

Dear Colleagues:

In this age of discovery, when scientific developments have the potential to rapidly improve human health, our HMS faculty are deeply engaged in advancing their research with the intent that it be translated into clinical therapies. The pursuit of these discoveries necessitates that we work in partnership with fellow academics and government agencies, as well as with companies that further develop and then commercialize innovations. At the same time, to ensure the integrity of our scientific endeavors, it is imperative that we identify and appropriately manage potential conflicts should they arise from these relationships.

The Faculty of Medicine Policy on Conflicts of Interest and Commitment, initially adopted in 1990, is periodically evaluated and revised to ensure that it strikes the appropriate balance between risk and benefit for our faculty, and for society at large. In November of last year, upon the interim recommendation of the Standing Committee on Conflicts of Interest and Commitment and support from the Faculty Council, I announced changes to the Research Support Rule (1b), including permitting a faculty member who holds equity in a privately held company to request an exception to the prior prohibition against receiving sponsored research support from that company.

Since then, the members of the Standing Committee, in consultation with colleagues across our HMS community, have been reviewing our COI policy, focusing particularly on the Clinical Research Rule (1a). The Rule has prohibited faculty who conduct clinical research on a technology from:

- receiving income in excess of \$10,000 from that company;
- holding stock in that company worth more than \$30,000 if the company was publicly traded; and
- holding any stock in that company if the company was privately held.

After a thorough assessment, the Standing Committee reaffirmed 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. The Standing Committee also concluded 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.

Accordingly, I have accepted the recommendations of the Standing Committee, as approved by the Faculty Council, to revise the Clinical Research Rule as follows:

- raising the income de minimis threshold from \$10,000 to \$25,000;
- maintaining the \$0 threshold for equity in privately held companies;
- raising the equity de minimis threshold for publicly traded companies from

\$30,000 to \$50,000; (This is consistent with the FDA's reporting thresholds for clinical investigators. Financial interests below these levels must be disclosed, but will not be automatically prohibited); and

- adopting an approach, similar to our peer institutions and consistent with guidance issued by the AAMC, whereby we would consider petitions for exceptions to the above-mentioned restrictions. Granting such exceptions would require demonstrable, compelling justification consistent with the rights and welfare of clinical research subjects.

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.

These changes have been incorporated into the revised COI policy, and are effective as of today. They are in no way intended to replace the authority of an affiliated institution and its IRB to assess the impact of any potential financial interest on human subjects research. The HMS Office for Academic and Research Integrity and our colleagues at our affiliated institutions will be working to implement these changes in the coming weeks.

For additional information, please visit the website of the [Office for Academic and Research Integrity](#). You may also contact Gretchen Brodnicki, dean for faculty and research integrity, or Jennifer Ryan, director of research integrity, at outside_activites@hms.harvard.edu. We are grateful to the many members of our community who provided valuable insight as part of the extensive review process.

Sincerely,
Jeffrey S. Flier
Dean of the Faculty of Medicine
Harvard University