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◆ **Arguing that the National Science Foundation (NSF) was "intricately involved" when it made a $1.125 million fixed amount subaward, Oklahoma University (OU) objected to a recent finding by auditors for the NSF Office of Inspector General that the subaward should be repaid**. The audit, dated March 6, encompassed approximately $42 million of costs claimed on 237 awards expended from Nov. 1, 2019, to Oct. 31, 2022. Auditors tested 49 transactions totaling $1,615 million. In its response to draft audit findings, which contains redactions, OU officials said the director of a program had informed NSF about the subaward and that the agency "approved" the arrangement because the subawardee was "the only institution in the United States or Canada able to provide the expertise for the completion of time-sensitive research and would not accept a cost reimbursement subaward." OU added that NSF was "intricately involved and even spoke directly with" an organization whose name was redacted. "The research could not have been completed without the [name redacted] and NSF provided additional funding for the work completed by them," OU said. Auditors, however, maintained NSF did not specifically okay the subaward type and exact amount.

OU agreed to repay a total of $126,322 that auditors also questioned, including $74,373 in internal service provider expenses that auditors said "only resulted in OU recovering the aggregate costs of the services" and which lacked documentation; $28,509 in Graduate Research Fellowship Program expenses auditors said exceeded per student limits; and $20,317 disallowed because OU executed a technical agreement instead of a subaward agreement. Auditors also made a number of recommendations for changes to strengthen controls and noted instances when OU did not always comply with its own and/or federal requirements. In addition to partial repayment, OU said it would make improvements and cited "significant staff turnover, multiple system implementations and COVID" as contributing to procedural and policy failures. (3/14/24)

◆ **The HHS Secretary's Advisory Committee on Human Research Protections (SACHRP) will hold its first meeting of the year March 20-21, gathering virtually to consider recommendations and continue discussions from its previous meeting in October**. According to a notice in the *Federal Register,* the committee will first discuss "Ethical and Regulatory Considerations for the Inclusion of LGBTQI+ Populations in HHS Human Subjects Research," draft recommendations that follow a presentation in October by a panel of experts. The meeting marks the first time the recommendations will be discussed publicly.

The second agenda item is "Considerations for Uninformative Research," a draft document that was presented during the last meeting. Developed by SACHRP's Subpart A Subcommittee, the document addresses six questions the Office for Human Research Protections (OHRP) asked it to consider that encompass the role that institutional review boards and human research protection programs play in assessing whether research is designed to be informative. "The second day of the meeting, March 21st, will begin at 11:00 with a discussion of Interpretation of the Best-interests Standard for the Retention of Subjects in Human Subjects Research that Has Been Halted or Suspended," the notice states. The meeting will be webcast. Links for viewing will be posted on OHRP's website closer to the meeting dates. (3/14/24)

◆ **Although Congress needs to act swiftly to pass appropriations legislation to avoid a partial government**

shutdown, the package of recently introduced bills for the balance of fiscal year (FY) 2024 would "reduce" the capacity of NSF "by almost $500 million or more than 5% below current levels. At a time when this agency has been identified as core to so many critical priorities, this decision is short-sighted and will cede U.S. leadership to our competitors," Barbara Snyder, president of the Association of American Universities, warned in a March 4 post.

Snyder called NSF "the heart of research and workforce training in these areas and is poised to transform regional economies all across the nation through new, congressionally-mandated programs such as the Regional Innovation Engines," and said the agency was "identified as critical to our national competitiveness in recent legislation, which set it on a five-year growth plan." If passed as proposed, the bills will "undercut" NSF's work and risk "our nation's future as a global leader in science and innovation." Congress needs to "pay more than lip service to ensure U.S. scientific leadership in the future and put real dollars forward to support NSF and its critical programs. We must refocus our efforts and ensure that we make up the deficit in FY 25," Snyder added. (3/7/24)

◆ **The Food and Drug Administration (FDA) OHRP are seeking comment on draft guidance issued March 1 that provides recommendations on compliance with provisions in the revised Common Rule** that "require informed consent to begin with key information about the research and to present information in a way that facilitates understanding and identical provisions" contained in a proposed rule FDA issued in September 2022.

"In this draft guidance, FDA and OHRP provide recommendations for developing a key information section for clinical trials or studies, including strategies to make consent information as a whole more understandable for prospective research participants. We also provide a sample approach to the key information section that is based, in part, on research regarding patient understanding of information found in labeling for prescription drugs," the agencies said in the *Federal Register.* "By using simple phrases and plain language principles, as well as formatting and organizational tools, researchers found that presenting information in a discrete bubble format with topics organized or grouped together can facilitate consumer understanding. In the appendix of the draft guidance, we provide an example of a key information section using the bubble format. We encourage interested parties, with input from [institutional review boards] to develop innovative ways to provide key information that will help prospective subjects better understand the reasons why one might or might not want to participate in research." The deadline for comments is April 30. (3/7/24)

◆ **In fiscal year (FY) 2023, which ended Sept. 30, the success rate for NIH R01 awards was essentially unchanged from the previous FY, according to new data posted by Michael Lauer, NIH deputy director for extramural research**. The success rate last FY was 21.6%, as it was the previous year, but this reflects a .3% increase, Lauer's blog post shows. Last year, NIH received 35,072 R01 or equivalent applications, a decrease of 3.1% from 2022. It made 7,592 such awards, a decrease of 2.9%. The average amount of an R01 award was $600,957, a $2.7% increase. Overall, this category accounted for $19.761 billion in awards.

"We spent $34.9 billion of our total $47.7 billion appropriation in FY 2023 for competing and noncompeting grant awards. This is a 4.7% increase (or $1.58 billion) in spending over the previous year. Monies for grants and Other Transaction awards are included while monies for [Advanced Research Projects Agency for Health] and research and development contracts are excluded," Lauer wrote on his Open Mike blog. "NIH supported 58,951 competing and non-competing awards in FY 2023. This was an additional 583 extramural grants compared to 58,368 in FY 2022, a 1.0% increase. NIH issued grants to 2,743 academic universities, hospitals, small businesses, and other organizations throughout the U.S. and internationally." (2/29/24)

◆ **FDA is accepting comments on draft guidance "intended to assist sponsors of clinical trials in determining when a data monitoring committee (DMC) (also known as a data and safety monitoring board (DSMB), a data and safety monitoring committee (DSMC)**, or an independent data monitoring committee (IDMC)) would be useful

for trial monitoring and what procedures and practices should be considered to guide their operation." FDA's announcement in the Feb. 13 *Federal Register* noted that, when finalized, the guidance would supersede the guidance for clinical trial sponsors issued in March 2006. The deadline for comments is April 15.

Updates to the guidance are needed because of the "significant changes in DMC structure and practice" since the 2006 document was issued, including increased use of DMCs in small studies to oversee "an entire clinical development program" and "implement certain adaptive clinical trial designs." According to the draft, "not all trials call for involvement or monitoring by a DMC"; the agency "strongly recommends establishing a DMC if trial subjects are at risk of serious morbidity or mortality (e.g., hospitalization, heart attack, stroke, death)." The agency said institutional review boards "should inquire as to whether a DMC has been established and, if so, seek information about its scope and composition as part of its oversight" for trials that may pose "serious morbidity or involvement of vulnerable populations." The draft guidance also addresses committee composition, training requirements, conflict of interest concerns and when a DMC would report safety concerns to a sponsor. (2/1/24)