

## Report on Research Compliance Volume 18, Number 7. June 24, 2021 NIH: Harassment Proposed Rules Could Mandate Training, Misconduct Disclosures

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By Theresa Defino

Although the item does not yet appear on a federal compendium of regulatory actions underway or planned for the future, NIH is drafting a regulation to beef up requirements for awardee institutions and principal investigators (PIs) related to sexual and other harassment and misconduct. New regulations could include mandatory harassment training and PI disclosures of investigations and past findings.

According to details NIH Deputy Director Michael Lauer provided during a recent meeting of the Advisory Committee to the Director,<sup>[1]</sup> NIH is currently drafting proposed regulations to address some unfinished recommendations forwarded in December 2019 by the ACD Working Group on Changing the Culture to End Sexual Harassment.<sup>[2]</sup>

In brief remarks at the same meeting, NIH Director Francis Collins indicated the Biden administration is viewing the proposed regulations in a more favorable light than had Trump's.

Other topics at the meeting included updates on NIH's efforts to improve rigor and translatability in research using animals.<sup>[3]</sup>

### Annual Training Required for NIH Workers

The topic of rulemaking first came up after Alfred Johnson, NIH deputy director for management, explained during the ACD meeting that NIH requires mandatory annual online harassment training for its employees.<sup>[4]</sup> NIH internal training encompasses requirements for both the Notification and Federal Employee Antidiscrimination and Retaliation Act and retaliation and prevention of sexual harassment, he said. Previously the training had to be completed every three years.

All NIH federal employees, trainees, fellows, and contractors must complete the training annually by Dec. 14, and newly hired individuals must take it within 90 days of their start date, Johnson said.

ACD member Shelley Berger, director of the Epigenetics Institute at the University of Pennsylvania, called NIH's training "really great," adding, "I wish that NIH would insist on that for all investigators that have NIH grants. That would be really fantastic."

Johnson responded that such a requirement was "not our call" at NIH to make of institutions. The agency can "set the model within NIH for the rest of the academic community." However, a few minutes later, Lauer disclosed that rulemaking was in progress after ACD member Francis Cuss, who was one of three co-chairs of the harassment working group, offered suggestions on how to keep the momentum going on antiharassment efforts and to hold NIH accountable for progress.

NIH is "going to be drafting potential regulations" regarding harassment that may include mandating harassment training, Lauer said.

## **Lauer: Assurance ‘May Not Be Enough’**

Currently institutions “have to provide an assurance that they will abide by civil rights laws, and that may not be enough,” Lauer said. NIH is moving deliberately to determine what the regulations would address and is using the working group’s report as a basis, he added.

NIH officials, Lauer said, “want to be as comprehensive as we can, because we don’t want to go through this process and then say, ‘Oh, we forgot to do X.’”

Lauer described an “interesting conversation” that he had with a vice president for research, “who noted that physicians and attorneys and other kinds of licensed professionals have to check boxes...when they apply for licenses or apply for hospital positions,” indicating “that certain things haven’t happened to them, and that’s not true for scientists.”

Collins asked Lauer if institutions could be required to “let students and postdocs know about mechanisms for harassment reporting.” Lauer said he thought “that would be a similar type of thing” that could be addressed in a regulation.

Lauer added that “asking people to attest that they have not had any misconduct findings against them” would require new laws or rulemaking.

Rulemaking typically takes several years. Once a proposed rule is published in the *Federal Register*, it is open for comments. A final rule with an effective date in the future would follow.

Lauer called the process of soliciting comments “healthy,” saying it “will help us do it in the best possible way.”

Added Collins: “Just to state the obvious, the atmosphere for such rulemaking, which was not encouraging last year, is now more encouraging.”

## **‘Very Intense’ Integrity Meetings**

The June 10-11 meeting may be the first time NIH officials have publicly addressed the issue of new regulations. In follow-up responses to questions submitted by RRC, NIH officials would not provide further details, such as when proposed regulations might be completed and whether the agency first would publish a request for information or advance notice of proposed rulemaking.

“We’re in the early stages of discussing the possibility of rulemaking,” an NIH spokesperson said.

Government agencies post their rulemaking progress on [www.reginfo.gov](http://www.reginfo.gov), under the section called “Current Unified Agenda and Regulatory Plan,” which is typically updated twice a year, in spring and fall. The spring update, published June 11, does not list this possible rule under current or future HHS or NIH actions.<sup>[5]</sup>

Also as recommended by the working group, NIH established a process to review and act on allegations in a more formal way akin to how it addresses research misconduct and related complaints. An extramural research integrity team reviews “all kinds of professional and research misconduct allegations,” Lauer said.

Members hail from the Office of Extramural Research and other parts of the Office of the Director along with a new employee who was hired expressly to handle sexual harassment cases full time, Lauer said.

The team meets every other Friday morning “for a very intense meeting where we go through all of our active misconduct cases that require a fair amount of thought,” he said, noting that cases are grouped by harassment, misconduct, compliance or suspected fraud. “It’s a tremendous amount of work; it’s also a fair amount of my

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time, as well. Part of the message we are communicating with senior leadership at institutions is that our [NIH] senior leadership is paying attention.”

## Keep Working Group, Tap OSTP?

Also in his remarks, Cuss noted that “there was a discussion about keeping the working group...together, on a semi, informal basis to come back and actually take a look at the progress” that NIH has made implementing the recommendations as they relate to the extramural research environment. “I do think the group was very good at trying to see how, if you like, sincere or effective those efforts were,” Cuss said.

Cuss also pointed out that Carrie Wolinetz, formerly NIH’s associate director for science policy, has joined the White House Office of Science and Technology Policy (OSTP); she was also a co-chair of the working group. Calling Wolinetz “an extremely effective co-chair with us,” Cuss wondered whether “there’s a role in [OSTP] for this, maybe to cover some of those areas that the NIH was unable to [implement] and acknowledged couldn’t be done” by the agency.

NIH has a “gigantic table” listing all the recommendations and their stage of implementation, Lauer responded, which he said officials “look at often and we present to our various oversight committees within NIH to show them what we are doing.” There was no discussion on the status of the working group or the possible role of OSTP on this topic.

Regarding other working group recommendations, Lauer said NIH is implementing a hotline to accept harassment allegations. As of the meeting in mid-June, Lauer said NIH was doing a soft launch of the hotline. NIH has a web-based form and an email address for reporting sexual harassment “and other kinds of inappropriate behavior,” he said. (For more information, see <https://www.nih.gov/anti-sexual-harassment>.)

Lauer also discussed the outcome of more than 300 complaints NIH has received related to sexual and other forms of harassment among external PIs, which RRC will address in a future issue.

**1** Michael Lauer, “Update on the ACD Working Group Recommendations on Changing the Culture to End Sexual Harassment,” meeting of the Advisory Committee to the Director, June 10, 2021, <https://bit.ly/2TV5rG1>; NIH, “Advisory Committee to the Director – June 2021 (Day 1),” VideoCast, 4:11:00, June 10, 2021, <https://bit.ly/3cZHhkv>.

**2** Theresa Defino, “Institutions Pushing Back Against Removing PIs From Awards, Despite Harassment Findings,” *Report on Research Compliance* 17, no. 7, (July 2020), <https://bit.ly/3iTzIQ9>.

**3** Theresa Defino, “NIH Embraces Recommendations to Enhance Rigor in Studies Using Animals,” *Report on Research Compliance* 18, no. 7 (July 2021).

**4** Alfred Johnson, “Internal NIH Efforts to Redress Harassment,” NIH Advisory Committee to the Director, June 10, 2021, <https://bit.ly/3gPK6Wr>; NIH, “Advisory Committee to the Director – June 2021 (Day 1),” VideoCast, 00:04:30, June 10, 2021, <https://bit.ly/3cZHhkv>.

**5** “Agency Rule List – Spring 2021: Department of Health and Human Services,” Office of Information and Regulatory Affairs, last accessed June 21, 2021, <https://bit.ly/3vMXeRH>.

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