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To: Jerry Moore
NIH Regulations Officer
NIH Office of Management Assessment

Dear Mr. Moore,

On behalf of the American Association for the Advancement of Science (AAAS), thank you for the opportunity to comment on the Advance Notice of Proposed Rulemaking (ANPRM) pertaining to objectivity in research, published in the *Federal Register* on May 8, 2009.

Over the past three decades, there has been dramatic growth in collaborative arrangements between academic researchers and their institutions and private industry. This trend shows no signs of abating. This trend is a positive sign because the benefits of university-industry collaborations are considerable for industry, universities, and, significantly, society at large. For universities, benefits include scientific collaboration, access to raw materials and instrumentation, and special opportunities for training and education. For industry, the benefits can mean access to first-rate academic researchers, inexpensive labor in the form of post-docs and students, advantageous licensing agreements, and reduced costs of conducting new research and development programs. Society gains from the increase in knowledge, new products, and a general boost to the economy.

At the same time, these partnerships have heightened concerns about the possible effects of conflicts of interest on professional judgment in the design, conduct, evaluation, and reporting of research, the mentoring of students, and objective advice given on important public policy matters. Conflicts of interest are not inevitable, nor is a conflict of interest necessarily problematic. What makes a conflict of interest worrisome is the possibility of bias from monetary or other gain that can distort the research process and/or the interpretation and presentation of findings.

It is worth emphasizing that public perceptions matter greatly, and the appearance of a conflict, even when no actual conflict exists, can undermine trust in ways that may never be adequately restored. While perception cannot be regulated by government, it can be influenced. We urge the Public Health Service (PHS) to include a strong statement in any subsequent rulemaking that researchers and their institutions have an obligation to consider how their relations with funders of their work will be perceived by others, and that they should proceed with due diligence in forming and managing those relationships.

While not the focus of the ANPRM, it is essential to bear in mind that potential economic rewards can both stimulate and corrupt the open intellectual rigor that is the ostensible standard of all academic and professional organizations.

Now we respond to the specific issues/questions raised in the ANPRM, selecting those for which we believe the experience of AAAS can offer much.

I. Expanding the Scope of the Regulations and Disclosure of Interests. The keystone of current regulations to manage conflicts of interest is disclosure. Researchers and their institutions should be held accountable for failure to reveal pertinent factors that may bias their work. The regulations should be clear on what is expected by way of disclosure. The regulations should also state how the government will utilize and weigh such information relative to other potential factors.

With disclosure such a critical component of managing conflicts of interest, it is surprising how little is known about its impact on decision-making and behavior. In this regard, the PHS should issue a Request for Applications (RFA) that would promote empirical studies on disclosure as a management strategy for conflicts of interest.

II. Definition of “Significant Financial Interest.” The definition of “significant financial interest” (SFI) should be broadened. The ANPRM lists six current categories of exemption from SFI. We believe at least two of those should be covered by the definition in any new policy: a) income from seminars, lectures, or teaching engagements sponsored by nonprofits entities (bullet #3), and (b) income from service on advisory committees or review panels for nonprofit entities (bullet #4). These interactions can create conflicts when, for example, nonprofit organizations have pronounced or even subtle biases on contentious policy issues.

III. Identification and Management of Conflicts by Institutions. The ANPRM asks whether institutions should be required to establish independent committees to review financial disclosures. In principle this appears to be a useful approach. But the PHS, in collaboration with the research community, should develop suggested best practices for establishing such committees and for selecting members, as well as for identifying reporting responsibilities that would insulate the committees from conflict situations.

While AAAS believes that an institution should be required to have a conflict-of-interest plan in place for each conflict situation it proposes to monitor, the government should not attempt to prescribe standards for such plans. Grant recipients are highly heterogeneous with respect to both their administrative systems and culture (and public institutions typically have another layer of oversight imposed on them by state governments) and conflict situations at times defy simple and unambiguous descriptions. This diversity makes it unlikely that uniform standards embedded in regulations would be helpful, either in guiding the development of institutional policies or in underpinning fair and effective enforcement by the government. Broad guidelines, however, likely would be helpful, and the PHS should reference best practices such as the conflict-of-interest guidelines released by the Association of American Universities (AAU) and the Association of American Medical Colleges (AAMC) in 2008. While institutions should not necessarily be required to submit their plans to the PHS in every case, they should be prepared for such requests, and the PHS should likewise be prepared to exercise diligent oversight.

Furthermore, investigators involved in participant selection, informed consent and clinical trial management should be prohibited from having a significant financial interest in a company whose interests could be affected by their work. The AAU/AAMC guidelines suggest a waiver would be justified in “compelling circumstances,” determined on a case-by-case basis by the nature of the work, the nature of the financial interest, and how the two are related. When the circumstances prove to be compelling enough for the research to proceed, rigorous monitoring of the research by impartial individuals must take place. AAAS endorses this approach.

AAAS also recommends that the conflict-of-interest requirements apply to all partners in collaborations, including contractors and other such collaborators. We see no reason why these individuals/organizations should not be held to the same, or at least consistent, high standards.

IV. Assuring Institutional Compliance. We believe that fair and effective enforcement of conflict-of-interest policies is necessary. So is effective training on these issues. AAAS supports including financial conflict-of-interest training for scientists as part of educational programs in research ethics aimed at PIs and lay research personnel, as well as post-docs, graduate students, and, where appropriate, other members of the research team.

V. Requiring Institutions to Provide Additional Information to the PHS. At a minimum, institutions should be required to provide information that will enable the PHS funding unit to understand the nature and seriousness of the conflict, to assess the appropriateness of the management plan, and to be able to judge whether the institution is in compliance with government regulations. Beyond that, it would be useful to build up a knowledge base of what criteria or factors institutions use to determine whether some sort of management is required and what it should include. A new regulation offers opportunities for collecting information, preferably by submission via a standard electronic format, that interested parties could use to improve policies and practices.

VI. Institutional Conflict of Interest. Institutional conflicts are complex, and in some cases will be far removed from the researcher funded by the PHS. AAAS recommends that the PHS encourage institutions to develop policies related directly to externally funded research and that the PHS provide guidance, not regulation, where appropriate. In that regard, we view the following components as essential for an institutional conflict-of-interest policy:

- Delineate what constitutes an institutional conflict of interest.
- Identify who is covered under the institutional conflict-of-interest policy and the channels of responsibility.
- Establish a separate committee for reviewing/managing institutional conflicts of interest that includes members unaffiliated with the institution and with no competing or aligned interest.
- Build a firewall between the investment and research activities of the university.
- State clearly the array of sanctions for violations of the policy.
- Develop educational programs and materials for all those covered by the policy.

In conclusion, any new PHS regulations should contain elements of both firmness and flexibility when it comes to objectivity in research. We hope these suggestions will assist the PHS in

developing further policies. AAAS is the world's largest multidisciplinary science society, representing the interests of ten million scientists worldwide, and publisher of the prestigious peer-reviewed journal *Science*. We have a long-standing interest and expertise in conflicts of interest in scientific research. We stand ready to work with the PHS in addressing this important and complex subject.

Sincerely,

A handwritten signature in black ink, appearing to read "Alan I. Leshner". The signature is fluid and cursive, with a long horizontal stroke at the end.

Alan I. Leshner