

## Commission redefines ethical research practices

The US Commission on Research Integrity has coined a new definition of research misconduct. Saying that ethical research should be "truthful and fair" (who would argue?), the commission goes on to say that scientific misconduct is "misbehavior that fails to respect the intellectual contributions or property of others, that intentionally impedes the progress of research, or that risks corrupting the scientific record or compromising the integrity of scientific practices."

At present, scientific misconduct is defined as fabrication, falsification, plagiarism and "other practices" that deviate from commonly accepted practice. The vagueness of the latter phrase, as well as its legal standing, have been the subject of considerable dispute.

If the commission's new definition is accepted by Donna Shalala, secretary of Health and Human Services (HHS), it could become the touchstone in the biomedical research community for assessing whether there has been misconduct. A new definition of scientific misconduct will also have to pass muster with legislative committees on Capitol Hill if it is to become law. If it achieves the force of law or federal regulation, the new, broader definition will apply to research funded by the National Institutes of Health (NIH) and other HHS research agencies.

The commission's findings also include a 'bill of rights' for whistle-blowers, recommendations for more education in ethical research practices and suggestions as to how professional societies can help raise ethical standards. At a meeting this month, the commission will clarify the mechanisms for implementing its findings. In particular, it will decide what recommendations to make about the responsibilities of the Office of Research Integrity (ORI), part of the Department of HHS. It will then forward its report to congressional committees and Shalala.

The commission began work more than a year ago under the chairmanship of Kenneth Ryan of Harvard Medical School. It was established as a result of the 1993 NIH Revitalization Act to define misconduct and to advise ORI on regulations to protect whistle-blowers from retaliation. The requirements stemmed from congressional concern that the ORI was not operating as effectively as it could and that research universities and

### The integrity commission would broaden the definition of misconduct to include failure to recognize the intellectual property of others

institutions were retaliating against whistle-blowers who filed accusations in good faith.

The crux of the issue is, of course, how to define misconduct. The current definition, which is intended to provide a clear divide between legally sanctionable behavior and that which is merely uncollegial, leads to two types of problems, according to some members of the integrity commission. First, serious misconduct occurs that does not fall under the rubric of fabrication, falsification and plagiarism. On the other hand, people bring trivial complaints against colleagues, alleging misconduct where nothing that serious

has occurred. The commission is attempting to address both issues, primarily through the new definition of research misconduct and the section of the report on whistle-blowing, which includes the bill of rights. Several examples of punishable behaviour, which are not intended to be all-encompassing, are given under the new headings of misappropriation, interference and misrepresentation.

For example, under "misappropriation," the commission states that an investigator or grant reviewer shall not use the "words or ideas of another . . . without attribution appropriate for the medium of presentation. A breach in any "duty of confidentiality" is also listed as an offense of misappropriation.

Under "interference," the commission declares it an offense to "damage any research-related property of another" — such as reagents, biological materials, hardware or software. And, in a further effort to clarify what it means, the commission explicitly states that an investigator or reviewer must not "omit a fact" that results in a false statement.

No doubt, all of these examples could well end up being tested in administrative

### The whistle-blowers' view

Lawrence Rhoades, director of the division of policy and education at the Department of Health and Human Services' Office of Research Integrity (ORI), says that the office recently sponsored a survey to collect information about whistle-blowers and their experiences.

The survey, which was conducted by the Research Triangle Institute on behalf of the ORI, found that 68 per cent of whistle-blowers would be willing to do it again.

The ORI drew up a list of 128 whistle-blowers from the office's completed cases up to 1993. Addresses were found for 105 of them and 68 responded. The whistle-blowers were contacted irrespective of the outcome of their accusations.

All were asked if they had suffered negative consequences as a result of their actions, and 69 per cent said that they had. Of the 68 responders, a quarter said that the consequences had been significant. The survey included a long list of consequences and among those defined as serious were loss of position, denial of

tenure and delays in grant applications. Less serious consequences included ostracism. Sixty-two per cent of those surveyed said that blowing the whistle had no impact on their careers, 28 per cent said it had a negative impact, and 10 per cent said it was mixed.

In addition to the 68 per cent who said they would go through it again, 12 per cent said they probably would, 10 per cent said they were uncertain and 10 per cent said no.

The results, Rhoades says, are in keeping with a small survey carried out in the early 1990s when the ORI asked nine whistle-blowers if they would do it again. Six said yes.

Rhoades says that the survey, which will be published soon, was necessary because the ORI had no real information about the consequences for whistle-blowers, except from those who said they had been badly affected by the experience. "Every story is not a horror story," he says.

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