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Pricey Patient Gift Presents COI Challenge; Research Is In the Spotlight

By Theresa Defino

Research subjects and patients may wish to show their thanks in any number of ways. For one physician, that gratitude came in the form of a Mikimoto pearl necklace, a treasure that, at least online, can cost more than \$100,000, depending on style and features.

But it wasn't just the value of the necklace that got Craig Conway's attention.

For Conway, associate vice president for institutional compliance at the University of Texas Medical Branch (UTMB), it was also a matter of the patient coming from a culture whose members would feel deeply insulted if the pearls were returned.

"We were in a predicament where we couldn't really give them back," Conway said. But the physician keeping the pearls also would have gone against UTMB's gift policy and possibly may have violated Texas law, he explained during a presentation on managing conflicts of interest (COIs) at HCCA's virtual Research Compliance Conference^[1] in June.

Gifts are one of many challenges in this arena. Another is foreign support for research. Violations of COI-related requirements have become an urgent matter due to recent failures to disclose foreign research support.^[2] The National Institutes of Health is investigating about 400 researchers, and has determined that of about half it has probed in more detail, 70% had an undisclosed foreign grant, and 54% had failed to disclose support from the Chinese government's Thousand Talents Program.^[3]

Multiple Policies Address COIs

UTMB's gift policy, Conway said, is combined with ethics and is just one of five COI policies. Other policies address:

- Research-related COIs.
- Individual COIs.
- Interactions with industry sponsors.
- Vendor/purchasing disclosures.
- Federal reporting and disclosure laws, such as the Physician Payments Sunshine Act.

Foundational to any COI discussion is an understanding of what constitutes a COI. While noting there are a number of definitions of a COI, Conway said he prefers the University of Florida's, which defines it as "when an individual's financial, academic, professional, commercial or personal interests or activities outside of the institution [affect, or appear] to affect, their professional judgment or obligations to the institution."

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