

# Managing Financial Conflict of Interest in Biomedical Research

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**A**S THE NATION'S BIOMEDICAL RESEARCH AGENCY, THE National Institutes of Health (NIH) must ensure that the research it funds on the behalf of US taxpayers is scientifically rigorous and free of bias. Over the course of more than 65 years and hundreds of thousands of awards, most researchers receiving funds from NIH have proved to be trustworthy stewards. Still, more must be done to retain, and in some instances regain, public trust in the biomedical and behavioral research enterprise.

The public may not always understand the intricacies of rigorous science, but most individuals quickly grasp the concept of bias. Plain and simple, Americans do not want financial conflicts of interest (FCOI) to influence the federally funded research they hope will yield better ways to fight disease and improve health.

Managing FCOI in biomedical and behavioral research, however, can prove to be a major challenge because of the complex relationships among government, academia, and industry. Partnerships between NIH-funded researchers and industry are often essential to the process of moving discoveries from the bench to the bedside. These relationships manifest as consultant agreements, in published works, and through a variety of other productive alliances. However, such relationships can sometimes lead to FCOI that may compromise—or appear to compromise—the integrity of research supported by NIH.

The US Public Health Service, of which NIH is a part, is the only federal agency to have regulations regarding FCOI in research.<sup>1</sup> In addition to the individual responsibilities ascribed to NIH-funded investigators, institutions that receive NIH funding have responsibilities to develop policies to implement the regulations and to adhere to such policies. In recent years, it has become increasingly apparent that the existing federal regulations, which were promulgated in 1995, need to be clarified and strengthened to ensure greater transparency and accountability. Without such changes, even more instances of real or perceived FCOI will likely be encountered in the future.

The following scenarios, which incorporate various elements of real-life cases, illustrate some of the many challenges that need to be addressed.

**University X.** The principal investigator of an NIH-supported clinical trial at university X fails to disclose more than \$750 000 in payments for serving on an advisory panel for a company involved in the trial. Although the researcher followed the university's policies concerning financial disclosure, NIH suspends the trial and requires all grant applications from university X to include details of investigators' FCOI. Subsequently, university X develops and implements new processes for managing FCOI. NIH lifts the special award conditions.

**Investigator Y.** Because she is an NIH grantee, investigator Y discloses to her university that she received lecture fees of "more than \$10 000" annually over the past decade from a company developing a drug based on her laboratory's findings. In fact, investigator Y receives more than \$500 000 annually in such fees. However, investigator Y does not violate her university's policy or the current federal rules because they do not require researchers to identify the precise amounts received from drug makers. The university decides to revise its FCOI policy.

**Institution Z.** NIH imposes special conditions on all grant awards to institution Z, citing deficiencies in its FCOI rules. The action follows institution Z's failure to report to NIH more than \$1 million in company payments that a researcher received for promoting a new diagnostic test. The NIH-supported investigator fulfilled institution Z's disclosure requirements, but those requirements were not in compliance with federal regulations. An ensuing investigation by institution Z finds that the researcher had no actual FCOI related to his NIH-supported research. Still, institution Z works with NIH to revise its policy and procedures to ensure they are consistent with federal regulations.

## Time for Change

Clearly, investigators, institutions, and NIH need to redouble collaborative efforts to uphold the integrity of federally funded biomedical and behavioral research. If NIH-supported researchers fail to disclose the full extent of their financial interests, universities fail to comprehensively manage FCOI, or NIH fails to diligently oversee the entire sys-

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tem, public trust will be jeopardized in ways that may have far-reaching implications for the future of science.

To reduce ambiguities in the current regulations and keep bias out of federally funded biomedical and behavioral research, NIH has sought extensive public input and labored for more than a year to develop a proposal for a revised regulation that more precisely spells out the roles of NIH, of grantee institutions, and of investigators in disclosing, identifying, and managing FCOI.

In May 2009, NIH posted an Advanced Notice for Proposed Rulemaking, inviting comment.<sup>2</sup> After careful consideration of the input received from the public, Congress, professional societies, universities, research institutions, and private companies, NIH on May 21, 2010, posted for public comment a Notice of Proposed Rulemaking, which contains substantial revisions to current regulations.<sup>3</sup>

### Current Regulations

To grasp the rationale behind the proposed rule changes, it helps to consider the current regulations. Under this regulatory framework, most of the responsibility for disclosing significant financial interests that could pose possible FCOI lies with individual investigators, not their institutions. Specifically, investigators determine and disclose to their institutions any significant financial interest that would reasonably appear to be affected by the NIH-supported research, as well as any significant financial interest involving entities whose financial interests would reasonably appear to be affected by the research. Institutions, in turn, are re-

quired to manage, reduce, or eliminate the conflict; to report to NIH; and to assure NIH that this process has been followed for all identified FCOI that could have a significant and direct effect on NIH-funded research.

### Proposed Rules

In the revised regulations, NIH seeks to make changes in several key areas that would enhance regulatory compliance, strengthen NIH and institutional oversight, and expand transparency (TABLE). First, the proposed regulations would require that NIH-funded investigators disclose to their institutions all significant financial interests related to their institutional responsibilities. This would move the responsibility for determining if an investigator's significant financial interests are related to NIH-supported research from the investigator to his or her institution. The proposal would also lower the monetary threshold at which interests require disclosure, generally from \$10 000 to \$5000.

Second, the proposed regulations would require institutions to develop a management plan for every identified FCOI, which may include reduction or elimination of the FCOI. The institution would be required to provide to NIH significant additional information on identified FCOI and their management.

The third major area of change centers on transparency. The proposed rules would require every NIH-funded institution to post, on a publicly accessible Web site, information on certain significant financial interests that the institution has determined are related to NIH-funded research

**Table.** National Institutes of Health Financial Conflict of Interest Rules at a Glance

Topic	Current	Proposed
Significant financial interest	Minimum threshold of \$10 000 generally applies to payments or equity interests Exclusions include income from seminars, lectures, or teaching, and service on advisory or review panels for public or nonprofit entities	Minimum threshold of \$5000 generally applies to payments and/or equity interests Includes any equity interest in non-publicly traded entities Exclusions include income from seminars, lectures, or teaching, and service on advisory or review panels for government agencies or institutions of higher education
Disclosure	Only significant financial interests that investigators deem related to PHS-funded research	All significant financial interests related to investigators' institutional responsibilities Institutions responsible for determining whether significant financial interests relate to PHS-funded research and FCOI
FCOI management	Manner of compliance not specified	For all identified FCOI, institutions must develop a management plan
Scope	Does not cover Small Business Innovation Research/Small Business Technology Transfer Research phase I applications	Includes Small Business Innovation Research/Small Business Technology Transfer Research phase I applications
Reports to PHS funders	Grant/contract number Project director/principal investigator or contact project director/principal investigator Name of investigators with FCOI Whether FCOI have been managed, reduced, or eliminated	Current requirements, along with: Value of the financial interest Nature of FCOI, eg, equity, consulting fees, travel reimbursements, honoraria, and description of how FCOI relate to PHS-funded research Key elements of the institution's management plan
Public notice	No requirement	Before spending funds for PHS-supported research, an institution shall post on a publicly accessible Web site information on certain significant financial interests that the institution has determined are related to the PHS-funded research and are FCOI
Investigator training	No requirement	FCOI training required for investigators before engaging in PHS-funded research, and every 2 years thereafter

Abbreviations: FCOI, financial conflicts of interest; PHS, Public Health Service.

and constitute FCOI. The full Notice of Proposed Rulemaking can be found in the *Federal Register*.<sup>3</sup>

### **New Era of Transparency**

The NIH looks forward to receiving comments from researchers, institutions, industry, patients, and others who have an interest in or stand to be affected by the proposed rule changes. All stakeholder comments will be carefully considered during the process of drafting the final rules, which are expected to be issued before the end of this year.

Capitalizing on innovation to benefit health requires a robust partnership that joins bias-free research with the most effective methods for translation and dissemination. As NIH strives to accelerate the movement of discoveries from the laboratory to the clinic, it is clear that already complex relationships between NIH-funded researchers and industry will likely become more complicated, even as they become more exciting and more productive.

Consequently, for the good of the research enterprise and for our nation as a whole, it is imperative to take collective steps now to usher in a new era of clarity and transparency in the management of FCOI.

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