

Report on Research Compliance Volume 17, Number 9. August 20, 2020

Lehigh U. Compliance Plan Provides Blueprint for Oversight, Audit Schedule

By Theresa Defino

As part of its recent settlement with the Department of Justice regarding allegations of False Claims Act (FCA) violations, Lehigh University of Pennsylvania is implementing an oversight and training structure that could serve as a template for others with federal research dollars, according to the compliance plan obtained by RRC.

Lehigh, based in Bethlehem, agreed to follow the two-year plan and pay \$200,000 in connection with the 2015 conviction of a former Lehigh professor and his wife for duping both the university and several federal agencies through the creation of a sham research firm called ArkLight.^[1] The university also separately implemented a number of other policies and procedures, according to information the university provided to RRC.^[2]

The unusual, government-endorsed plan applies broadly, consisting of “compliance requirements [to be followed] in connection with any application seeking federal grant funds or cooperative agreements with any federal agency,” William McSwain, U.S. attorney for the Eastern District of Pennsylvania, announced July 31.

Plan Requires Certain Roles, Responsibilities

Under the compliance plan, Lehigh must “continue to support” a series of positions and policies during the term of the settlement, indicating they were already established at the time of the settlement. It also must create new policies and a research handbook, institute employee training at specified intervals, conduct periodic audits of its own compliance with the plan, and submit reports to the U.S. government.

The oversight structure calls for a central office and specific individuals with prescribed duties. The following are the components of the program.

- Overseeing research projects is the Office of Research and Sponsored Programs (ORSP), “which provides research proposal planning, preparation, submission, and research grant award management services” to Lehigh.
 - An assistant vice president (AVP) of research and sponsored programs “oversees and is ultimately responsible for the operation” of the ORSP. “The AVP develops policies, procedures, and systems, and leads staff to ensure quality of service to research faculty and investigators as well as full compliance with research sponsor and regulatory requirements.”
 - An associate director of the ORSP “supervises non-exempt staff in the ORSP; provides oversight, management and appropriate stewardship of sponsored funding; maintains a broad interface with sponsors and the research and educational communities; interprets, implements and monitors government and sponsor mandates as they effect the management of grants and contracts; and provides advice and training in relevant areas of sponsored research.”
 - A director of research policy and compliance is described as Lehigh’s “primary research compliance
-

position.” This individual, who reports to the vice president and associate provost for research and graduate studies, “is responsible for overseeing the administration, support, monitoring, and assessment of research compliance functions.” He or she “develops, drafts, and implements policies and procedures; sets standards for policy development, implementation, and maintenance and provides appropriate tools and training; monitors federal, state, and local research compliance laws and regulations; and disseminates compliance information to the appropriate university constituencies.”

- A senior research integrity specialist, reporting to the director of research policy and compliance, manages the “workflow” of the institutional review board (IRB) and the institutional animal care and use committee (IACUC) in Lehigh’s Office of Research Integrity.
- A research integrity specialist, who also reports to the director of research policy and compliance, “is responsible for supporting the workflow of the IRB and the IACUC in the Office of Research Integrity.”
- A conflicts of interest review committee reviews “potential or actual conflicts of interest arising in research, and make[s] decisions regarding management, avoidance, or elimination of conflicts of interest in research.” The committee is composed of five voting members—“four faculty” and an administrator appointed by the provost. The university will “use its best efforts” to fill positions on the committee that become vacant during the two-year term of the agreement.

This document is only available to subscribers. Please [log in](#) or [purchase access](#).

[Purchase Login](#)