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Managing COI and foreign influence in research: strategies for success

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Conflict of interest (COI) and foreign influence in research issues have recently affected prominent healthcare and academic institutions. The subsequent news coverage, investigations, and high-level resignations are a call to action for organizations to review their COI programs and learn from these public failures. Here we offer eight strategies to consider to strengthen current COI programs and advance objectivity and legality in clinical care, research, and business decisions.

Healthcare and academic COI programs are charged with identifying; reviewing; and, as appropriate, managing potential COI and foreign influence for employees and the organization. While regulation exists around COI requirements, including research funded by the Public Health Services (PHS),^[1] disclosure of investigator interests to the FDA,^[2] and IRS requirements around 501(c)(3) status and related Form 990, COI-related risks are also reputational. As witnessed particularly over the past two years, organizations are hindered when patients, payers, vendors, donors, and the public do not have confidence in their ability to make unbiased, ethical decisions.

The following strategies can be considered to better identify and mitigate potential conflicts and influence to meet the standards and expectations of regulators and the patients and communities your organization serves.

Tone at the top

An organization's leaders are at a higher risk of potential COI issues due to the inherent authority and profile of their roles. Consider a routine review of COI disclosures by leadership at the executive vice president (or comparable) level and above by a COI or compliance governing body, such as the COI or audit and compliance committee. Additional oversight of these high-profile and high-risk disclosures can promote proper conflict identification, raise awareness of management strategies, and provide ethical guidance by example for employees.

Board-level conflicts

The board of trustees (or a comparable entity) should receive regular reports on the activities of the COI program, including status of the annual disclosure campaign, updates to relevant policies, and training on COI-specific issues at orientation and annually thereafter. Board members are often required to disclose their own financial interests and external relationship, and their disclosures are reviewed by the chairman of the board and office of general council. As with leadership, board members are in positions of power and influence, so additional COI oversight is essential.

COI committee

A leading practice is to establish a COI committee that includes multidisciplinary members representing key areas of your organization affected by COI (e.g., clinical care, research, technology transfer, human resources, supply chain, compliance, legal, development). The committee's role is to review and decide on COI disclosures, management plans, and other conflict-mitigation strategies. The COI committee should be founded by a charter, meet regularly and often enough to process timely the volume of reviews, and have final say in the decision-making process when reviewing a case. Further, we suggest the COI committee form subcommittees to focus oversight on high-risk relationships (e.g., a related start-up) or particularly complex cases.

The COI committee should report at least quarterly to the audit and compliance committee (or comparable Board-level committee) on the status of disclosure review, management plans, and other significant COI-related issues across the organization.

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