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Report on Research Compliance Volume 21, Number 2. January 25, 2024
In This Month's E-News: February 2024

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◆ **The Food and Drug Administration (FDA) is seeking strategies from Jeffrey W. Taub, M.D., to prevent future violations of human subject regulations the agency said were documented during site visits in September and October 2022.** In a Dec. 19, 2023, warning letter posted online, FDA officials said that a six-year-old participant in a trial run by Taub, chair of pediatric cancer research at Wayne State University and a pediatric hematologist/oncologist at Children's Hospital of Michigan, received three additional dosages of an unidentified treatment, causing the child to be "exposed to an increased risk of these toxicities." Additionally, institutional review board (IRB) approval for a study lapsed for a 10-day period in January 2022, but one subject received the study drug, and bone marrow and blood samples were taken during this period, according to FDA.

Taub told the agency by letters in October 2022 and January 2023 "that these additional treatments occurred because a physician subinvestigator misinterpreted the drug administration plan" and that the IRB was notified, FDA said. Taub said the lapse in IRB approval was "attributable to a multitiered review of the continuing review, which delayed the continuing review from being addressed at a timely, regularly scheduled IRB meeting, as well as to staff turnover after submission of a continuing review." FDA was unsatisfied with corrective actions Taub told the agency were or would be, taken, saying the "response is inadequate because you did not include sufficient details about your corrective action plan. For example, you did not provide sufficient details about the policies and procedures that you would institute at your site to ensure compliance with study protocols and to ensure that ongoing and future clinical investigations will be conducted in compliance with applicable FDA regulations." FDA requested, "given the significance of the protocol violation involving a pediatric subject... follow-up documentation regarding the policies and procedures being implemented at your site to ensure compliance with study protocols, including randomization assignments." FDA asked Taub for a response within 15 days of receipt of its letter. He did not respond to a request for comment from *RRC.* (*1/18/24*)

◆ **With funding for HHS and related federal agencies due to run out Jan. 19, the Association of American Medical Colleges (AAMC) urged leaders of the House and Senate to pass appropriations legislation that ensures "appropriate investment in NIH's capacity to support research nationwide to continue making progress against existing and emerging threats to our nation's health, security, and economic competitiveness with global adversaries."** The Jan. 11 letter from Danielle Turnipseed, AAMC's chief public policy officer, said Congress should "enact robust fiscal year (FY) 2024 appropriations for key science, health workforce, and public health programs. In doing so, policymakers will support and protect our nation's medical schools, teaching health systems and hospitals, faculty physicians, and the patients and communities they serve."

AAMC supports funding of $47.7 billion for NIH, as included in S. 2624, the Senate Appropriations Committee's Labor-HHS-Education bill, "in addition to continued funding for the Advanced Research and Projects Agency for Health (ARPA-H)." Turnipseed called the "longstanding, bipartisan federal commitment to medical research" essential to "supporting patients, families, and scientists [pursuing] medical advances against Alzheimer's, cancer, mental health conditions, substance use disorders, and other health challenges that affect people in every congressional district, from urban centers to rural frontiers." The leaders must "reject harmful and misguided cuts to academic medical centers, which would imperil access to care for vulnerable and under-

resourced patients and communities," she concluded. (*1/18/24*)

◆ **In a new report required under the CHIPS and Science Act, the Government Accountability Office (GAO) recommended that the White House Office of Science and Technology Policy (OSTP) coordinate the efforts of NIH, the Departments of Energy and Defense and the National Science Foundation (NSF), among others, which are employing separate policies to manage foreign risks to their funded research and face challenges doing so.** "As the lead for interagency coordination on science and technology policies, OSTP can help agencies collaborate and share information on identifying and addressing complex challenges with foreign ownership," according to the Jan. 11 report. GAO noted that OSTP's recent guidance "does not address the issue of foreign ownership, control, or influence. OSTP officials told GAO that they handle this issue on a case-by-case basis and acknowledged the challenges agencies face in addressing such risks. Information sharing on such complex matters would better position agencies to more fully safeguard" research and development (R&D) funds.

"As part of OSTP's ongoing efforts to address research security risks, the Director of OSTP, in coordination with federal R&D awarding agencies, should facilitate the sharing of information on identifying foreign ownership, control, or influence. This could occur, for example, in conjunction with OSTP's existing efforts to support the national security strategy or its existing role to enhance the federal research agencies' awareness of research security risks and policies under NSPM-33," GAO said. It noted that although OSTP is developing a "strategic document" also required under the CHIPS legislation, "OSTP officials told us they plan to address issues related to foreign entities of concern broadly and do not anticipate addressing foreign ownership, control, and influence directly in the forthcoming strategy." (*1/18/24*)

◆ **The House Education and the Workforce Committee has launched its own investigation into allegations of plagiarism by now-former Harvard University President Claudine Gay, who stepped down Jan. 2.** Plagiarism and other instances of research misconduct such as fabrication and falsification are generally investigated by institutions and federal agencies, such as the NSF Office of Inspector General and the HHS Office of Research Integrity. In a letter to Harvard sent last month, chairwoman Virginia Foxx, R-N.C., said her committee is reviewing Harvard's "handling of credible allegations of plagiarism" against Gay spanning her 24-year history with the university.

Foxx is seeking a host of documents, including those connected with "the initial allegations of plagiarism" and Harvard's review of Gay's scholarship; and "all meeting minutes, transcripts, notes, coordinating communications, memoranda, or other materials relating to any discussion of this issue by the Harvard Corporation and Board of Overseers." Foxx also asked for "documents and communications concerning allegations of plagiarism" against Gay and "a list of any disciplinary actions taken against Harvard faculty or students on the basis of academic integrity violations, research misconduct, inadequate citation, or other forms of plagiarism, from January 1, 2019, to present. This list should include an anonymized description of the subject of discipline, the date of the alleged misconduct, dates of any adjudicatory or disciplinary meetings, whether any outside counsel or supportive individual was permitted (and whether such an individual was present), and any disciplinary action imposed." The documents were due to Foxx by Dec. 29. (*1/11/24*)

◆ **The HHS Office for Human Research Protections (OHRP) is seeking nominations from individuals wishing to serve on the Secretary's Advisory Committee on Human Research Protections (SACHRP).** According to a notice in the *Federal Register*, nominees "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 11-member committee typically meets three times a year often virtually; members serve three- or four-year terms. Material submitted for nominees 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." People may self-nominate. Committee membership is not open to federal employees. OHRP said it was looking to fill two positions that will be "vacated during the 2024 calendar year." However, it is already down two members, with nine currently serving. (*1/11/24*)

◆ **FDA has issued a final rule implementing provisions in the revised Common Rule that address IRB waiver of informed consent for minimal risk studies.** The rule finalizes a proposed regulation issued in November 2018. "For an IRB to approve a waiver or alteration of informed consent requirements for minimal risk clinical investigations, the rule requires an IRB to find and document five criteria that are consistent with the revised rule," the agency said.

The criteria are: "(a) The clinical investigation involves no more than minimal risk to the subjects; (b) The clinical investigation could not practicably be carried out without the requested waiver or alteration; (c) If the clinical investigation involves using identifiable private information or identifiable biospecimens, the clinical investigation could not practicably be carried out without using such information or biospecimens in an identifiable format; (d) The waiver or alteration will not adversely affect the rights and welfare of the subjects; and (e) Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation." FDA noted that it is still working on other rulemaking to address the ability for IRBs to forgo continuing review for research deemed eligible for expedited review. The rule takes effect Jan. 22. (*1/11/24*)