



## NEWS

# Harvard relaxes COI rules for clinical researchers

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Harvard Medical School has relaxed its conflicts of interest (COI) rules for faculty members who conduct clinical research, more than doubling the amount they can receive from the companies whose products they are investigating.

Previous rules allowed faculty members to receive no more than \$10 000 from each company whose technology they were studying. But under new rules issued on 12 May, faculty members can now receive up to \$25 000 from a company. For some prolific researchers this may mean substantial amounts of industry funding.

Faculty members can also hold up to \$50 000 worth of stock in a company if the company is publicly traded—an increase of \$20 000 from the old rule which was set in 1990.

Faculty members would continue to be banned from holding any stock in a company if that company was privately held. However, the new policy allows faculty members to ask to be exempted from the COI rules if they can demonstrate “compelling justification consistent with the rights and welfare of clinical research subjects.”

In a letter to Harvard Medical School explaining the new policy, Jeffrey S Flier, dean of the faculty of medicine at Harvard University, said that “research involving human study participants should be subject to heightened scrutiny because bias can directly impact the safety and welfare of clinical research participants.” But he also argued that “a strict application of the existing Clinical Research Rule may, in certain circumstances, stifle research that is in the best interest of patients and human study participants.”

Flier concluded, “These changes represent a small but meaningful revision to the COI policy in support of our shared mission to alleviate human suffering. I believe it will encourage a balanced, thoughtful approach that helps ensure the consistent application of rules and restrictions that ultimately benefit our clinical research subjects.”

Last year Robert Steinbrook, professor adjunct of internal medicine at Yale University School of Medicine, wrote in *The BMJ* criticising a series of articles in the *New England Journal of Medicine* that “sought to reinterpret and downplay the importance of conflicts of interest in medicine by publishing.”<sup>1</sup>

Commenting on the new rules introduced at Harvard, Steinbrook said, “It’s a bad decision and sends the wrong message to the academic medicine community. The elaborate rationalizations about the reasons for change are not at all convincing. Instead of weakening its conflicts of interest policies for clinical research, Harvard Medical School should be advocating for other institutions to adopt stronger policies. Harvard has taken a big step backwards.”

Elizabeth Loder, acting head of research at *The BMJ* and a professor at Harvard Medical School, said, “This increase may seem modest for an individual company, but for prolific investigators who can be involved with five, 10, or even more companies at a time, it could be a huge jump in income for them and influence for the industry in general.”

1 Steinbrook R, Kassirer JP, Angell M. Justifying conflicts of interest in medical journals: a very bad idea. *BMJ* 2015;350:h2942. doi:10.1136/bmj.h2942 pmid:26036926.

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