

## VIEWPOINT

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# Institutional Conflicts of Interest and Public Trust

The **World Medical Association** developed the Declaration of Helsinki as a statement regarding ethical principles for medical research involving human research participants and directs physicians to promote and safeguard the health, well-being, and rights of patients. Included in this declaration is the requirement that each potential research participant be informed of possible conflicts of interest among the researchers conducting the study.<sup>1</sup> Many clinical trials and biomedical research projects are funded by the private sector and have led to the development of important novel therapeutics and devices that improve the health of individuals and society.

Funding by the private sector is important to meeting the missions of many institutions and to the development of science, but may lead to potential or real individual conflicts of interest that must be effectively disclosed, reported, and managed. Institutional conflicts of interest related to clinical trials and biomedical research may occur because many research institutions and universities increasingly rely on funding from the private sector as state and federal funding has become more competitive and difficult to secure. Most research institutions and universities have conflicts of interest policies for individuals because of federal mandates issued under the auspices of the US Department of Health and Human Services. The same cannot be stated

managed or resolved, then the research should not be allowed to proceed by the involved parties.

The recent investigation and public disclosure of a prominent cancer researcher and administrator who failed to disclose substantial financial and administrative relationships with pharmaceutical and health care companies to high-impact journals has once again tarnished the public's view of biomedical research because this incident was not an isolated event. The related investigations also revealed institutional conflicts of interest and lack of appropriate management of these conflicts by executive leadership and board governance.<sup>3</sup> Although the public may be technically able to connect the financial relationships of investigators and institutions and bring to light conflicts of interest and alleged research bias, these conflicts should be disclosed upfront by researchers and institutions.

The reputation of an individual researcher or an institution can be seriously jeopardized if conflicts of interest are not managed appropriately and transparently. This jeopardy is only enhanced when prominent and highly paid faculty, administrators, and institutional decision makers fail to abide by institutional policies and best practices, leading the public to perceive either correctly or incorrectly that the research is biased. The public has little sympathy for lapses in integrity and transparency among leadership.

Research institutions and universities must take the lead in strengthening research integrity policies to include institutional conflicts of interest or face the consequences of external regulation that could result in making financial ties to industry more difficult. Funding from industry has helped researchers to develop

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about the institutions even though institutional conflicts of interest can affect patients, multiple investigators, and the entire institution.<sup>2</sup>

The lack of consistency among research institutions and universities related to managing institutional conflicts of interest must be addressed. Potential and real conflicts of interest require full disclosure to participants enrolled in research studies so that informed decisions can be made regarding participation. Institutional officers and committees responsible for protecting the integrity of research must also provide full disclosure and sufficient explanation regarding an investigator's or the institution's relationship to external entities that can either directly or indirectly affect research judgment.

Individuals who are either considering or are participating in research studies have the right to understand how the conflicts of interest are being managed, if not eliminated, by both the investigator and the institution. These conflict of interest disclosures must also be made publicly available. If a conflict cannot be appropriately

many lifesaving therapeutics and devices. It would be a great loss to the health of society if industry support of biomedical research is stifled due to a lack of self-regulation. Institutional conflicts of interest can occur whenever the external financial interests or business relationships of the research institution or of one of its key decision makers, including trustees, are such that their actions could affect, or could reasonably appear to affect, the conduct, review, or oversight of the institution's research studies and programs or even the clinical care they provide.

Institutional conflicts of interest may arise (1) when an institution licenses intellectual property to an outside entity and holds substantial royalty or equity interest in the entity, which may be affected by ongoing institutional research or other institutional activities; (2) when substantial gifts to the institution appear to be connected to any decision related to the institution's primary mission in ways that may not be appropriate; (3) when an institution holds a substantial investment or equity interest in an outside entity that has a financial

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or business relationship with the institution; (4) when a significant outside financial interest affects or appears to affect the decisions of the institution; or (5) when an institution enters into a transaction that compromises or appears to compromise the institution's research mission.<sup>4,5</sup>

It is no longer enough for institutions conducting research to only have conflict of interest policies for individual researchers, they also must directly address the growing concern about institutional conflicts of interest. Every research institution and university deserving of the public's trust needs to have well-defined institutional conflict of interest policies. A process must be established that will ensure research is untainted by any personal financial interests of the researcher, and that no financial interests exist for the institution or the institution's key decision makers that could cloud otherwise open and honest decisions regarding the institution's research mission.

Education and culture are fundamental to the successful implementation of any policy. It is incumbent upon institutional decision makers and all employees involved in research to be knowledgeable about individual and institutional conflict of interest policies. It may not always be obvious to researchers that they have a perceived or real conflict of interest or bias. Therefore, it is important to establish a culture of transparency and disclosure of any outside interests that could potentially influence research and include individuals at the highest level of the institution. Policies should be clear and easy to implement and permit pathways to provide disclosure with adequate explanation, as well as information regarding how potential or real conflicts of interest are managed or eliminated. This will require the establishment of interactive databases aimed at mitigating, to the extent possible, both individual and institutional conflicts of interest.

Policies alone are not sufficient to protect an institution from conflicts of interest. Institutional compliance toward these policies and dedication toward establishing processes by which to identify, resolve, or eliminate institutional conflicts of interest are necessary. Institutions and their respective boards of trustees should be prepared to address sensitive situations when a supervisor, executive leader, or trustee is identified as contributing to an institutional conflict of interest and be prepared to direct specific actions to resolve such conflict. In this regard, it would be prudent for governance to establish an institutional conflicts of interest committee with sufficient authority to manage or eliminate perceived or real conflicts of interest affecting the institution.

The committee must have broad representation by expert faculty from the institution as well as external members and consideration should be given to include general counsel and an ethicist. A likely challenge for such a committee will be establishing an appropriate institutional conflicts of interest assessment and management process that is capable of rendering timely decisions and directives. Institutional monitoring of specific management plans to resolve the institutional conflict must be free of bias and be reviewed on a continuing basis. The institutional conflicts of interest committee should have a reporting relationship to the president of the institution and the institution's board of trustees. Good governance should also provide a pathway for a concerned individual to anonymously report a research conflict of interest or research misconduct to the highest level of an organization.

It is an expectation that scientific publications are free of individual and institutional conflicts of interest that could bias conclusions. Journals should request disclosure of any potential or real conflict of interest and respective management plans from both authors and the institutions linked to the research. Failure to disclose conflicts of interest should be associated with consequences appropriate to the seriousness of the findings. Journals and institutions need to establish accountability measures for failure to disclose conflicts of interest within their respective policies and instructions to authors. There should be meaningful sanctions for violating the public's trust and the integrity of research. Best practices involving the management of individual and institutional conflicts of interest should be shared publicly.

Private-sector support of clinical trials and biomedical research is important for the advancement of science and the health of mankind, but safeguards against conflicts of interest need to be established to ensure that research integrity and the public's confidence in academic and clinical institutions are preserved regardless of how research is funded. It is paramount that all research is unbiased and of the highest integrity because not doing so could result in harm to patients, violating the most deeply held standards of the medical profession as well as the professional code of ethics described in the Declaration of Helsinki.<sup>1</sup> A culture of disclosure, transparency, and continual management of individual and institutional conflicts of interest needs to be established to include leadership and boards of trustees. According to Harry Y. Benedict, PhD, LLD (10th president, University of Texas, Austin), "The greatest endowment of an institution is the public trust."

#### ARTICLE INFORMATION

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