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◆ **Given the already "heavy…burden" faced by small institutions and the National Science Foundation's (NSF) low award rate, the Council on Governmental Relations (COGR) has asked NSF to delay the use of a biographical template for 12 months and refrain from imposing disclosure requirements at the proposal stage.** COGR's June 13 comments are in response to NSF's draft Proposal & Award Policies & Procedures Guide (PAPPG), which was published in April. Once finalized, the PAPPG is scheduled to go into effect for funding applications submitted in January. "COGR requests that NSF delay the requirement to use SciENcv exclusively to develop and submit Current and Pending Support for an additional 12 months to provide time for NSF to make further refinements and for recipient institutions to build efficient processes and interfaces to support Current and Pending Support disclosures through SciENcv," the organization said in comments posted on its website. SciENcv is a system for federal awardees administered by the National Center for Biotechnology Information.

Additionally, COGR took issue with the draft's provisions on the resubmission of current and pending support before an award is made. "We understand the need for NSF to assess budgetary and scientific overlap before award. However, we see this as an NSF business review and unrelated to scientific peer review of the application. This raises questions about why this information is needed at the time of proposal since the data is often stale within a few months of proposal submission," COGR said. "Submission should be delayed until the project is selected for funding" to "significantly reduce the administrative burden" on principal investigators. COGR noted that "only about 28% of proposals are selected for funding," and added that such a change on submissions would be "consistent with the current NIH process." (*6/16/22*)

◆ **On June 29, NIH will hold a five-hour meeting to discuss federal policies governing dual use research of concern (DURC), with the format changed from a hybrid to a virtual event.** "To ensure U.S. government's policies keep pace with evolving science and society, NIH is hosting a virtual stakeholder engagement meeting to gather feedback from stakeholders about their experiences implementing the policies, the effect of these policies in terms of achieving their stated goals, the overarching definition of DURC, and possible alternative approaches for the oversight and responsible conduct of DURC," the Office of Science Policy announced June 14. "This feedback will also be used to inform the discussions of the National Science Advisory Board for Biosecurity (NSABB) in fulfillment [of] their current charge to evaluate and analyze the DURC policies."

The meeting, which begins at noon, includes three panel discussions—focusing on "key questions" addressing scope and definition of DURC policies, implementation and effects, and "anticipating the future." Thirty minutes are allocated for public comment, according to the agenda posted online. Individuals who wish to speak should email NIH by June 27; the deadline for written comments is July 9. For both purposes, NIH should be contacted via SciencePolicy@od.nih.gov. (*6/16/22*)

◆ **HHS has named Adam H. Russell, chief scientist at the Applied Research Laboratory for Intelligence and Security at the University of Maryland, acting director and formally announced the establishment of the Advanced Research Project Agency for Health (ARPA-H), created by Congress to be an independent agency within NIH.** In a May 25 announcement, Secretary Xavier Becerra said officials were "ecstatic" about the hiring of Russell, who HHS said will "help launch ARPA-H" and "guide the early stages of building the administrative

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structure of the agency and oversee the hiring of initial operational staff to ensure the agency is stood up as effectively and efficiently as possible."

A permanent director will be appointed by President Biden, HHS said. According to a May 27 *Federal Register* notice, ARPA-H "provides leadership for high-risk, high-reward biomedical and health research to speed application and implementation of health breakthroughs equitably"; "creates, supports, and manages programs to catalyze the development of transformative, evidenced-based, use-driven capabilities, platforms, and technologies in a range of biomedical and health research areas"; "facilitates partnerships and collaboration among government, academia, industry, and other sectors to accelerate the translation of innovation into meaningful and measurable benefits for the nation"; and "converts use-driven research into tangible, sustainable solutions for patients." It will have a Treatment Innovation Office, Health Promotion and Disease Detection Office, and an Innovation and Entrepreneurship Office, among others. (6/9/22)

◆ **Auditors for the NSF Office of Inspector General (OIG) have concluded that another institution incorrectly applied lower indirect cost rates, and like others before it, the awardee is challenging the finding**. The latest audit is of the University of Maine (UMaine), which did not question any costs. "We selected 27 NSF awards with a total of approximately $9.7 million in costs that UMaine claimed as of September 2, 2020," auditors said. "We judgmentally selected 15 transactions, totaling $60,854," and "identified no questioned costs charged to NSF awards. However, there is one finding related to UMaine guidance for monitoring indirect cost rates on NSF awards. UMaine did not have proper controls in place to ensure it applied the indirect cost rates in effect as of the award date as required by federal regulations and NSF guidance."

UMaine officials agreed "it did not always apply the indirect cost rates in effect as to the award date and, under certain circumstances, applied the rate in effect at the date of submission. However, we disagree that this was due to a lack of controls. In order to reduce the financial impact on university research faculty, UMaine made a university wide decision to charge the indirect rate in effect at the time of the proposal because it was lower than the NICRA [negotiated indirect cost rate agreement] rate in effect at the time of the award. UMaine has proper controls in place to ensure it applies the award date rate should approved rates decrease between the proposal and date of award." NSF officials will decide whether to support the auditors' finding. In two recent audit resolutions—pertaining to the University of Delaware and the University of Utah—NSF said the correct NICRAs were used and that institutions have the discretion to use lower amounts. (6/9/22)

◆ **Three years after auditors for the NSF OIG issued a report of the University of Delaware (UD) questioning $426,667 in costs, NSF has resolved the findings, mostly in favor of UD**. The audit covered Dec. 1, 2013, to Nov. 30, 2016, and encompassed more than $1.8 million of the $82 million in costs. In a three-page letter to UD dated May 12, NSF agreed with $258,467 of the questioned costs, but in a somewhat unusual move, said that "based on alternative documentation reviewed and accepted during resolution, NSF will require repayment of only $214,027." As part of its initial response to the audit, UD had agreed to repay $170,287 but disputed the balance.

The largest category of costs auditors questioned is $233,075 for what they called unsupported costs. Of this amount, NSF allowed $185,685, due to "consideration of circumstances and alternative documentation." In the category of equipment purchases at the end of an award or that provided no benefit to an award, "NSF's management decision [is] to sustain and disallow $26,177 and to allow $99,281." It provided no specifics on its reasoning. Regarding unallowable or unreasonable travel, NSF agreed that $23,277 should be repaid, but again referring to "circumstances and alternative documentation," said it was allowing $21,192. NSF also said UD has not adequately addressed three "compliance and internal control recommendations." NSF is requiring UD to provide "corrective actions and updated policies in response to the recommendations" within 30 days of the letter. Strengthening administrative and management controls over the use of credit cards, equipment and related purchases near the end of awards and revising travel policies and procedures are among the

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recommendations. (*5/19/22*)

◆ **In nearly identical letters to both House and Senate appropriations committee leaders, Pamela Morris, president of the Federation of American Societies for Experimental Biology, has called on Congress to include language in fiscal year 2023 bills** "that supports and expands large animal translational research" funded by NIH and to "specifically" call for validation studies comparing animal and nonanimal research models. Moreover, the May 3 letters request that Congress "allocate additional funding" for the National Primate Research Centers. "The unexpected pivot to COVID-19 research and enduring lack of nonhuman primates forced numerous investigators to halt ongoing studies into other diseases that rely on these animals, including tuberculosis and HIV/AIDS," Morris wrote. She also asked the committees to "address the ongoing refusal of numerous airlines to transport animals for research purposes" and said they should "include language that directs NIH to collaborate with the Centers for Disease Control and Prevention and the Food and Drug Administration to develop a federal plan that ensures the long-term support, breeding locations, veterinary oversight, and enrichment and social needs of nonhuman primates in the U.S. to bolster availability of animals to researchers."

Moving to NIH's implementation of the Cures Act, FASEB said "several policy concerns remain unaddressed more than five years after the law's enactment," although these were not specified. Morris said the committees should "include language that directs NIH to provide a list of steps the agency intends to take over the next year to reduce investigator burden, accompanied with implementation timelines and planned strategies for communicating new information with the extramural community." In conclusion, Morris wrote that Congress should "sustain support for large animal translational research, ensure availability and transportation of nonhuman primates, and fund research facility and technology modernization. Importantly, federal support for these areas should be coupled with policies that enhance rather than hinder research productivity, as administrative burden continues to unnecessarily delay critical research studies." (*5/19/22*)

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