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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
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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.

Numerous Policies Were Updated

According to the settlement, Lehigh recently updated a number of policies and guidance that “aid in the detection and prevention of research fraud and abuse.” During the settlement term, Lehigh “will maintain these improved policies and guidance.”

Among the topics addressed in policies are eligibility to serve as a principal investigator; how research administration policies themselves are developed, revised and posted; financial conflicts of interest; cost allocation; and record retention of research data and materials.

Guidance documents address eligibility to serve as a principal investigator; managing conflicts of interest for investigators who have financial interests or operational roles in companies sponsoring university research; and faculty ownership and operation of businesses, consulting, and other external professional or business activities.

The settlement agreement also requires Lehigh to “draft, review and/or revise” a new set of policies and guidance to “aid in the detection and prevention of research fraud and abuse.” Due within five months of the settlement agreement, these are to address subcontracting, additional compensation for research faculty, and proposal submission deadlines.

Research Handbook, Hotline Required

Within one year of the July 31 effective date of the agreement, Lehigh must develop two other policies: one on conflicts of interest and another on the “Ethical Conduct in Academic Research, Scholarship and Creative Activities.”

A research handbook must be finalized by next July. The agreement provides little information about the handbook, besides noting that active research faculty “will be required to acknowledge receipt and review” of it.

Regarding training, the agreement calls for Lehigh to “continue to provide training and education on research compliance, including training on University policies and applicable federal law and regulations, to staff within the ORSP and to faculty engaged in, administering, and/or supporting research.” It does not specify a required

form of training, stating it “may include educational pamphlets, videos, intranet systems, in-person training, and explanatory memos.” Materials should be “tailored to correspond with the employee’s daily tasks.”

ORSP staff who are “newly hired” should receive training within two months of starting their job. Faculty “engaged in, administering, and/or supporting sponsored research” are to be trained within three months. Lehigh must “maintain records of who received training, the dates of training, and the subject matter of the training.”

The settlement notes that Lehigh’s research and related policies are available online at <https://bit.ly/2E4a6xV>.

“This webpage will provide notice of the promulgation of new or revised policies and procedures and links to additional helpful information,” and Lehigh should make the website known in its training and education.

A web-based ethics hotline that currently exists will be maintained; this “utilizes an outsourced third party platform for any faculty, staff or student to report (including an option to report anonymously) incidents of non-compliance with University policies, legal requirements, or University ethical codes or any behavior inconsistent with University professional or behavioral standards.”

As noted earlier, Lehigh must report to the government on its adherence to the compliance plan. Specifically, at six months and 12 months from the July 31 date, the university’s internal audit department will “review its adherence to the compliance portions” of the settlement that refer to staffing, training, and policies and procedures, among others.

The reports aren’t due right away, however. Although they will be conducted at six and 12 months, the results of the audits don’t have to be sent to the government until 14 months after the effective date of the settlement.

Investigative Processes Must be Maintained

However, should the audits uncover “material non-compliance” with the settlement agreement, Lehigh has 60 days to “cure” it and to “propose an adequate plan of correction.” Then, within 15 days after the 60 days has passed, the audit department “shall report its finding and transmit the plan of correction to the United States and shall include a certification that: (i) the University has (or has not) cured the cited material non-compliance; and (ii) the plan of correction is (or is not) appropriate.” The government may review the plan and propose changes, with the concurrence of the audit department, that Lehigh would be required to implement within 30 days or longer if the parties agree that more time is needed.

Lehigh will keep in effect its ethics policy, which requires a “multi-tiered inquiry and investigation process of complaints of research misconduct” and continue to adhere to its policy for “when and how a faculty member will be dismissed for cause.”

Unrelated to specific compliance tasks, the agreement calls for Lehigh to refrain from billing the government for unallowable costs on awards, and to make an accounting of—and repay—any possible past unallowable costs. That report and any overpayments are due within 90 days of the settlement. The government notes it is “entitled, at a minimum, to recoup from Lehigh University any overpayment plus applicable interest and penalties as a result” of payment of any such costs.

1 Department of Justice, U.S. Attorney’s Office for the Eastern District of Pennsylvania, “Lehigh University Agrees to Pay \$200,000 Settlement to Resolve False Claims Act Allegations Arising from Convicted Professor’s Grant Fraud,” news release, July 31, 2020, <https://bit.ly/3fXxLNn>.

2 Theresa Defino, “Deception by Professor Costs Lehigh \$200K As Yet Another University Settles an FCA Case,”

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