

AAU Association of American Universities
AAMC Association of American Medical Colleges

June 29, 2009

Jerry Moore
NIH Regulations Officer
NIH, Office of Management Assessment
6011 Executive Boulevard
Suite 601, MSC 7669
Rockville, MD 20852-7669

Reference: Responsibility of Applicants for Promoting Objectivity in Research for Which Public Health Service Funding is Sought and Responsible Prospective Contractors; Request for Comments, May 8, 2009

Dear Mr. Moore:

In connection with our June 10, 2009 comment letter on the Advance Notice of Proposed Rulemaking (ANPRM) referenced above, two of our constituent institutions have pointed out a possible ambiguity. We write to make certain that the meaning of our comments is clear.

The current PHS regulations governing objectivity in research provide for a three-step process leading to required disclosure to the awarding component by the awardee institution of investigator conflicts of interest. Step one is that the institution must require by the time an application is submitted to the PHS that an investigator planning to participate in the PHS-funded research has reported to the institution's designated officials "a listing of his/her known Significant Financial Interests (and those of his/her spouse and dependent children)".

Step two is that the institution's officials must review these reports of Significant Financial Interests and "determine whether a conflict of interest exists and, if so, determine what actions should be taken by the institution to manage, reduce or eliminate such conflict of interest".

Step three is that prior to the institution's expenditure of any funds under the award, the institution "will report to the PHS Awarding Component the existence of a conflicting interest. . . found by the institution and assure that the interest has been managed, reduced or eliminated...".

Because we understood the questions in the ANPRM to be focused on step one and step three, our comments were directed only to those steps. Thus we commented in connection with step one that the institution should require investigators to report to the designated officials all of their financial interests related to their research responsibilities, so that the officials could then determine which of them "would reasonably appear to be affected by the research for which PHS funding is sought", as required by the regulations.

Further, in response to the questions in the ANPRM about step three of the process, that is, the definition of Significant Financial Interest for purposes of disclosure of the financial interest to the awarding component, we

commented that the threshold for disclosure of the financial interest to the awarding component be changed from \$10,000 income/\$10,000 + 5% ownership interest for stock and options to \$5,000 income/\$5,000 + 0.1% ownership interest for stock and options in publicly traded firms and zero threshold for non-publicly held funds.

Because the ANPRM did not raise a question about step two, that is, the essential institutional determination of whether or not a significant financial interest constitutes a conflict of interest, we did not comment on step two. However, the absence of commentary on this point in no way is intended to imply that every financial interest over the recommended threshold (\$5,000/\$5,000+0.1%/zero) be disclosed to the awarding component.

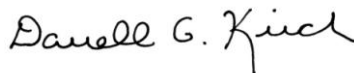
On the contrary, the Associations strongly support the continuation of the current regulatory requirement that the institution must make a determination of which financial interests, if any, reported by the investigator and rising above the “significance” level, constitute a conflict and thus must be disclosed to the PHS. We urge PHS to retain this crucial step of the institutional determination of whether or not a conflict exists. Thus only those interests above the threshold, wherever set, that constitute a conflict as determined by the institution should be reported to the awarding component by the awardee institution.

Thank you for your consideration.

Sincerely,



Robert Berdahl, Ph.D.
President
AAU



Darrell G. Kirch, M.D.
President
AAMC