Director (ACD) meeting, Wolinetz, also associate director for science policy and acting chief of staff to NIH Director Francis Collins, said institutions are willing to remove PIs from supervisory positions and teaching duties and impose other restrictions as a result of harassment issues.

“But we don’t think you should do anything to the grant” a PI had, institutions have said to NIH, according to Wolinetz. This has happened with “a number of institutions,” she said, and reflects a practice known as “protecting the rainmakers.”

Wolinetz said at the ACD meeting last month that she wanted to share NIH’s concern over this “to spark discussion” and because it is something the research enterprise “needs to grapple [with].”

Institutions are taking this position even though they acknowledge “it is not safe for [the PI] to supervise people or train graduate students or post-docs,” said Wolinetz. “In our view, that’s not really in keeping with the focus on safe environments that we’ve really been trying to promote under the leadership of the ACD.” If the PI can’t be trusted around others, “there might be an issue with trust for public dollars” and with the person’s ability to meet other terms of the award, she said.

Little Response to Concern

The pushback from institutions “does seem to support this perception, which we heard about a lot through the work of the ACD working group and continue to hear, that institutions are protecting their rainmakers; essentially, that funded PIs are protected even if they’re compromising the safety of the research environment,” Wolinetz said.

No solutions to this issue were raised at the ACD meeting, although Collins and working group co-chair Francis Cuss said they shared Wolinetz’s concerns.

“I'm really rather disappointed, but not surprised, that the institutions are beginning to adapt to the new reality” of NIH pushing them to act on sexual harassment, said Cuss, a retired research executive formerly with Bristol-Myers Squibb. He added that “certainly some members of the working group who had experience with this warned us this would happen.”

Working group members “had a very large debate” about whether NIH should take action against an institution in such instances and “more teeth” should be added to its policies and requirements, he said.

“There’s some effort maybe now to try to game the system and limit the requirements to actually take a firm action that’s needed,” Collins acknowledged. “We think we’re making progress, but it took us, I’m afraid, a long time to get into this difficult place. It’s turning out that it is not that easy to change the culture, but...we’re really serious about changing the culture for the women in science so that there’s an opportunity for the diversity that we know is correlated with scientific productivity to flourish and not to be in some way intimidated or set off in the corner.”

‘Still a Lot to Do’

Aside from revealing the numbers, Wolinetz provided no details about the 14 individuals who were removed as PIs or the 24 now-former peer reviewers. She also briefly noted that, during calendar year 2019, NIH had been “involved” in 115 cases in which sexual harassment was reported to the agency. For the first six months of this year, there were 27 new cases.

“Collectively, these involve 71 institutions,” she said. In 2019, 64 individuals were removed as peer reviewers, according to Wolinetz. She said the current numbers don’t reflect the full picture because “many of these incidents are in process [amid] ongoing conversations with the institutions, or there is an adjudication process going on. These numbers are changing all the time.”

In addition to describing NIH’s efforts to remove PIs, Wolinetz gave other updates on the agency’s implementation of the working group’s recommendations.

She noted that the recommendations are “nuanced” and “multifaceted” and that NIH is still working through their implementation. “Progress is being made but...there’s still a lot to do,” Wolinetz said. There has been an unavoidable slowdown in implementation due to COVID-19, but efforts remain “a very high priority” within NIH, she said.

Change Requests Must ‘Mention’ Harassment

Perhaps the most concrete developments are new NIH statements that institutions requesting to remove or replace a PI or change a recipient institution on an award must mention whether the requests stem from “concerns about safety and/or work environments (e.g., due to concerns about harassment, bullying, retaliation, or hostile working conditions).”

NIH announced these changes as guidance, versus a policy change, in a grants notice issued a day before Wolinetz updated the ACD.^[3]

Information about an investigator will make NIH “better positioned to enable informed grant-stewardship decisions regarding matters including, but not limited to, substitute personnel and institutional management and oversight,” according to the notice.

The change, as applied to switching institutions, is also meant to close a “loophole” and solve the problem of “passing the harasser,” where PIs “involved in situations of sexual harassment or other forms of inappropriate

behaviors, such as bullying, or creation of the hostile conditions, could sort of quietly resign from the institution, move [to] a different institution and then ask for us to transfer the grant,” Wolinetz said. Often the new institution is “not aware of [the] past record with the PI,” she added.

But if the relinquishing institution tells NIH, as it is now required to do, the agency “would be able to provide that information to the new institution, and hopefully this will help mitigate the risk of passing the harasser from one institution to another,” Wolinetz said.

Harassment Procedures to Be Released

Additionally, NIH is addressing sexual harassment internally among staff and its intramural research activities, including anti-harassment plans developed by individual institutes and centers and the creation of best practices. NIH is also working to ensure “consistent” disciplinary actions across the agency, among other activities, Wolinetz said.

To implement the working group’s recommendation to treat “sexual harassment and other inappropriate behaviors as seriously as research misconduct, as well as to establish mechanisms of accountability for findings of professional misconduct,” NIH’s integrity team has developed, and expects to soon publish, “standard operating procedures on harassment,” Wolinetz said.

These will put “issues related to sexual harassment, and other inappropriate behaviors that compromise the safety of the research environment, on parallel with the way we handled research misconduct,” she added. The hope is that making the procedures “publicly available will aid in both transparency and accountability.”

In service of another ACD recommendation to “support research on procedures and policies that model and promote a positive climate that cultivates respect, civility, and safety,” NIH is partnering with the National Academies of Sciences, Engineering, and Medicine (NASEM) to “bring together stakeholders and experts to discuss approaches, and develop strategies for measuring the effectiveness of sexual harassment interventions” at a workshop.

Said Wolinetz: “There are a lot of things being tried right now out there in the community, which is great, but we want to make sure that, in fact, they’re effective, and if they are effective, [we] think about how we scale them up and actually demonstrate change to organizational climate or culture, as opposed to just a feel-good measure that you checked the box and did something but [that] doesn’t actually move the needle. We hope this workshop will serve as a resource for federal funding agencies and institutions.”

FOAs, Expectations in Development

The recommendation to develop mechanisms of “restorative justice” to repair the careers of targets of harassment and whistleblowers is taking shape via a revision in NIH’s “reentry supplements” funding opportunity announcements. These “actually always allowed individuals who have been adversely affected by harassment or other unsafe working environment to use that mechanism,” Wolinetz said. Later this year or early next year NIH hopes to establish a “new pathway...to reenter safely.” The funding opportunity announcement (FOA) will specifically note that “reentry following a hiatus due to an unsafe or discriminatory environment is allowed.”

NIH is also “moving forward with trying to “strengthen the language” in its terms and conditions, FOAs and applications, particularly for conferences, to respond to the ACD recommendation that NIH have “specific expectations and requirements for maintaining a safe training and research environment including, but not limited to, at the research institution, conferences, other research settings (e.g., field work) and clinical

settings,” she said.

NIH plans to insert in all FOAs a National Institute of General Medical Sciences award requirement that a “senior institutional official must address how the institution will ensure that proper policies, procedures and oversight are in place to prevent discriminatory harassment and other discriminatory practices and to appropriately respond to allegations of such discriminatory practices, including providing any required notifications to NIH,” according to Wolinetz.

This language “led the way and essentially put the institution on the hook [to assure] that all of the policies are in place to prevent discriminatory, harassment and other practices and to respond appropriately,” she said. When in place, the requirement gives NIH “another tool in our oversight toolbox to be able to go in and check for compliance if we are informed that there are issues related to harassment” or the maintenance of a safe work environment. Although this requirement is already an “expectation built into the grant policy statement,” NIH also intends to make this an “explicit” term and condition of awards, Wolinetz said. She did not offer a timetable for any of these changes.

Efforts Would Foster Independence

So far this year, NIH has issued two new FOAs that support the recommendation that it fund research “on the effective interventions tailored to different types of organizations and climates that improve the health and safety of biomedical researchers,” Wolinetz noted, adding this is something NIH is also working with the NASEM on.

To foster culture change, the ACD recommended that NIH “address funding strategies that contribute to male-dominated power structures, including addressing grant mechanisms that are awarded predominantly to men.” To this end, NIH’s Center for Scientific Review is completing a report “looking at bias in review,” she said. Wolinetz’s slides indicated this is an “anonymization study where names were redacted from applications to test for potential bias in review.”

NIH has also issued several notices of special interest, including award supplements to “promote research continuity and retention” of recipients of mentored career development awards and of first-time recipients of biomedical and behavioral research project grants.

Additionally, the ACD placed “a lot of emphasis...on creating new mechanisms where research awards are given directly to trainees in order to disrupt those power structures that then foster harassment,” she said.

These efforts are still in development and include the Stephen Ira Katz Award (a new program NIH announced a year ago) that Wolinetz said had been delayed by COVID-19. Related activities include a working group empaneled by NIH’s Office of Research on Women’s Health that has been working on ways to use the NIH career transition awards in this regard. Also, the Division of Biomedical Research is exploring whether its career development awards (K) or fellowships (F) “can be modified to achieve greater independence,” according to Wolinetz.

1 NIH, “Update on the ACD Working Group on Changing the Culture to End Sexual Harassment,” virtual meeting, June 12, 2020, <https://bit.ly/37S5ntB>.

2 Theresa Defino, “To Stop Protection of Harassers, NIH ‘Must Sanction Institutions,’” *Report on Research Compliance* 17, no. 7 (July 2020).

3 NIH, “Guidance Regarding Change in Status, Including Absence of PD/PI and Other Key Personnel Named in the Notice of Award,” NOT-OD-20-124, June 11, 2020, <https://bit.ly/3fHjFAa>.

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