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Contact: Paulette W. Campbell  
(301) 571-7795  
[campbell@opa.faseb.org](mailto:campbell@opa.faseb.org)

## **FASEB Supports Goal of ORI Training Guidelines But Strongly Criticizes its Approach**

Bethesda, Md. – A draft policy by the Office of Research Integrity (ORI) that would require all research staff supported by grants from the Public Health Service (PHS) to undergo training in the "responsible conduct of research," is too broad, has a flawed approach and could be prohibitively expensive, said Mary J. C. Hendrix, the president of the Federation of American Society of Experimental Biology (FASEB).

In an August 7 letter to Chris B. Pascal, ORI's acting director, Dr. Hendrix wrote, "Scientific misconduct offends the high ethical standards held by the vast majority of scientists. Responsible scientists are the first victims of dishonest practices. Our progress is dependent on accurate, reliable, and reproducible research findings, and any deviation from this standard wastes valuable time, effort, and resources. As scientists and educators, we strongly support the principles of honesty and integrity in all aspects of research. Therefore, we have read the draft policy with great interest. Nonetheless, we have serious concerns about the scope of the draft policy, the approach mandated, and the financial implications."

ORI's draft guidelines would expand its current policy – which current applies only to trainees – by requiring all PHS-supported research staff, including researchers, data management staff, technicians, nurses, subcontractors and other personnel, to undergo responsible research conduct training. "All researchers, from the inexperienced to the expert scientist, should be afforded educational opportunities that contribute to the development of the whole researcher and encourage the proliferation of life-long attitudes toward conducting research in a responsible manner," the authors state in the draft's introduction. The new instructional policy would apply to all types of research, including animal, human or basic research or research training conducted with PHS support.

This scope is too broad, according to Dr. Hendrix. "Students and trainees must have instruction in the responsible conduct of research," she wrote. "But the extension of this requirement to 'all staff,' including subcontractors and consultants, will result in an enormous involvement of time and resources."

Dr. Hendrix also questioned the effectiveness of the guidelines. "We support the objectives of increasing knowledge of responsible conduct of research issues, improving ability to make ethical choices, developing appreciation for accepted scientific standards, providing information about regulations and supplying resources for further study," she wrote. "But many of these issues involve field-specific standards. The judgement criteria appropriate for research in anthropology may not be the same as those for x-ray crystallography. A single program for all research personnel cannot adequately treat all of the parameters for every discipline."

And the anticipated costs of developing, implement and maintaining the proposal could be problematic, she said. "In addition to the cost of creating a huge and diversified program of instruction, the institutions are also being asked to provide certification of the compliance status of all research personnel. The new reporting burden will be substantial. We are not convinced that there is justification for expenditures of this magnitude. We know of no evidence that the benefits expected from this undertaking will justify the cost, and there is no allowance for this cost in the new policy."

Dr. Hendrix encouraged ORI to develop educational resources and course modules. "I believe that a more effective expenditure of time and resources would be to have ORI develop teaching aids that could be incorporated into research education programs, such as those already in place and my institution, the University of Iowa, as well as at other institutions across the nation," she said.

The FASEB letter can be found on the Web at [www.faseb.org/opa/ltr/oriltr.html](http://www.faseb.org/opa/ltr/oriltr.html).

This ORI policy is available on the Web at <http://ori.dhhs.gov/TheRCRPolicy.htm>. The public has until August 21 to respond to the ORI draft policy. But Dr. Hendrix has asked for an extension "to allow the research community more time to present its viewpoint."

*FASEB is comprised of 21 societies with more than 60,000 members, making it the largest coalition of biomedical research associations in the United States. The mission of FASEB is to enhance the ability of biomedical and life scientists to improve, through their research, the health, well-being and productivity of all people. FASEB serves the interests of these scientists, particularly in those areas related to public policy. FASEB also facilitates coalition activities among Member Societies and disseminates information on biological research through scientific conferences and publications.*

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