

Report on Research Compliance Volume 16, Number 3. March 01, 2019 In This Month's E-News: March 2019

By Theresa Defino

♦ In a one-page ruling, District Court Judge Karin Crump of the District Court of Travis County, Texas, has determined that the University of Texas Austin did not have "express" or "implied authority" to revoke the Ph.D. of a former graduate student in 2014. According to Retraction Watch, Suvi Orr's Ph.D. was revoked in 2014 after it was found that "scientific misconduct occurred in the production of [her] dissertation," leading to several legal challenges.

At one point the university reversed itself but attempted to revoke the degree a second time. In 2017, a judge granted an injunction against further action by the university until a ruling could be made "on the central case," which occurred Feb. 11. In a statement to *Retraction Watch*, university officials said they "respectfully disagree" with the ruling and are weighing their next steps. (2/14/19)

♦ In a Feb. 5 determination letter, the HHS Office for Human Research Protections (OHRP) informed Columbia University Medical Center that corrective actions it took after failing to file a timely report of an unanticipated problem were adequate. The email addresses of 145 subjects in an HIV-related study were visible in an email a coordinator sent inviting participation in an upcoming research project, according to the letter. The exposure of the information constituted a "breach of subject confidentiality that represented an unanticipated problem involving risks to subjects or others. This problem should have been reported to OHRP promptly," the agency said. Although the study coordinator informed the institutional review board of the breach in November 2016, OHRP had not been notified by the time it received the complaint several months later.

OHRP contacted the medical center in February 2017, the same month it received the complaint; it was not until April of that year that OHRP received the unanticipated problem report and a list of corrective actions. The medical center said it was still investigating the incident at the time it first heard from OHRP. The corrective actions included terminating the study coordinator's employment, providing additional staff training in HIPAA, sending an apology letter to subjects, and temporarily pausing recruitment "until a secure process for sending recruitment emails to potential participants was fully developed and implemented," according to OHRP's letter. OHRP did not address whether the email constituted a HIPAA violation and whether it was reported as required to the Office for Civil Rights if it was. (2/14/19)

This document is only available to subscribers. Please log in or purchase access.

Purchase Login