

# Study of IRB members' industry relationships finds improvement, but some issues persist

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A follow-up to a 2005 study of industry relationships among members of Institutional Review Boards (IRBs) at academic health centers finds both improvements in the management of such relationships, with increased levels of disclosure and fewer problematic relationships, and the persistence of problems such as IRB members' voting on protocols with which they may have conflicts of interest, a violation of federal regulations. The new study from the Mongan Institute for Health Policy at Massachusetts General Hospital appears in the July 13 issue of *JAMA Internal Medicine*.

"IRBs are the primary mechanisms by which institutions oversee research that involves human participants, and [industry relationships](#) of IRB members have the potential to impact their IRB-related activities in both positive and negative ways," says Eric G. Campbell, PhD, director of research at the Mongan Institute and corresponding author of the paper. "While our principal findings are that, compared to a decade ago, IRBs appear to be doing a much better job at managing their members' industry relationships, there still are findings that are concerning."

Every U.S. institution that conducts research involving human participants must have an IRB, which reviews proposed studies to make sure their design is scientifically valid and does not violate ethical and regulatory guidelines. IRBs also monitor ongoing studies to make sure they maintain appropriate practices. The first study to examine industry

relationships of IRB members, conducted by Campbell and his colleagues, was based on a 2005 survey of IRB members and published in the November 30, 2006 *New England Journal of Medicine*. It found that more than a third of IRB members had some sort of financial relationship with commercial firms, and while most respondents did not believe that such relationships had an inappropriate impact on IRB decision making, significant percentages were not aware of institutional guidelines for disclosing industry relationships or defining [conflicts](#) of interest.

The current study reports on the results of an identical 2014 survey of nearly 500 IRB members at medical schools and teaching hospitals around the country. As in 2005, respondents were asked about specific types of relationships with commercial companies, whether they received any industry funding and for what purposes, and how many protocols related to companies with which they had a relationship had come before their IRB. For protocols with which they had a conflict - relating either to companies with which they had relationships or to competitors - they were asked whether they had disclosed their relationships to the IRB, whether they participated in discussion of those protocols and whether they voted on the protocols.

While there was no significant difference in the percentage of IRB members who reported having industry relationships overall, the percentage who reported receiving payments for attending meetings and conferences or for serving on speakers bureaus, relationships that are considered problematic, dropped significantly - from 16 percent to 9 percent for meeting/conference participation and from 14 percent to 4 percent for speakers' bureaus. Christine Vogeli, PhD, of the Mongan Institute, a co-author of the study, says, " We were encouraged to see that the prevalence of potentially beneficial relationships - such as industry funding to support research studies - was essentially unchanged, indicating IRBs have not tried to eliminate members' industry

relationships across the board."

Survey respondents were also more likely to say that their IRB had a written definition of conflicts of interest - 63 percent compared with 46 percent in 2004 - and the percentage who reported their IRB had no policy related to conflicts dropped from 14 percent to 5 percent. However, the fact that 32 percent of respondents still did not know whether or not their IRB had a policy on conflicts, even though that had dropped from 41 percent, was still considered by the research team to be concerning.

The percentage of respondents who handled their [conflicts of interest](#) in an appropriate manner increased; 80 percent of those with conflicts reported them to the IRB, up from 55 percent, and 68 percent indicated they always left the room when a protocol with which they had a conflict was being discussed, up from 38 percent. But one quarter of respondents with conflicts indicated they had voted on protocols with which they had a conflict. While that was a drop from what was reported in the 2004 survey, a step in the right direction Campbell says, it was not statistically significant for a study group of this size.

The percentage of [respondents](#) who felt that at least one protocol had been presented to their IRB in a biased fashion because of another member's industry relationships dropped from 14 percent to 8 percent. And when asked about the types of bias they perceived in the presentation - questions not included in the 2005 survey - 8 percent reported a pro-industry bias while 14 percent reported an anti-industry bias.

"The fact that we found any bias - either pro- or anti-industry - is an issue, since bias is antithetical to research and should be eliminated," says Campbell, a professor of Medicine at Harvard Medical School. "IRBs should address that issue, along with increasing efforts to educate

their members about what constitutes a conflict of interest and the inappropriateness of voting on protocols with which they have a conflict."

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