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Rethinking conflict of interest training

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As part of a robust corporate compliance program, many organizations will require periodic disclosures of financial interests and relationships, including some familial relationships and certain outside activities, from board members, senior leaders, and other designated employees. For healthcare-centric organizations, such as large multidisciplinary healthcare providers and academic medical centers, researchers, faculty, physicians, advanced practice providers, and other key personnel must also periodically disclose their financial interests to the organization.

Usually organizations require these disclosures on an annual basis. Disclosures are also expected to be updated promptly—with an exact time frame that is defined by institutional policy—when an employee’s financial interests, relationships, outside activities, and familiar interests and/or relationships change. Depending on an organization’s size, this can amount to hundreds, if not thousands, of individuals providing disclosures on an annual basis.

Training requirements

Those hundreds to thousands of employees submitting disclosures should receive training. The Public Health Service (PHS) regulations^[1] for research funded by PHS (e.g., through the National Institutes of Health) require training on conflict of interest (COI) prior to engaging in research related to any PHS-funded grant and then once every four years, or more often if there is a change in institutional policy that affects disclosure requirements, and immediately when an investigator is noncompliant with institutional policies.^[2] Investigators with ongoing PHS-funded research who change institutions must also receive training at their new institution.

Another relevant regulatory agency for healthcare organizations, the Food and Drug Administration, also maintains its own set of COI-related regulations and the associated guidance for financial disclosures by clinical trial investigators.^[3] However, those regulations are silent on the subject of training.

Most organizations establish a periodic training requirement, regardless of whether the PHS regulations are applicable to them. Over the past few years, providing COI or related training has become a best practice within healthcare compliance. Training focused on COI can certainly contribute to an organization’s and compliance office’s successful efforts to maintain employee compliance to organizational and applicable federal disclosure requirements.

Training goals

COI training should facilitate and confirm employee understanding of financial and other COIs based upon institutional policies and definitions and enable them to identify sources of COIs while performing their job.

Employee identification of sources of potential COIs can help them avoid problematic relationships and activities that could jeopardize the unbiased execution of their job responsibilities, result in institutional action, and/or harm the institution's reputation.

Ensuring that employees are knowledgeable about what constitutes financial and other interests that must be disclosed, and when, to their employers facilitates compliance to PHS and Food and Drug Administration regulations and enhances an organization's compliance efforts. It also assists with organizational compliance to the Internal Revenue Service Form 990 requirements for nonprofit organizations. A specific obligation within Form 990 is the reporting and description of board members' COIs.^[4] Related regulations provide a definition of a conflict of interest for the purpose of Internal Revenue Service reporting, a definition that focuses on compensation and/or property transfers received.^[5]

Training should also explain to employees the mechanisms by which the organization will manage or require the elimination of any identified COIs. Providing that information prior to any institutional action taken with respect to the conflict, which typically occurs in the form of issuing the employee a management plan, requiring divestiture of the interest, or requiring the discontinuation of a problematic relationship or financial interest, can help prepare disclosers for what will be expected from them as everyone works toward the best way to ensure ethical and compliant behavior.

Providing training, ensuring disclosures are submitted, eliminating nonpermissible COIs, managing identified COIs, and mitigating continuing COIs collectively represent the core of an entity's financial COI program.

Unfortunately, two common COI training philosophies do not represent the best overall approach to fully support an organization's financial COI program. The first approach is an overreliance on the training to equip employees with a thorough understanding of COI, which can encourage employees to self-identify their COIs, or COIs that others may have, rather than rely on the organization's decision-making process for final COI determinations. This leads to the self-management and nondisclosure of COIs—employees may feel that since they have taken certain actions, no conflict exists, which circumvents the organization's structure that is meant to identify, eliminate, mitigate, and manage COIs. The second approach involves the incorporation of COI training into stand-alone/annual general compliance training, perhaps as part of a one-hour session as recommended by the Office of Inspector General, where it becomes even more difficult to thoroughly review the relevant material and underscore the importance of the process.

PHS requires that training be provided on institutional policies, individual responsibilities for disclosing, and relevant regulations.^[6] Notably absent in these training requirements is instructing individuals about what constitutes a COI and how COIs may be managed, as those are the actions to be taken by the institution, rather than the individual employee.

Just-in-time training

Compliance professionals know that the list of employee financial interests, outside activities, familial relationships, and other pursuits that could result in a financial and other COI is long and ever-changing. Even the most comprehensive training will probably fall short in covering all of the potential ways COIs are created or identified.

A better way to approach COI training is through a just-in-time (JIT) model that focuses primarily on educating employees about what they must disclose. Under this model, training incorporates the needed information at the time that the individual needs it most. The time when COI training is needed most is immediately before employees submit their disclosures, which is usually done on an annual basis.

There are several advantages to the JIT approach:

- COI JIT training becomes disassociated with mandatory compliance training, thus ensuring a more significant emphasis on COI and the disclosure process.
- COI training becomes meaningful and actionable, two components of effective adult learning training programs.^[7]
- COI training highlights organizational COI policy requirements and describes exactly what disclosers need to make known during the disclosure process. This can improve compliance during the disclosure process by providing employees with immediate access to resources to assist with disclosing.

Better training and preparedness for the disclosure process increases the chances that individuals will submit more accurate disclosures on time, translating into an organization's enhanced ability to identify, eliminate, mitigate, and manage COIs.

The ideal structure for COI JIT training is to have the discloser first be presented with the training module that covers the requisite information, preparing them for the disclosure process. Completion of the training module should be compulsory. An employee should not be able to begin the disclosure process until they have successfully completed the training module.

Implementing JIT training

To move toward a JIT approach with COI training, an organization will likely have to move away from traditional in-person instruction or commercially provided online modules for delivering the required COI training (since this article is being written during the COVID-19 pandemic, in-person instructions will not be discussed as an option even though they are preferred by many compliance specialists).

Commercially available online modules often focus exclusively on COI regulatory requirements (e.g., PHS), which may or may not be relevant to nonresearch-based organizations. Or, such modules may focus excessively on how employees can and should identify and manage their own perceived conflicts without giving adequate directions on exactly what to disclose or how the organization may elect to manage or eliminate such conflicts (leading to self-management of perceived conflicts by individuals within the organization). Since the determination of what constitutes a financial or other COI is highly dependent on an organization's definition of COIs and associated policies, it is nearly impossible for any commercially available COI training module to effectively convey an organization's unique COI viewpoint. Therefore, to achieve a more targeted training outcome with JIT training, some level of customization, which may or may not be offered with commercial training modules, will almost always be necessary.

Instead, tailored content should be developed to present policy requirements and walk disclosers through the disclosure process based on the institution's policies, along with applicable regulatory requirements. Training content should also review how the information they provide allows the institution to identify and manage COIs. More timely and relevant education at this point translates into better information within the COI disclosure itself, enabling the improved reviews of disclosures and determinations on any COIs. Tailored content also allows for the ability to quickly revise the module based on changes to regulatory expectations and/or institutional policies.

Other ideas for training content include supplying links to organizational policies, questions to test learner knowledge, and scenarios that also provide a bit of storytelling about COI expectations (scenarios or hypothetical examples emphasizing and identifying potential COIs are best included here). All of these tactics represent

additional adult-learning-focused training strategies.^[8]

Given the importance of COI to every employee, once COI JIT training is launched, a high-level overview of pertinent COI policy requirements can still be included within mandatory compliance training. However, that training can be shortened and highlight relevant policies, as well as refer to the JIT training as the required training for disclosers, assuring individuals who have to disclose that they will get the information when they need it so they can remain compliant.

Takeaways

- The Public Health Service’s regulations provide the most recognized requirement for training on conflicts of interest in healthcare workplaces, but they are focused exclusively on conflicts arising due to the conduct of research.
- Just-in-time training provides an alternative to annual compliance training for delivering conflict of interest training.
- Just-in-time conflict of interest training can facilitate improved compliance to institutional policies as well as enhance the identification and management of disclosed conflicts through better disclosures.
- Just-in-time training can be a superior form of training because it incorporates elements of proven adult-learning-focused training strategies and tactics.
- Commercially available conflict of interest online training modules may be insufficient for just-in-time training, and customization may be required to adequately prepare employees for the disclosure process.

¹42 C.F.R. § 50 .

² Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought and Responsible Prospective Contractors, 76 Fed. Reg. 53,256, 53,268 (August 25, 2011) .

³21 C.F.R. § 54 .

⁴ U.S. Department of the Treasury, Internal Revenue Service, “Form 990: Return of Organization Exempt From Income Tax,” at 6, revised January 2020, <https://bit.ly/3dEop6R>.

⁵26 C.F.R. § 53.4958-6 .

⁶42 C.F.R. § 50.604(b) .

⁷ Banan Abdulrzaq Mukhalalati and Andrea Taylor, “Adult Learning Theories in Context: A Quick Guide for Healthcare Professional Educators,” *Journal of Medical Education and Curricular Development*, April 10, 2019, <https://bit.ly/3dH9Uly>.

⁸ Banan Abdulrzaq Mukhalalati, “Adult Learning Theories in Context.”

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