

Tighter ethics rules have reduced industrial relationship of NIH scientists

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The 2005 ethics rules that govern relationships between researchers within the National Institutes of Health (NIH) and pharmaceutical, biotechnology and other industrial companies have significantly reduced the prevalence of such collaborations without affecting standard measures of research productivity, according to a study in the November issue of *Academic Medicine*. However, this report from the Mongan Institute for Health Policy at Massachusetts General Hospital (MGH) also finds that NIH scientists and administrators believe the new rules are too restrictive.

"Our findings are particularly significant since many universities, academic medical centers and other research institutions are considering whether and how to tighten their own conflict-of-interest policies," says Darren Zinner, PhD, now at the Heller School of Social Policy and Management at Brandeis University, who led the study. "The NIH experience suggests that – at least in the government setting – tightening these policies can be achieved without harming other important relationships or researcher productivity."

In 2005, in response to media reports of conflicts of interest within the NIH's intramural research program – based at its campuses in Bethesda, Maryland, and other locations – the NIH implemented new policies limiting the nature and frequency of collaborative relationships with industrial entities. Restrictions against outside consulting with companies, health care providers and supported research organizations were strengthened. Personal investments in such organizations were

limited, and many types of industrial relationships and outside professional activities required prior approval from an advisory committee.

The current study, the first peer-reviewed analysis of the policy's impact, was primarily designed to investigate whether the new rules made the agency more insular by limiting interactions with colleagues at other institutions. It investigated whether the policies had affected the rate at which NIH scientists published and patented new scientific discoveries, along with any changes to industrial, professional organization or academic collaborations. The survey included questions on recipients' knowledge and perceptions of the ethics rules and how the new standards might have affected their activities. Of the 800 eligible NIH faculty members who were sent the survey in late 2008 or early 2009, 566 responded for a 70 percent response rate.

About half of the respondents who were at the NIH before 2005 indicated they had relationships with industry before the new rules were implemented – a proportion similar to that seen in the same team's 2009 study of academic science researchers – but only one-third reported having such relationships after the more restrictive rules were in force. The number of respondents who consulted for industry dropped by three quarters, and the percentage who served on scientific advisory boards was cut in half. There were no significant changes, however, in the rates at which respondents reported publishing in scientific journals, applying for research patents or volunteering for such professional service roles as journal editors or association board members.

Respondents' perceptions of the impact of the rules were multifaceted. While 45 percent believed they improved public perceptions of the credibility of NIH research, 77 percent thought they impeded the NIH's ability to fulfill its scientific mission. Almost 80 percent felt the rules were too restrictive, with around half reporting negative effects on their

personal collaborations with industry and academia, and two-thirds indicating reduced job satisfaction. Respondents with any prior or current industrial relationships were even more negative about the effects of the rules than those without.

"Any reasonable conflict-of-interest policy in this area requires balancing the benefits and risks of industrial collaboration, which was reflected by our respondents' mixed attitudes about hypothetically relaxing the existing rules," adds Zinner. "While one-third thought that loosening the restrictions would increase industry bias and secrecy in NIH research, almost 85 percent felt it would allow new studies that could not otherwise be done."

Eric G. Campbell, PhD, of the Mongan Institute for [Health Policy](#) at MGH, the study's senior author, cautions against applying these results more broadly. "The NIH is considering new rules regarding disclosure of the industrial relationships of NIH grant recipients. While both the intramural programs we studied here and the extramural studies conducted at institutions across the country are funded with public money, there are substantial differences. So while we support increased disclosure of academic-industrial relationships, more studies are needed to determine whether the types of restrictions implemented at NIH would be appropriate for academic scientists." Zinner is a senior lecturer at Brandeis University, and Campbell is an associate professor of Medicine at Harvard Medical School.

Provided by Massachusetts General Hospital

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