

Report on Research Compliance Volume 21, Number 8. August 01, 2024 In This Month's E-News: August 2024

By Theresa Defino

◆ **The Food and Drug Administration (FDA) has given Massachusetts Institute of Technology (MIT) 15 days from receipt of its June 21 warning letter to elaborate on corrective actions to address violations of federal requirements for informed consent and institutional review board (IRB) operations identified during a 2023 remote regulatory assessment.** After their May 30 to June 9, 2023, assessment, agency officials shared with MIT various “observations” and asked MIT to address them, which occurred on June 30, 2023, FDA said. However, the responses are insufficient. FDA “determined that your IRB violated IRB regulations, as published in Title 21, Code of Federal Regulations (CFR) Part 56,” the letter said. “The applicable provisions of the CFR are cited for each violation listed below. The violations include, but are not limited to the following: failure to ensure that information given to subjects as part of informed consent is in accordance with 21 CFR 50.25 [21 CFR § 56.109(b)]” and “failure to prepare and maintain adequate documentation of IRB activities [21 CFR 56.115].”

FDA provided several examples related to informed consent failures. MIT’s IRB failed to ensure that a study’s informed consent documents “included a disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject, as required by 21 CFR 50.25(a)(4).” Other informed consent forms for more than minimal-risk research failed to “include an explanation as to whether any compensation is available if injury occurs and, if so, what it consists of, or where further information may be obtained as required.” Some forms did not “include a statement that notes the possibility that the FDA may inspect the records.” Regarding IRB operations, FDA said some meeting minutes didn’t accurately track member participation and votes; member names weren’t always current and “lists did not include IRB members’ earned degrees, representative capacity, or indications of experience such as board certifications, licenses, etc., sufficient to describe each member’s chief anticipated contributions to IRB deliberations.” FDA said MIT needs to provide a “description of the standard of care approaches that will be added to the [consent forms] for the identified protocols” and recommended that “a roster of active members at the time of the meeting should be prepared and appended to the respective meeting minutes,” among the actions MIT should describe in its response. (7/25/2024)

◆ **The National Science Foundation (NSF) on July 24 announced a five-year award to create the Safeguarding the Entire Community of the U.S. Research Ecosystem (SECURE) Center, which it said “will serve as a clearinghouse for information to empower the research community to identify and mitigate foreign interference that poses risks to the U.S. research enterprise.”** The center “will share information and reports on research security risks, provide training on research security to the science and engineering community and serve as a bridge between the research community and government funding agencies to strengthen cooperation on addressing security concerns,” NSF said.

The center “will also serve as the nexus for five regional centers managed by six institutes of higher education: SECURE Northeast—Northeastern University; SECURE Southeast—Emory University; SECURE Midwest—University of Missouri; SECURE Southwest—The University of Texas at San Antonio and Texas A&M University; and SECURE West—University of Washington. Additionally, Mississippi State University, University of Michigan and Stanford University’s Hoover Institution “will provide expertise on sensitive research, threat types,

geopolitical analysis and international collaboration. Participation by the College of Charleston and Mississippi State University, located in NSF Established Program to Stimulate Competitive Research jurisdictions, ensures that emerging research and minority-serving institutions are included in SECURE Center activities.” In terms of funding amounts, NSF said \$50 million would go to University of Washington and \$17 million to Texas A&M. (7/25/2024)

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