August 16, 2010

Attention: Jerry Moore  
NIH Regulation Officer  
Office of Management Assessment 
National Institutes of Health  
6011 Executive Boulevard  
Suite 601, MSC 7669 
Rockville, MD 20852-7669

Re: “Responsibility of Applicants for Promoting Objectivity in Research for Which Public Health Service Funding is Sought and Responsible Prospective Contractors”

RIN 0925-AA53  
NIH-2010-0001

Dear Mr. Moore:

The American Physiological Society (APS) thanks you for the opportunity to offer these comments in response to the Department of Health and Human Services (DHHS) Notice of Proposed Rulemaking (NPRM) “Responsibility of Applicants for Promoting Objectivity in Research for Which Public Health Service Funding is Sought and Responsible Prospective Contractors.” As a scientific society, the APS represents individual investigators rather than research institutions and will therefore restrict our comments to matters directly involving extramural researchers.

The APS recognizes the need to conduct taxpayer funded research in accordance with the highest ethical standards in order to maintain the public trust and ensure research integrity. Relationships between academic researchers and their colleagues in industry are both beneficial and necessary for facilitating the flow of scientific information and advancing basic research discoveries to applied technologies, including treatment and prevention strategies for disease. The importance of bridging the basic and applied sciences was recently highlighted with passage of the Cures Acceleration Network (CAN) as part of the Patient Protection and Affordable Care Act. The CAN will focus resources on translational research in both academia and industry with the goal of speeding drug discovery and development. We strongly urge the NIH to express its support for such collaborative arrangements lest research institutions see the new FCOI regulations as a reason to discourage important collaborations between academic researchers and for-profit entities.
In light of these principles, the APS offers the following recommendations in response to the proposed rules:

- **Adoption of a risk-based strategy for assessing the potential for a given financial relationship to pose a conflict of interest would maximize efficiency and ease regulatory burden as a result of the proposed regulations.**

  Central to the goal of managing COI and ensuring scientific integrity is efficiently identifying which relationships represent a potential conflict and which do not. One approach to evaluating relationships would be to promote the use of a risk-based strategy in assessing the potential for a given relationship to pose a conflict of interest. Institutions should be encouraged to take into account whether financial relationships pose a low or high risk of conflict of interest. Once a determination has been made with respect to potential risk, institutions could then utilize simplified procedures such as expedited review for low risk entities that are unlikely to pose an actual conflict of interest. This would have the effect of maximizing the efficiency of the system while significantly reducing regulatory burden.

- **NIH should consider the practical ramifications of the proposed regulations as they apply to subrecipients of award funds when subrecipients are based in foreign countries.**

  The proposed regulations address institutional responsibilities for subrecipients of award funds and would require that awardee institutions ensure that subrecipients comply with FCOI rules. This requirement could be problematic when researchers are collaborating with subrecipients operating under a different set of laws and regulations in a foreign country. We therefore urge the NIH to consider the practical effect that the regulations would have in those instances where subrecipients of grant funds operate in foreign countries.

- **NIH should provide guidelines for the content of required training on FCOI, or standard training programs and templates.**

  The proposed regulations would require regular training for investigators on conflict of interest policies. We recommend that the NIH clearly articulate its expectations for the content of the required training, or provide standard training programs or templates to institutions.

- **NIH should consider restricting the period of time following the completion of an award during which the DHHS can request documentation related to FCOI disclosure.**

  We are concerned about the proposed authority of DHHS to inquire “at any time (i.e., before, during, or after award) into any Investigator disclosure of financial interests and the Institution’s review of, or response to, such disclosure, whether or not the disclosure resulted in the Institution’s determination of a FCOI.” We recommend that NIH consider restricting the inquiry period after the completion of an award to a defined number of years in accordance with agency record retention requirements.

- **Non-profit, member-based professional scientific and engineering societies should be excluded from the regulations.**
As a member of the Federation of American Societies for Experimental Biology (FASEB), we endorse the recommendations made in its response to the NPRM, including the suggested modification of the term “Significant Financial Interest” as follows:

“(2) The term significant financial interest does not include the following types of financial interests: reasonable and customary reimbursements for expenses incurred; salary, royalties, or other remuneration paid by the Institution to the Investigator if the Investigator is currently employed or otherwise appointed by the Institution; any ownership interest in the Institution held by an Investigator, if the Institution is a commercial or for-profit organization; income from seminars, lectures, or teaching engagements sponsored by a federal, state, or local government agency, or an institution of higher education as defined at 20 U.S.C. 1001(a), or a non-profit, member-based professional scientific or engineering society; or income from service on advisory committees or review panels for a federal, state, or local government agency, or an institution of higher education as defined at 20 U.S.C. 1001(a), or a non-profit, member-based professional scientific or engineering society.”

Professional societies play a vital role in the scientific community by providing a forum for scientists to interact and advance their discipline through scientific meetings, journals and education programs that foster the next generation of researchers. Many scientists generously volunteer their time and expertise to these organizations as board members, journal editors, peer reviewers and in other roles. Researchers receive modest compensation for some of these activities, but more often they receive only reimbursement for travel expenses related to their activities. To include these types of financial relationships as possible sources of conflict of interest casts a negative light on these valuable interactions. We recommend that non-profit, member-based professional scientific and engineering societies be excluded from the regulations.

The APS is a professional society dedicated to fostering research and education as well as the dissemination of scientific knowledge concerning how the organs and systems of the body work. The Society was founded in 1887 and now has nearly 10,000 member physiologists who conduct research at colleges, universities, medical schools, and other public and private research institutions across the U.S. The National Institutes of Health (NIH) supports the research of many APS members, who will thus be directly affected by the proposed regulations on Financial Conflict of Interest (FCOI). In closing, the APS appreciates this opportunity to provide input on the proposed FCOI rules. We remain committed to working with the NIH and DHHS to ensure that research is conducted in accordance with the highest ethical standards.

Sincerely,

Peter D. Wagner, M.D.
President
American Physiological Society