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## NIH misconduct rules reviewed

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The US Department of Health and Human Services, which includes the National Institutes of Health (NIH), has [proposed changes](#) to rules governing misconduct in federally sponsored research and the status of [whistleblowers](#) who allege scientific wrongdoing.

The proposed rules, which update and standardize the definition of misconduct and the process for investigating and adjudicating complaints, would also expand the scope of plagiarism to cover individuals conducting peer review for funding or journal publication as well as scientists performing research.

Representatives of professional research societies and US medical schools generally support the proposed changes, which replace regulations originally approved in 1989 and have been amended several times since. Among the changes are government-wide policies and procedures on research misconduct issued by the White House Office of Science and Technology Policy in 2000. The department is [seeking public comment](#) through June 15, 2004.

The new rules are designed to "help ensure public confidence in the integrity of scientific data and the Public Health Service - supported research process," according to Chris B. Pascal, director of the department's Office of Research Integrity. "We're pleased to see these," said Howard Garrison, public affairs director for the Federation of American Societies for Experimental Biology. "We have to take a closer look at the provisions, but many of the changes are consistent with positions we have taken over the past several years," he told us.

Under the new rules, the scope of misconduct would be expanded to include research conducted under contract as well as that supported by grants. While continuing to define misconduct as "fabrication, falsification, or plagiarism," the reach would be expanded to include scientists engaged in peer review for funding or publication in a scientific journal. "Since plagiarism in reviews has been known to occur, extending the reach of misconduct regulations seems perfectly appropriate," said David Korn, senior vice president of Biomedical and Health Sciences Research at the Association of American Medical Colleges (AAMC).

The proposed rules also redefine several key terms: "scientific misconduct" is changed to "research misconduct," while "other practices," a catchall phrase intended to be inclusive, would be dropped. "It was vague and confusing," Garrison said, "and could lead to mistaken allegations of what is fair and not fair." To be misconduct, the new rules would require fabrication, falsification, or plagiarism to be a "significant departure" from accepted practices, as opposed to the current standard of "serious deviation."

Once an allegation is made, the new rules would separate the inquiry and investigation phases from the adjudication and appeal phases. This "would level the playing field by providing the accused researchers with much needed notice of the required process to be used and protections offered in addressing the allegations," the notice states.

Whistleblowers, who historically have brought to light the majority of misconduct cases, would no longer be considered a "party" to the probe and guaranteed a role in the investigation. Instead, they

would be "complainants" who do not participate beyond being a witness. "The institution may, but would no longer be required, to give the complainant an opportunity to comment on the inquiry and investigation reports," the notice states. Institutions would still be obliged to pursue an allegation of misconduct and to protect the whistleblower from retaliation as long as the complaint was made in "good faith."

Not everyone is pleased with the proposed change in whistleblower status. "This is an effort to protect the institutions from serious investigations and accountability," said Vera Hassner Sharav, president of the Alliance for Human Research Protection. "They are trying to eliminate the whistleblower's inclusion in the process. By doing that, they are insuring they will not obtain the relevant information," she said. "If they don't know what to ask for, they are not going to get it."

But the AAMC's Korn said whistleblowers were like witnesses in a criminal trial. "They present their knowledge and their facts," he said. "They don't actually participate [in conducting] the trial."

## References

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