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Navigate the Compliance Universe

Compliance Today - December 2022

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The benefit of cross collaboration between research and corporate compliance for conflict-of-interest management

By Arinayo Apara, DrPH, MPH, CCRP, CHES and Patricia Cooper, JD, RN, PNP, CHC

Compliance professionals are tasked with managing conflicts of interest (COI) in a constantly growing field. Institutions and healthcare organizations that conduct research face the challenge of managing both corporate and research conflicts. Managing internal and external engagement practices that can potentially impact the integrity and operations within healthcare organizations that conduct research can be quite challenging. Research is unique because an industry (i.e., pharmaceutical companies) can act as a research study sponsor as well as a business engagement. Cross collaboration between research and corporate COI programs can effectively foster a culture of ethics, honesty, and transparency that builds trust with patient/research subjects while ensuring compliance with regulations and policies. This enhances consistency across COI disclosure reviews, escalation, and mitigation, facilitating better decision-making processes.

Managing COIs in healthcare settings with academic research components can be challenging when considering both fiduciary obligations and conflict-mitigation requirements. The effective oversight needed for both corporate healthcare compliance and research compliance requires workflows that help identify and subsequently prioritize potential and actual conflict risks. COI programs within healthcare and academia are responsible for reviewing and managing actual and potential conflicts of interest for individual employees and the organization. For most nonprofit organizations, oversight of both federal and state requirements is needed to ensure the organization maintains its nonprofit status. If the organization is conducting research, it would also involve oversight of individuals engaged in designing, conducting, and reporting research. Fostering an ethical and transparent environment encourages individuals to be honest when disclosing interests to ensure objectivity and trust between providers and patients/research subjects. However, assessing risks associated with industry interactions should include collaborative efforts by corporate and research compliance departments to ensure a comprehensive evaluation is conducted. This article will outline how corporate and research compliance departments can benefit from ongoing collaboration.

Alignment of goals

Corporate and research compliance programs safeguard the institution's integrity, protect the institution from risk, and enhance the safety of clinical programs, including patients, staff integrity, data, and information. Employed individuals' external involvements can potentially create or increase risk in these areas, which requires additional review and mitigation. On a system level, the corporate program's focus is to protect the organization, while the research program's focus is to protect the integrity of the research and the enrolled

participants. Aligning focus and goals can foster a collaborative environment that aids in enhanced review and mitigation of potential conflicts. Corporate and research compliance programs can benefit from annually reviewing, assessing, and outlining the organization's goals. For example, reviewing and confirming data reported on the Centers for Medicare & Medicaid Services' Open Payments database against submitted voluntary disclosure forms supports an organization's goal of promoting transparency. This is a process that benefits both corporate and research programs by reducing administrative burden when shared collaboratively and streamlined between both spaces.

Outlining goals that ensure compliance for both research and corporate programs can increase the effectiveness of each program's ability to meet individual requirements. This includes regularly reviewing responsibilities of conflict reviews, evaluations, and escalations. With an ever-changing regulatory environment, it is essential that both programs regularly discuss and align goals to minimize duplicating efforts. This alignment will allow the collaborative COI program to effectively determine what changes to practice are needed to confirm comprehensive oversight. This collaboration would benefit both corporate and research compliance programs when drafting annual work plans.