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NIH set to tighten financial rules for researchers

After a wave of financial scandals over the past few years involving biomedical researchers, the US National Institutes of Health (NIH) in Bethesda, Maryland, last week proposed far-reaching changes that would lead to tighter oversight of agency-funded extramural investigators and their institutions.

In the first proposed overhaul of financial reporting regulations since 1995, the agency is moving to counter a perception that researchers are being compromised by a growing number of consulting relationships with drug and medical-device companies.

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The proposed rules state that a

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“significant financial interest” exists when the combined value of an investigator’s equity holdings in, and payments from, a publicly traded company exceed US\$5,000 in any given year. Under current rules, the reporting threshold is \$10,000.

Any amount of equity in a privately held company would be considered a significant financial interest under the new rules.

Principal investigators and other key personnel on NIH-funded projects would be required to

report to their institutions any significant financial interest that could touch on their “institutional responsibilities”. Although current NIH rules allow investigators to decide which interests need to be reported, the new rules would put the onus on institutions to determine whether

investigators’ financial ties constitute a true conflict of interest. Institutions would also have to report to the NIH, in far greater detail than they currently do, how they are managing conflicts of interest for each investigator. For example, a university would have to tell the agency whether an investigator was required to sell all or part of any stock held in a company.

The proposed changes “will allow the NIH to determine whether the institution has made the proper decisions”, says Sally Rockey, the NIH’s acting deputy director for extramural research.

Senator Charles Grassley (Republican, Iowa), who has investigated financial conflicts among researchers, called the new proposal “an important step”. The proposed changes are open for public comment until 19 July and will be finalized “later this year”, says Collins. ■

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