

**Proposed Revisions to DHHS Conflict of Interest Policies:
Concerns About Effects on Commercialization of Research**
September 9, 2010

Background—On May 21, 2010, the Department of Health and Human Services called for public comments on proposed revisions to its regulations on “Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought and Responsible Prospective Contractors”. The initial comment period, which ended on July 20, was extended by an additional 30 days, through August 19. Public comments were compiled at <http://www.regulations.gov/search/Regs/home.html#docketDetail?R=NIH-2010-0001>. The site lists 268 public submissions, though this includes a number of duplicates. Submitters include universities, trade associations, private companies, scientific societies, and individuals.

One of the primary concerns expressed in the comments are the possible negative effects of the proposed revisions on the development of relationships between academic researchers and outside entities, ultimately hindering commercialization of research. Defining conflict so broadly, and requiring public disclosure on a website, is likely to hamper many researchers’ interest in pursuing activities and relationships that lead to commercialization. That these activities will be publicized this way implies that there is some stigma associated with them, and the larger public may not understand the broader context.

This concern about conflict of interest regulations was raised by AAU along with four other higher education associations (APLU, ACE, AAMC and COGR) even prior to the release of the NIH COI notice of proposed rulemaking. Noted the five associations in the joint response to the March 26, 2010 Federal Register request for information issued by OSTP and NEC concerning the commercialization of university research:

“Increased economic engagement inevitably raises the likelihood of more financial relationships between institutions and their researchers and the companies with which they engage. In fact, one gauge of the effectiveness of commercialization is the growth of such relationships. Current perceptions that such relationships are inherently suspicious or invariably lead to unmanageable conflicts of interest must be changed. Both policymakers and the public must understand that these relationships are positive and necessary for universities to achieve greater success in commercializing their research. At the same time, it is critical that as federal agencies move to regulate potential conflicts of interest, they do not put in place regulations which inadvertently discourage appropriate interactions among research faculty, universities, and industry. We understand that conflicts of interest must be closely monitored and kept in check. However, an overly strong focus on elimination, rather than management, of conflict of interest by federal agencies would produce a chilling effect on universities’ willingness and ability to engage in economic development and be directly counter to the Administration’s interest in increasing commercialization by universities. As purveyors of objective knowledge, universities have their own built-in interest in managing conflicts of interest, or perceptions of such conflicts, to ensure that the integrity of research findings are not compromised.”

Several of the public comments provided to NIH in response to its proposed COI regulations echo this concern. Examples appear below:

Survey results—One of the comments includes the results of a survey conducted by the company ClickCommerce. They surveyed 149 professionals involved in the conflict of interest process at 106 North American research institutions about their concerns with the proposed revisions. The addition of significant financial interest (SFI) relationships beyond those that are research related, including those with Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs as well as nonprofit organizations, was the chief concern of 38% of respondents. Nearly a third of respondents (31%) thought the biggest concern was public disclosure, which might impact researchers’ willingness to engage in research relationships with industry or other sponsors given the misperception that may ensue from a potential conflict that is being managed versus an actual conflict that has been uncovered.

Specific comments

- American Physiological Society: “Relationships between academic researchers and their colleagues in industry are both beneficial and necessary for facilitating the flow of scientific information and advancing basic research discoveries to applied technologies, including treatment and prevention strategies for disease. The importance of bridging the basic and applied sciences was recently highlighted with passage of the Cures Acceleration Network (CAN) as part of the Patient Protection and Affordable Care Act. The CAN will focus resources on translational research in both academia and industry with the goal of speeding drug discovery and development. We strongly urge the NIH to express its support for such collaborative arrangements lest research institutions see the new FCOI regulations as a reason to discourage important collaborations between academic researchers and for-profit entities.” “The proposed regulations address institutional responsibilities for subrecipients of award funds and would require that awardee institutions ensure that subrecipients comply with FCOI rules. This requirement could be problematic when researchers are collaborating with subrecipients operating under a different set of laws and regulations in a foreign country.”
- American Society of Hematology: “...the proposed rule appears to have no tolerance for any real or perceived conflicts. The Society believes it is important to recognize that success in translating basic discoveries into clinical practice, in fact, requires effective collaborations between NIH-funded investigators and industry. Therefore, while strongly supporting disclosure, ASH urges the NIH to reconsider this proposal and require that financial information be made only available to the NIH and not posted to a public website.”
- American Society of Nephrology: “...the society urges NIH to be mindful that a final rule balance vigilance in assessing potential conflicts of interest with the danger of stifling future innovation by adopting a policy under which researchers with ties to industry are viewed with undue suspicion. The relationship between the research and industry communities is vital to the development and distribution of future effective new therapies. This important role should be reflected in any final rule.”
- Arizona State University: “Public posting of fCOI in the manner proposed by PHS is of questionable value because there is no guarantee that the public will have the context necessary to measure the importance of the information in the posting. The likely result is

that a less-informed public will conclude that each disclosure is negative, that fCOIs are not being managed, and that the research outcome will be biased. Any one of these conclusions could harm the reputation of the investigator making the disclosure and could generally lead to investigators limiting or abandoning useful translational relationships. ASU is further concerned that investigators will limit their research activities generally and abandon years of fruitful research that may have led to important discoveries because the proposed regulations (1) expand to an unreasonable degree the types of remuneration to be reported and (2) include as reportable SFIs an investigator's relationships with small businesses through PHS-sponsored SBIR and STTR programs and nonprofit organizations."

- Association of Clinical Researchers and Educators: "Translation basic research into effective therapies is a low yield activity. If physicians and researchers are hesitant to work with industry because of a negative perception bias of relationships with industry, this will undoubtedly result in stymieing of biomedical research. We may end up with a corporate sponsored research silo that focuses on medications and improved technologies, and a cadre of basic science NIH funded physicians and researchers that focus on basic science, further amplifying the so called "valley of death." The problem with separation is that it will undoubtedly hurt patients. Taxpayers want medications, and new technologies that provide cures. They are less concerned with some false "purity" that potentially shuts down translational (curative) research."
- Biotechnology Industry Organization (BIO): "Thus, while there is a small risk that some relationships between industry and academia may be abused by bad actors, this must be balanced with the great benefits that continue to accrue to patients because of industry funding to augment public funding of academic research. Among these benefits are added opportunities for the full and appropriate testing of biotechnology products to secure approval for their marketing. Policies that prohibit such funding, rather than ensure that it is properly disclosed, may appear to address the small risk but, at the same time, ignore the great benefit. Such policies are not in the best interest of patients."
- Cleveland Clinic: "...as it is currently written, the Proposed Rule has the potential to greatly hinder innovation."
- Council on Government Relations (COGR): "The danger lies in the assumption by a less-informed public that any and all financial conflict of interest (FCOI) is bad and will, with certainty, bias the research outcome. Because such an assumption will result in a diminution of the reputation of the investigator, we fear investigators will either limit or abandon useful translational relationships with industry. With the inclusion as reportable SFI relationships with small businesses through PHS-sponsored SBIR and STTR programs and nonprofit organizations; the expansion of the types of remuneration to be reported; and other changes throughout the proposed rule, we are concerned that investigators, especially new investigators, will no longer be as willing to engage in the applied and development work that helps translate research to treatments and, ultimately, improvements in public health."
- Daniel Weeks, University of Pittsburgh: "My colleague and I are co-investigators on an NIH subcontract. We are also co-inventors on a patent filed by and assigned to our institution; this

patent, recently awarded, has been licensed, so we have received royalties. When we applied for IRB approval of a new part of our study, we received this: "Due to a change in the interpretation of the Human Subject Research COI Policy, your right to royalties through the University for IP licensed to Ophtherion now precludes you from being the PI of this study. Please identify another faculty-rank individual with no financial interest in the IP being evaluated and no reporting relationship to you to serve as the PI of this study." So our IRB excludes us from being PI of our own research! Their line of reasoning is that 'You've been awarded a patent, so that causes a potential conflict whether or not royalties are paid because you have a right to future royalties'. But the patent was assigned to the institution, not to us."

- Emory University: "...a large number of our pediatric faculty are paid by Children Healthcare of Atlanta for clinical services. Others are editors of major peer-reviewed journal and receive stipends for these roles. Countless are reviewers for non-profit agencies that provide competitive awards, e.g., American Cancer Society, Juvenile Diabetes Foundation, etc. Under the proposed regulations, these faculty would be required to disclose their remuneration for activities that are clearly expected of them as faculty members."
- FASEB: "Voluntary participation in non-profit, member-based, professional scientific and engineering societies, including such activities as peer review, governance, and other volunteer service, is an essential part of scientific life. Such activities allow investigators to engage and interact with one another and support the scientific activities of their disciplines. Unless these activities are excluded from the FCOI regulations, scientists volunteering in their respective professional societies could be identified on institutional websites as having FCOI, resulting in a negative public perception of these relationships and their value to the broader biomedical research enterprise."
- FasterCures: "When reviewing SFI disclosures from investigators, institutions should consider mechanisms of assessment that take into account the stage of research – from "proof of concept" to commercial. An unbalanced focus on potential conflicts that are far in advance of commercial potential will only slow the development of new therapies at a time when cross-sector interests are often converging, not diverging." "We recommend that income for academic activities from not-for-profit entities be excluded from the disclosure rule. For example, this might include activities such as lecture or committee engagements with trade and professional associations, think tanks, nonprofit disease research foundations, and patient groups....we feel it is an important distinction to be made as such relationships often foster the type of collaborations that bring research findings into development. Indeed, translational research, which is the least supported and developed phase of research, can only thrive if crosstalk between basic scientists and developers are not only allowed, but also encouraged."
- HIV Medicine Association: "...public disclosure of information on financial interests should include a visible caveat stating that the existence of a financial interest does not in itself constitute a financial conflict of interest. For example – in the HIV research arena, physicians and researchers can play an important role in informing HIV drug development initiated and sustained by industry through participation on advisory committees. Without this exchange of information, the industry's drug development efforts are less likely to reflect the needs and realities of the HIV patient population."

- Johns Hopkins University: "...the requirement to report most SFIs in not-for-profit organizations will slow or discourage a host of relationships between investigators and educational organizations, teaching hospitals, charitable groups, and professional associations – relationships that play an important role in disseminating researchers' knowledge and expertise."
- Michael Gorin, UCLA Medical Center: "We should encourage investigators to continue to engage in research that involves IP that they have generated. The potential COI should be managed in such a way as to ensure integrity of the data, but you need investigators to move their own ideas forward. It is essential that the COI rules do not poison the environment to move research into potential applications for the public good. The rules should clearly define how to judge when research is moving from "proof of concept" to a pre-marketing or pre-commercialization status."
- Pfizer: "...the ongoing productivity of medical innovation depends on continued if not more, and more fruitful, collaborations among academia, scientists in the public sector, and industry. If the proposed rules materially discourage or deter collaboration with industry, they could damage the needed productivity in ways that are both profound and hard to measure." "Pfizer has a growing number of collaborations with NGO and NIH scientists on research projects to further scientific innovation. In particular, these collaborations address areas of high-unmet medical need such as Autism and Tuberculosis. We look forward to continuing these relationships under the new FCOI Rules, and trust that reasonable compliance requirements will serve to strengthen, not hinder these vital partnerships."