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In This Month's E-News: October 2021

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◆ **An audit by the HHS Office of Inspector General (OIG) of the National Human Genome Research Institute's (NHGRI) pre-award risk assessment process** concluded that "some risks associated with foreign applicants and applicants demonstrating higher risk factors may not have been identified and mitigated before grant funds were awarded." OIG reviewed 32 grant awards, totaling $107.9 million, and found that "NHGRI generally had adequate policies and procedures in place for assessing risk in its grant pre-award process when awarding grant funds."

But OIG also made a series of recommendations, including that NIH direct NHGRI to "(1) improve its policies and procedures to ensure Grants Specialists monitor whether required audit reports are submitted for foreign applicants; (2) clarify existing procedures to specify when Grants Specialists should take additional steps, including the imposition of specific award conditions, to mitigate risk for new grantees; and (3) update policies and procedures for Grants Specialists to require that they review available Internal Revenue Service (IRS) Form 990s regarding grant applicants' risk factors before awarding grant funds." In its response to the draft report, NIH said it had already implemented the second recommendation and that it "plans to issue enhanced guidance to monitor whether required audit reports are submitted for all applicants, not limited to foreign entities." Additionally, NIH "stated that it will review its pre-award risk assessment policies and procedures and integrate the review of available IRS Form 990s where appropriate. NIH plans to complete this process by the summer of 2022," OIG said. (*9/16/21*)

◆ **The HHS Office for Human Research Protections (OHRP) will hold a one-day "exploratory" workshop Sept. 24 to address risks that third parties may face and "potential protections" for them**. Scheduled for 9:45 a.m. to 4 p.m., the workshop is designed to "provide a platform for open dialogue and exchange of ideas between stakeholders in the regulated community," OHRP announced. The workshop will "identify third parties impacted by research and consider what types of risks they might face in a variety of studies"; "consider whether researchers and the research community have a responsibility, moral or otherwise, to protect third parties and, if so, in what capacity"; "review real-world examples for potential protections against research risks to third parties"; and "reflect on the role of institutional review boards (IRBs) for protecting third parties."

The first of two sessions will address what is meant by third parties in research and the "rights and protections" they may merit. The second session will focus on whether IRBs "have a role in the review of third-party research risks." Speakers and moderators include Leslie E. Wolf, Georgia State University College of Law and School of Public Health professor and former member of the Secretary's Advisory Committee on Human Research Protections, and Daniel M. Hausman, research professor at Rutgers University's Center for Population-Level Bioethics. The free workshop will be live-streamed, and registration is not required. (*9/16/21*)

◆ **The Howard Hughes Medical Institute has terminated its relationship with biologist David Sabatini for sexual harassment and other workplace misconduct, following an external investigation by a law firm**. Sabatini also resigned from the Whitehead Institute and his tenured position at the Massachusetts Institute of Technology (MIT) is under review, according to *Science.* The publication's reporting and public Twitter posts of internal emails revealed that complaints emerged about Sabatini's 39-person lab as the result of a survey of Whitehead

Institute workers conducted last winter. In an email posted on Twitter, Whitehead Institute Director Ruth Lehmann said on Aug. 20 that Sabatini "violated the Institute's policies on sexual harassment among other Whitehead policies unrelated to research misconduct." MIT placed Sabatini on administrative leave, according to a letter to biology faculty members by Nergis Mavalvala, dean of MIT's School of Science, that was posted on Twitter. (*9/2/21*)

◆ **Two researchers at a private firm in Miami were recently sentenced to several years in prison after pleading guilty for falsifying research data in clinical trials**. Eduardo Navarro was sentenced to 46 months in prison and Nayade Varona to 30 months, and collectively they were also required to pay $2,134,503 in restitution, according to the Department of Justice. Navarro and Varona worked at Tellus Clinical Research; Navarro was a nurse practitioner and "sub-investigator," while Varona was an assistant study coordinator, according to DOJ. "As part of their plea agreements, Navarro and Varona admitted that they conspired with others to falsify data in connection with two clinical trials by, among other things, fabricating medical records to make it appear as though subjects were participating in the clinical trials when, in truth, they were not."

The case is a continuation of one that first came to light this spring. In March, DOJ announced that Tellus Research employee Dr. Martin Valdes and associates Fidalgis Font, Julio Lopez and Duniel Tejeda were indicted in February on six charges of "conspiracy to commit mail and wire fraud and at least one substantive count of mail fraud. In addition, Valdes and Font were charged with money laundering and Valdes was further charged with making a false statement" to Food and Drug Administration inspectors. Their cases are still pending at the time, DOJ said. Dr. Valdes was the "primary investigator for the clinical trials conducted at Tellus, Font was the owner of the business, and Lopez and Tejeda were senior Tellus employees." (*9/2/21*)