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Focusing on Whistle-Blower Not Best First Step for Sites

When sites are hit with a federal inquiry stemming from whistle-blower allegations, they often make the mistake of first trying to figure out who blew the whistle, an expert says.

"Whatever agency is making the inquiry — FDA, OHRP, NIH — the first necessary step is to address the allegations and worry about who maybe gave information to [the regulatory agency] later," Mark Rogers with the Rogers Law Firm in Massachusetts told *CTA*. If sites try to investigate who blew the whistle as a first step, they risk retaliation claims, he added.

"The issue is common at academic medical centers and teaching hospitals," Rogers said. "The problem is that they don't usually happen on the clinical trial side." But recently, sites have found themselves subject to whistle-blower allegations.

Suzanne Stratton, the former vice president for research at the Carle Foundation Hospital, filed suit last November in the U.S. District Court for the Central District of Illinois, Urbana Division, alleging she was fired in retaliation for her repeated warnings that the Carle Hospital and the Carle Clinic had violated federal regulations intended to protect cancer patients enrolled as subjects in clinical trials (*CTA*, Nov. 12).

The same month, HHS' Office of Human Research Protection (OHRP) sent determination letters to Children's Hospital of Philadelphia, Cincinnati Children's Hospital Medical Center and the University of California, San Francisco, clearing clinical sites of whistle-blower allegations about the conduct of a trial comparing treatments for twin-twin transfusion syndrome (*CTA*, Dec. 10).

When they become aware of whistle-blower allegations, sites should begin an internal investigation as quickly as possible, J. Michael Slocum, senior member of the Virginia law firm Slocum & Boddie, told *CTA*.

Sites should report the findings from internal investigations to the appropriate regulatory body before the agency starts its own investigation, Slocum said.

"This tends to insulate institutions," he added. "You get into pretty tense negotiations sometimes about when you knew [of the allegations] and so forth."

Prevention

Sites can prevent whistle-blower allegations by encouraging employees to raise issues of misconduct internally, Jill Williamson, a lawyer with the Washington, D.C.-based law firm Patton Boggs, told *CTA*.

"You want to demonstrate that these issues will be taken care of," she said. "If an employee feels that his or her complaint is taken seriously, then an organization is less likely to be retaliated against overtly or covertly."

Establishing a complaint-handling mechanism also could help mitigate a problem that's subject to enforcement, Williamson added.

Internal communication is important once allegations have been made. "When there's an inquiry, it's key to have everyone on board to what's going on," Rogers said. "You want to have a united front in responding to allegations, making sure the sponsor, or sponsors, are involved, as well as clinical trial employees, the administration, risk

management divisions, in-house counsel and investigators."

Williamson refers researchers to the HHS Office of Research Integrity's website on how to properly handle complaints of misconduct. A sample of policy and procedures for responding to such allegations is available at ori.dhhs.gov/policies/documents/SamplePolicyandProcedures-5-07.pdf. — Owen Skoler

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