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In This Month's E-News: December 2021

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◆ **A month after rumors circulated that President Biden planned to tap former Food and Drug Administration (FDA) Commissioner Robert Califf to serve again, the nomination has become official**. On Nov. 12, Biden announced his intention to nominate Califf, who had served under President Obama from February 2016 to January 2017. Calling him "one of the most experienced clinical trialists in the country," Biden said Califf "has the experience and expertise to lead the Food and Drug Administration during a critical time in our nation's fight to put an end to the coronavirus pandemic." He added Califf would provide "a steady, independent hand to guide the FDA." Three days later, the nomination was referred to the Senate, and then to its Health, Education, Labor and Pensions Committee, which will hold hearings; they have not yet been scheduled. Califf is currently professor of medicine and of cardiology at Duke University. The FDA position requires Senate confirmation.

The watchdog organization Public Citizen has expressed opposition to Califf's nomination, as it did when President Obama put his name forward, saying he is actually not independent and has too many ties to pharmaceutical firms. "During just the few years before his previous stint as FDA commissioner, Califf reported receiving personal fees for consulting from at least 19 major pharmaceutical manufacturers, including Amgen, GlaxoSmithKline, Johnson & Johnson, Novartis and Pfizer," Public Citizen said in a statement. "After exiting the FDA, Califf revived his lucrative ties with FDA-regulated pharmaceutical companies, receiving consulting fees totaling tens of thousands of dollars from AstraZeneca, Boehringer Ingelheim Pharmaceuticals, Eli Lilly, Merck Sharp & Dohme and Sanofi. And in February 2018, he was appointed to the board of directors of the biopharmaceutical company Cytokinetics." (*11/18/21*)

◆ **The HHS Office for Human Research Protections (OHRP) has launched an online system for reporting incidents** "such as unanticipated problems involving risk to subjects or others, serious or continuing noncompliance with [45 C.F.R. § 46], or suspension or termination of IRB [institutional review board] approval to OHRP," the agency announced in a Nov. 16 email. Online reporting using the new web-based form will become mandatory Jan. 2, according to OHRP's website. "If an institution or IRB is unable to submit incident reports using the online form, a written explanation of why the institution or IRB is unable to use the web form to submit the report must be emailed to IRPT.OS@hhs.gov."

The email also included "tips" for completing the form. "Information provided on the online form is submitted directly to OHRP's database for processing. Each field in the online form must be completed with the required information regarding the incident versus referring to an external document," OHRP said. "Users are permitted to provide additional attachments to supplement the report, as needed. Upon submission of the report, users will receive an automatic email message confirming successful submission. In addition, a detailed confirmation containing the information submitted in the report will be provided via email, generally within a few business days." (*11/18/21*)

◆ **Next year the HHS Secretary's Advisory Committee on Human Research Protections (SACHRP) will have three openings on the 11-member panel and is seeking nominations**, according to a notice in the Nov. 10 Public Inspection section of the *Federal Register.* "Nominations of potential candidates for consideration are being

sought from a wide array of fields, including, but not limited to: public health and medicine, behavioral and social sciences, patient advocacy, health administration, and biomedical ethics. To qualify for consideration of appointment to the Committee, an individual must possess demonstrated experience and expertise in any of the several disciplines and fields pertinent to human subjects protection and/or clinical research," the notice states.

Nominations, due within 60 days, should include "(1) A letter of nomination that clearly states the name and affiliation of the nominee, the basis for the nomination (i.e., specific attributes which qualify the nominee for service in this capacity), and a statement that the nominee is willing to serve as a member of the Committee; (2) the nominator's name, address, daytime telephone number, and the home and/or work address, telephone number, and email address of the individual being nominated; and (3) a current copy of the nominee's curriculum vitae." Terms are for up to four years. (*11/11/21*)

◆ **The HHS Office of Laboratory Animal Welfare (OLAW) will host a webinar in December featuring officials from the NIH Library and U.S. Department of Agriculture Animal Welfare Information Center** to "discuss how to find 3Rs methods (replacement, reduction, and refinement) and animal use alternative information in bibliographic databases." Most investigators conducting research involving animals are required as part of protocols submitted for approval by institutional animal care and use committees to explain why there are no nonanimal alternatives for the proposed research.

According to OLAW's announcement of the Dec. 9 webinar, "participants will also learn how to find journal articles, patents, NIH-funded research projects, and genetic information related to animal models and model organisms." They hear about "requirements and resources for the NIH Model Organism Sharing Policy." Scheduled speakers for "Best Practices for Conducting a Search for Alternatives and Finding Animal Model/Model Organism Information" are Jessie Kull, a supervisory technical information specialist with AWIC, and Joelle Mornini, an informationist with the library. (*11/4/21*)

◆ **The National Science Foundation (NSF) Office of Inspector General is recommending that NSF require the University of Rhode Island (URI) to repay $627,748**. Auditors "tested more than $1.9 million of the approximately $39.5 million of costs claimed to NSF, and more than $7.8 million in costs reported as cost sharing" on four Established Program to Stimulate Competitive Research awards from January 2011 to August 2020.

"The report highlights concerns about URI's compliance with certain Federal and NSF award requirements," according to the Oct. 15 audit. "Specifically, the auditors found $268,340 of inadequately monitored and inappropriately reported cost sharing, $206,643 in unallowable expenses, $121,719 of inappropriately applied indirect costs, $24,683 of inadequately supported expenses, and $6,363 of inappropriately allocated expenses," the report states. "The auditors also identified two compliance-related findings for which there were no questioned costs: non-compliance with URI policies and insufficient controls related to the application of indirect cost rates." Auditors explained that URI "expressed varying levels of agreement and disagreement with the findings throughout the audit report, agreeing to reimburse, or otherwise credit, NSF for $8,623 in questioned costs, but disagreeing with the remaining $619,125." (*11/4/21*)