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Creating an institutional conflict-of-interest policy at Johns Hopkins: Progress and lessons learned

ABSTRACT

Unlike policies that address biomedical conflict of interest for individuals, conflict-of-interest policies for academic medical institutions are rare and lack consensus principles. Johns Hopkins Medicine is currently developing an institutional conflict-of-interest policy that emphasizes case-by-case review and disclosure of conflicts to research subjects and the public. Implementation of the policy will focus on transparency, consistent enforcement throughout the institution, thorough employee education about the policy, and ongoing policy review.

While biomedical conflict-of-interest policies for individuals abound, policies on institutional conflict of interest are few. Johns Hopkins Medicine (which includes the Johns Hopkins Hospital and Health System as well as the Johns Hopkins School of Medicine) is completing development of a policy on institutional conflict of interest. This article discusses the impetus and rationale for the new policy, its key provisions, and broader issues for academic medical centers looking to effectively manage institutional conflict of interest.

CONFLICTS ARE INEVITABLE; MANAGING RISKS IS KEY

Conflicts of interest are inevitable byproducts of translational research and institutional interaction with industry. The Bayh-Dole Act of 1980 mandated such interaction by giving US universities, small businesses, and nonprofit organizations intellectual property control of their inventions that result from federal government-funded research.

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Institutional relationships with industry generate financial interests. Conflicts of interest are driven by economics, such as the needs of institutional budgets and local economies. The inherent risk is that financial interests will compromise or endanger primary objectives, such as patient safety, research integrity, independence in clinical decision-making, and, most fundamentally, the public trust and institutional credibility.

Academic medical centers should focus not on eliminating conflicts of interest altogether but on managing the risks associated with them.

THE STATE OF CONFLICT-OF-INTEREST POLICY

Individual conflicts: An emerging consensus

A relative consensus on policies concerning *individual* conflict of interest has taken shape in recent years. Leading academic medical centers have robust policies concerning individual conflicts as a result of direction from the Association of American Medical Colleges (AAMC), the Association of American Universities (AAU), the AAMC's Forum on Conflict of Interest in Academe, and similar bodies. Disclosure of individual conflicts is now required in publications and presentations, and individual conflicts of interest are limited in clinical research.

There remain some inconsistencies among institutions in their policies on individual conflicts, particularly on points such as disclosures to research participants and the scope of clinical research activity allowed, but policies on individual conflicts are now widespread and characterized by an emerging consensus.

Institutional conflicts: Little progress, growing pressure

In contrast, *institutional* conflict of interest remains unregulated and largely unaddressed in a formal way. Few institutions have policies on institutional conflicts, and little consensus exists on principles, despite some guidance from the AAMC, the AAU, and the US Department of Health and Human Services. Meanwhile, highly publicized cases of institutional conflict of interest have arisen recently at prominent

institutions such as the University of Pennsylvania, University of Toronto, Cleveland Clinic, and Johns Hopkins Medicine. These cases have driven concern about institutional conflict of interest in Congress, at the National Institutes of Health, and at academic medical centers themselves.

WHAT CAN HAPPEN WITHOUT A POLICY ON INSTITUTIONAL CONFLICT

Johns Hopkins Medicine recently had a formative experience in the context of having no institutional conflict-of-interest policy in place. We entered into a business arrangement with Klinger Advanced Aesthetics (KAA), which markets skin care products under the name Cosmedicine. The company's objective was to add scientific rigor to its skin care products; Johns Hopkins' objective was to generate income for the institution. Johns Hopkins agreed to help design clinical trials of KAA products and analyze the data but not to endorse the products in any way. In the original agreement, Johns Hopkins was to receive payments, have stock in KAA, have a seat on the KAA board, consult on research, and define the use of our name.

In April 2006, the *Wall Street Journal* ran a front-page story about this arrangement, claiming that Johns Hopkins endorsed the products. Following this, there was a substantial renegotiation of our contract with KAA.

Lessons learned

What lessons did Johns Hopkins learn from this experience?

- If it "smells" like research, the public will probably consider it research despite disclaimers.
- Owning stock must be justified while engaging in research.
- Clear, consistent policies on institutional conflict of interest are needed, both internally and across all academic medical centers. These policies should cover more than just clinical research.
- Institutions must educate their employees about their policies.
- Institutions must enforce their policies.

CREATING A POLICY AND A CULTURE OF ETHICS

Johns Hopkins University is in the final stages of drafting a policy regarding institutional conflicts of interest that will include both the university and the health system. The policy is guided by a pair of principles: (1) institutional conflicts of interest are not inherently problematic and risks need to be assessed on a case-by-case basis; and (2) risks cannot be assessed without disclosure and clear procedures.

Key provisions of the draft policy are as follows:

- Disclosure will be required from institutional officials and from institutional actors responsible for technology transfer.
- Disclosures will be cross-checked against research and other activities.
- A process of case-by-case review will be used to identify and evaluate risks.
- Institutional conflicts of interest will be managed, reduced, or eliminated, based on the case-by-case details.
- The default position will always be to disclose potential conflicts to research subjects, the scientific community, and the public.

More broadly, we are working to create a culture of ethics by attempting to evaluate risk, anticipating how the public will view it, and having clear, accessible, and manageable policies and guidelines in place. We are working to get the message out as widely as possible (there are about 30,000 employees in the system) and to educate employees not just about what the rules are but about why they are important—that institutional credibility and scientific integrity are at stake.

Educate employees about why the policy is important—that institutional credibility and scientific integrity are at stake.

Implementation strategies

Although we begin from the assumption that our faculty and administration consist of honest people, we intend to enforce our policies consistently. Our process will be transparent with regard to review criteria, possible outcomes, and management techniques. We are moving toward implementation of an electronic disclosure process linked to other databases (those of the institutional review board, the institutional animal care and use committee, etc.) so that all employees have access to the same information.

We already have trained more than 12,950 employees on the conflict-of-interest policy using Web-based didactic, small-group training. We stress leading by example: institutional officials should set a good example, as should principal investigators and the institution as a whole.

The policy will be reviewed over time to ensure that it is effective and that we are monitoring compliance, practicing consistent enforcement, and addressing breaches. Currently, cases drive our poli-

cies, and we advocate evaluating cases individually rather than devising a blanket policy.

MOVING FORWARD AT HOPKINS AND BEYOND

Changing institutional culture is not easy and can be slow and labor-intensive. Change takes resources and commitment from the entire leadership, including institutional officials, department heads, and faculty.

On a national level, research needs to be done to better understand the positive and negative impacts of conflicts of interest on research integrity, the translation of research to the bedside, and health care costs. We at Johns Hopkins are trying to add data to the debate.

Another of our goals is to educate the public, both locally and nationally, about the issues and considerations involved in institutional conflicts of interest. Indeed, the challenge for all academic medical centers is to educate Congress, the press, and the public about these issues and to demonstrate that we are managing these conflicts appropriately.

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