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By Theresa Defino

◆ **The Department of Commerce and the National Institute of Standards and Technology are requesting comments on a “draft guidance framework designed to help federal agencies evaluate when it may be appropriate to exercise ‘march-in’ rights under the Bayh-Dole Act,” NIH announced.** “March-in refers to a federal agency’s right to march-in and require the contractor, an assignee, or exclusive licensee of a federally funded subject invention to grant a license to a responsible applicant or applicants, upon terms that are reasonable under the circumstances, and if the contractor, assignee, or exclusive licensee refuses such request, to grant a license itself. Currently, an agency can exercise march-in rights only under four specific circumstances. To date, no agency has exercised its right to march-in,” the agency said Dec. 12.

In a Dec. 8 announcement, the U.S. Patent and Trademark Office (USPTO) explained that, for 40 years, “the Bayh-Dole Act has promoted the commercialization of federally funded research and technology by according the recipient of those funds the right to retain ownership and seek patents on those inventions,” but also noted the lack of action by agencies. “The draft framework released today encourages funding agencies to consider both the practical impact and the potential impact the use of march-in rights could have on the broader research and development (R&D) ecosystem. It guides agencies in assessing three overarching questions and provides eight hypothetical scenarios in which march-in could emerge, to demonstrate how an agency might apply the framework to its decision-making process,” USPTO said. The deadline for comments on the framework, published in the Dec. 8 *Federal Register*, is Feb. 6. (12/14/23)

◆ **Auditors for the National Science Foundation (NSF) Office of Inspector General (OIG) are recommending that NSF seek repayment of \$7,870 in costs claimed among 92 NSF awards totaling \$25.5 million that North Dakota State University (NDSU) expended from Nov. 1, 2019, to Oct. 31, 2022.** The questioned amount was found after auditors tested more than \$2.1 million in claimed costs. Auditors said one award was charged \$6,351 “in lodging expenses for four participants whose participation in the conference did not benefit the NSF award,” which NDSU “confirmed it incorrectly charged the lodging expenses to this award.” Additionally, auditors questioned \$579 in airfare charged to a February 2022 award and \$940 for a principal investigator’s (PI) lodging.

The airfare was for personal travel a student tacked on to a work trip; the lodging was for one extra day for the PI. “Although six of the PI’s seven travel days benefited the NSF award, the PI stayed this additional day to collaborate with industry partners on projects that did not benefit the NSF award,” auditors said. Additionally, NDSU “did not always comply with its effort reporting policy.” Specifically, “[d]uring three effort reporting periods, NDSU charged salary expenses to three NSF awards without obtaining certified Personnel Activity Confirmation forms to support the expenses, as required by NDSU policy,” OIG said. The PI “and/or the Department Chair did not always sign Personnel Activity Confirmation forms when NDSU made the forms available and only signed the forms in March 2023 as a result of the audit.” In a response to draft audit findings, NDSU officials said they “worked diligently with [auditors] over the course of several months” and had already paid back the questioned amounts. NDSU also planned to “implement new processes to strengthen our effort reporting to ensure compliance with federal requirements.” (12/14/23)

◆ **Three serious complaints that a University of California, Los Angeles (UCLA) investigator violated human research protections—including allegedly not reporting study-related injuries—are unfounded, according to the HHS Office for Human Research Protections (OHRP).** As described in a Nov. 21 determination letter posted online, OHRP contacted UCLA about the complaints in February 2017, although it is not clear when they were received. UCLA responded the following month. The parents of a person involved in spinal cord function research said the UCLA principal investigator (PI) caused or may have caused injuries, did not provide appropriate monitoring, did not provide treatment as promised, nor notify the institutional review board of the injuries.

However, OHRP said, “documentation provided by UCLA, the PI and an independent physician determined that the participant’s injuries and associated pain were unrelated to the research procedures,” which meant that complaints were unfounded. Without offering a reason for the delay, Lisa Buchanan, director of OHRP’s Division of Oversight, said officials “regret the amount of time it has taken us to respond.” The UCLA document is only the second OHRP determination letter posted this year. (12/7/23)

◆ **The HHS Office of Research Integrity (ORI) has extended the comment deadline on its Oct. 6 proposed rule amending misconduct regulations until Jan. 4, acceding partly to requests from research associations and organizations for more time.** On Oct. 23, the Association of Research Integrity Officers, the Council on Governmental Relations, the Association of American Universities and the Association of American Medical Colleges were among those seeking a 45-day extension in a letter to ORI. The proposed rule makes major revisions to the regulations for the first time since they were published in 2005, and groups expressed a variety of concerns about the draft regulation. They also asked for more time due to the Thanksgiving holiday.

Three days later, Deputy Director Wanda Jones, citing a host of reasons, including that ORI had its own experiences with the regulations and knew what changes were needed, denied the requests to extend the comment period. However, ORI reversed Jones’ decision. According to a notice in the Dec. 4 *Federal Register*, the original comment deadline of Dec. 5 has been extended to Jan. 4 “in response to requests for an extension to allow interested persons additional time to submit comments.” (12/7/23)

◆ **Sarah Elizabeth Martin, a former graduate teaching assistant in the Department of Biological Sciences at Auburn University, engaged in research misconduct by “intentionally or knowingly falsifying and/or fabricating experimental data and results obtained under different experimental conditions”** as part of a published paper, a submitted manuscript, a funded grant application and six presentations, according to the HHS Office of Research Integrity (ORI).

Martin agreed to exclude herself from any involvement in government-funded research and other projects for three years, according to ORI. The exclusion period began Nov. 3. When such exclusion is not agreed to, it is referred to as debarment; it has the same impact on the individual. Martin also agreed to have her work supervised for two years, should she be involved in any Public Health Service-funded research following the exclusion period. Martin’s paper, published with other coauthors in *RNA* in 2021 and retracted a year later, purported to represent “the first comprehensive overview of the dynamic interplay that takes place between the cellular epitranscriptomic machinery and a specific viral RNA in the context of [Kaposi's sarcoma-associated herpesvirus] infected cells.” According to a notice in the publication, the paper was retracted “because the authors have lost confidence in the validity of some of the data and conclusions drawn from them.” (11/30/23)

◆ **Auditors for NSF OIG questioned nearly half of the \$584,451 in direct and indirect costs they tested among 50 transactions made by the University of Arkansas from Oct. 1, 2019, to Sept. 30, 2022.** The university agreed to repay all but \$4,739 of the \$257,693 auditors questioned in the Nov. 15 audit. Overall, the university claimed \$36.8 million for 215 NSF awards during the audit period. “Specifically, the auditors found \$125,124 of Award Cash Management Service (ACMS) drawdowns that exceeded expenses, \$122,090 of unallowable expenses,

\$6,203 of inappropriately allocated expenses, and \$4,276 of indirect cost rates inappropriately applied,” according to the audit. “The auditors also identified one compliance-related finding for which the auditors did not question any costs: non-compliance with Arkansas professional/consultant services policy. In addition to the findings, the audit report includes one area for improvement related to controls for applying indirect cost rates.” The unallowable expenses consisted of \$52,448 in June salary “incorrectly” charged to an award; \$48,430 in participant support funds that were used for equipment without rebudgeting approval from NSF, “\$13,200 associated with an equipment expense that had previously been charged to the award and therefore represented a duplicative expense” and “\$8,012 in equipment expenses that Arkansas acknowledged it had incorrectly charged.”

The \$4,739 represented partial travel costs for a graduate research assistant who did not acknowledge a specific NSF award but did acknowledge two others during two presentations at a conference. Two papers later published about the conference cited the NSF award that was not acknowledged during the conference, according to the audit. “Because the material presented during the travel also related to three other NSF awards and Arkansas did not provide a reasonable justification regarding why none of these costs were allocable to these awards, we are questioning \$4,739—or 75 percent—of the costs associated with this travel expense that appear to have benefitted other awards,” auditors said. The university balked at repayment, arguing that the “total amount charged was allocated in its entirety to awards sponsored by NSF.” Auditors also made 13 recommendations. (11/30/23)

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