

Report on Research Compliance Volume 17, Number 8. July 23, 2020 UTMB Shares Strategies to Reduce Noncompliance with COI Policies

By Theresa Defino

When confronted with an allegation of violating a conflict of interest (COI) policy, faculty and employees will commonly claim they just didn't know they had done anything wrong. "So, it's vitally important that employees have an awareness or an understanding of the relevant regulations and institutional policy," said Craig Conway, associate vice president of institutional compliance at the University of Texas Medical Branch (UTMB) in Galveston.

An employee who is noncompliant due to ignorance is likely to face a different institutional response than a "person who knew the requirements and then willfully chose to ignore them," he added. Conway recently discussed different types of COI policies during a session at the HCCA Research Compliance Conference.^[1]

In terms of how institutions should respond, knowing the reason will help officials select the appropriate sanction.

Different Types of Noncompliance

During the talk, Conway listed five common types of noncompliance with research COI policies, adding that the list is not exhaustive.

- Failure to complete annual disclosure(s)
- Leaving off entities from a disclosure
- Failure to complete training requirements prior to the initiation of research
- Failure to comply with a management plan
- Noncompliance with action required by, for example, an institution, COI committee, institutional review board or institutional official

With some overlap, Conway listed the following examples of nonresearch noncompliance:

- Failure to complete annual disclosure(s)
- Prohibited speaker's bureau activity, if applicable per institutional policy
- Outside clinical activity that conflicts with policy
- Collaboration with a foreign entity without prior approval or disclosure
- Failure to comply with a management plan
- Noncompliance with an institutional decision or one by a COI committee

Conway also pointed out that the consequences of COI noncompliance are likely to be "different than other types

of noncompliance.” COI noncompliance can have “a little more narrow” impact on an institution, but it also has the “potential to be very much broadened or expanded,” he said.

He termed “negative media attention...the biggest thing we’ve seen that could be tied directly to COI noncompliance.” But Conway also pointed out that the government has increasingly focused on COI issues related to lack of disclosure of foreign support and that institutions may also be subject to “adverse action,” including fines. Institutions may also find their reputations are damaged if they are perceived to have COI programs that are “weak and ineffectual.”

Institutions or physicians that are noncompliant with Stark anti-kickback rules and the False Claims Act (the latter of which may also be research-funding related) may face fines and other consequences, Conway said.

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