

## Report on Research Compliance Volume 18, Number 1. January 02, 2021 In This Month's E-News: January 2021

By Theresa Defino

◆ The National Science Foundation (NSF) will be accepting comments on a revised version of its Proposal & Award Policies & Procedures Guide (PAPPG) expected to be finalized sometime next year. "To facilitate review, revised text has been highlighted in yellow throughout the document to identify significant changes. A brief comment explanation of the change also is provided," the agency said in a Dec. 14 *Federal Register* notice. In an email to stakeholders, NSF Policy Head Jean Feldman said the draft incorporates "the revised [ 2 C.F.R. § 200 ]: Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Award that was effective November 12, 2020," noting that "we have not highlighted the revised references throughout the document." Feldman also said NSF award conditions currently apply "if there is a discrepancy" between them and the revised 2 C.F.R. § 200 .

The actual draft PAPPG was not included in the *Federal Register* announcement but is available for download from the policy office website. The comment deadline is close-of-business Feb. 12. In her email, Feldman also noted the posting of an updated FAQ about current and pending support requirements in effect now. It appears the document has one new question: #17. It addresses whether a "subawardee on a proposal that was submitted by a prime organization to NSF" should list "the total amount requested for our subaward" or "the total award amount for the overall proposal." The answer is to list "the award amount requested or received by the subawardee organization." (12/17/20)

♦ The Association of American Universities (AAU) is pushing back after a speech by Secretary of State Mike Pompeo at Georgia Tech that the State Department described as "urging American universities to defend against the Chinese Communist Party's research theft and other threats to academic freedom." In a statement responding to Pompeo's Dec. 9 address, AAU President Barbara Snyder called Pompeo's comments an "attack" and said his "claim that America's leading research universities value foreign contracts over the livelihood of our international students, scholars, and researchers is simply wrong." According to the state department, Pompeo said that "Americans must know how the Chinese Communist Party [CCP] is poisoning the well of our higher education institutions for its own ends. We cannot let the CCP crush the academic freedom that has blessed our country and blessed us with great institutions." The state department summary also said Pompeo "asked university administrators nationwide to review their receipt of foreign funding to prevent undue financial influence and to review the activities of Confucius Institutes on campus."

In her Dec. 10 response, Snyder noted that AAU members "take our responsibility to protect our students, faculty, staff, research, and the nation with the utmost seriousness. For decades we have worked closely with the federal government to properly identify and address threats to our country and its security." Snyder bemoaned that Pompeo's statements come at a time "when our doctors, nurses, medical faculty, residents, and researchers are on the front lines fighting a deadly pandemic that is raging unchecked across the country." She termed Pompeo's claims "less a serious assessment of our efforts to protect national security and attract and support international talent than a dishonest and partisan attack." (12/17/20)

• Charles A. Downs, who joined the University of Miami (UM) in August 2018 as an associate dean for research in

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the School of Nursing and Health Studies, submitted to NIH a half-dozen grant applications that contained 12 fabricated "figures and related text," according to the HHS Office of Research Integrity (ORI). Downs' misconduct consisted of "intentionally, knowingly, or recklessly falsifying and/or fabricating data" by "reusing and relabeling previously published figures to represent results from different experiments" when he submitted five applications to the National Institute of Nursing Research and one to the National Heart, Lung, and Blood Institute, ORI said. ORI gave no details about when the applications were submitted or whether they were funded, but said the misconduct occurred when Downs was an adjunct assistant professor at Arizona Health Sciences Center and was supported by an award from the National Center for Advancing Translational Sciences. NIH's database of awards lists one three-year award totaling approximately \$111,000 in 2008 and a two-year award of \$928,023 given in 2018, with half assigned to the University of Miami in 2019.

In its Dec. 8 announcement, the agency noted that Downs did not admit or deny ORI's findings, and that both parties had accepted the settlement terms out of a "desire to close this matter without further expense of time and other resources." Downs agreed to a four-year supervisory plan should he apply for Public Health Service (PHS) funds. Under the agreement, Downs would be supervised by a committee with expertise in his field that would also submit periodic reports to ORI. He also agreed to not advise PHS during the four-year period, which began Nov. 9. RRC's request for comment to Downs was forwarded to UM. In a statement to RRC, UM officials said Downs had resigned the administrative position effective Dec. 4 and remains an associate professor in the School of Nursing and Health Studies. No "evidence of misconduct was found" following UM's "comprehensive evaluation" of Downs' time at UM, the statement said. (12/10/20)

◆ The AAU, the Council on Governmental Relations and 44 other organizations and associations submitted a letter to President-elect Joe Biden and Vice President-elect Kamala Harris outlining nine areas of "regulatory changes" they would like to see "to modify previous executive branch actions that affect students, educators, and institutions." The Nov. 18 letter addresses "reinstating Deferred Action for Childhood Arrivals protections; rolling back changes to Title IX regulations; halting expanded, burdensome, and unneeded reporting requirements; terminating several politically-motivated investigations; and withdrawing the June 2020 interim final rule that restricts students' eligibility to receive CARES Act funding."

Specific actions requested include repealing the administration's executive order (EO) on race and sex stereotyping. "Needless to say, colleges and universities are totally opposed to race and sex stereotyping, but the EO is sweepingly overbroad and has chilled the implementation of critical diversity training programs that ensure more respectful and productive work and learning environments." The signatories also asked for the incoming administration to "[w]ork with all stakeholders to address aspects of the Title IX regulations that are deeply problematic and that micromanage campus processes in an inflexible manner and undermine college and university efforts to effectively, fairly and compassionately address the problem of campus sexual assault." (12/10/20)

◆ David Panka, M.D., who ORI described as a former instructor of medicine at Harvard Medical School and a former associate professor of medicine at Beth Israel Deaconess Medical Center, engaged in misconduct in research supported by two NIH grants by "intentionally, knowingly, and/or recklessly falsifying and/or fabricating Western blot images by selectively cutting, flipping, reordering, and reusing the same source images or non-correlated images to represent different results" in three papers and one conference presentation. Overall, there were 12 figures that had been published from 2005 to 2013 at issue, ORI said in its Nov. 20 announcement.

Panka agreed, for a three-year period that began Nov. 9, that any research he submits for possible funding by the PHS will be accompanied by a plan for supervision of his duties that is submitted to ORI for approval. His research would be supervised by a committee of several senior faculty members familiar with the field of study who would

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review his data and send periodic reports to ORI. (12/3/20)

◆ A former professor and rheumatology researcher from The Ohio State University (OSU) pleaded guilty to one count of making false statements on NIH grant applications "in order to use approximately \$4.1 million" in awards "to develop China's expertise in the areas of rheumatology and immunology," the Department of Justice announced. Song Guo Zheng entered a guilty plea on Nov. 12 before Chief U.S. District Judge Algenon Marbley of the Southern District of Ohio. He faces five years in prison; a sentencing date was not announced. (12/3/20)

◆ Following a review by the Government Accountability Office (GAO) of how HHS manages its intellectual property (IP), NIH has agreed to implement some changes that may provide more insight into its processes. But the GAO report, issued Nov. 20, also contains revealing information of its own. According to GAO's data, the number of NIH patents that have resulted in licenses granted and drugs approved by the Food and Drug Administration (FDA) has significantly declined since 2000. There were a total of 12 licenses and approved drugs from 2000 to 2009, and seven from 2010 to 2019. In contrast, there were 24 licenses and drugs from 1980 to 1989 and 23 from 1990 to 1999. Thirty-four drugs overall were "associated with NIH's licensed inventions," of which the National Cancer Institute "provided patented inventions for 21 drugs, and the National Institute of Allergy and Infectious Diseases contributed patented inventions for four." The balance came from seven other institutes. GAO noted that "10 of the 34 FDA-approved drugs were jointly invented with researchers outside of HHS intramural programs. NIH officials stated that the vast majority of co-inventions are with universities." (12/3/20)

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