



ADVANCING SCIENCE, SERVING SOCIETY

Alan I. Leshner
Chief Executive Officer and
Executive Publisher, *Science*

July 20, 2010

To: Jerry Moore
NIH Regulations Officer
Office of Management Assessment
National Institutes of Health
6011 Executive Blvd., Suite 601, MSC 7669
Rockville, MD 20852-7669

Dear Mr. Moore,

The American Association for the Advancement of Science (AAAS) appreciates the opportunity to comment on the Proposed Rule on the “Responsibility of Applicants for Promoting Objectivity in Research for Which Public Health Service (PHS) Funding is Sought and Responsible Prospective Contractors,” published in the *Federal Register* on May 21, 2010.

We are very pleased that several of the recommendations that AAAS and other groups made in response to the Advance Notice of Proposed Rulemaking (ANPRM) pertaining to objectivity in research have been incorporated into the current proposal. These suggestions included training requirements for investigators, the inclusion of subgrantees, the removal of the exemption from disclosing non-profit income, and management plans in which the specifics would fall to the institution’s discretion.

Before we address specific elements within the Proposed Rule, we would like to address a broader challenge that recent events have raised: specifically, when a research institution imposes sanctions for conflict of interest violations, and the guilty researcher leaves that institution for another, thereby avoiding the original sanctions. This seems contrary to the principles and intent that underlie the proposed rulemaking. While an increased role for institutions, as reflected in the new proposal, is warranted, individual researchers must be held accountable for their behavior and the public must be assured that this will indeed be the case. We strongly recommend that the proposed rules follow the PHS model governing research misconduct, where individuals and institutions found to have violated existing regulations are both held accountable and the sanctions applied to individuals stay in force no matter where the individual does his/her research.

With respect to specific elements within the Proposed Rule, AAAS has some concerns, recommendations, and questions for clarification. Our primary concerns center on “significant financial interest,” travel reimbursement, and institutional responsibilities.

- **Definition of Significant Financial Interest.** The definition of “significant financial interest” (F.R., page 28705) potentially includes equity interests that are not necessarily directed or controlled by the investor—for example, a retirement account. It would be difficult to parse out an investigator’s financial interest with regard to those types of

