

*AAU Association of American Universities*  
*AAMC Association of American Medical Colleges*

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June 10, 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:

The Association of American Universities (AAU) represents 60 leading U.S. research universities who together perform nearly 60 percent of all federally funded university-based research and annually award more than half of all Ph.D. degrees earned in our country.

The Association of American Medical Colleges (AAMC) is a not-for-profit association representing all 130 accredited U.S. medical schools; nearly 400 major teaching hospitals and health systems, including 68 Department of Veterans Affairs medical centers; and nearly 90 academic and scientific societies. The AAMC member medical schools and teaching hospitals collectively perform about 60 percent of all extramural research sponsored by the NIH, and a significant portion of research supported by other agencies.

The AAU and the AAMC welcome the opportunity to comment on the Advanced Notice of Proposed Rulemaking (ANPRM) and endorse without reservation the principles it articulates as those that should guide regulatory and policy provisions in addressing the predominant areas of concern in the identification, analysis, and management of conflicts of interest in research. The Associations appreciate the opportunity to comment on the ANPRM's questions as a means to assist NIH as it develops measures to assure that institutions deal effectively with the challenges raised by conflicts of interest.

The ANPRM's principles affirm the primacy of the protection of human subjects who participate in research, the protection of the integrity of the research itself, and the value of principled relationships with industry. They also underscore the absolute necessity of complete and timely disclosure of financial interests and effective management of conflicts, commensurate with the level of risk involved.

These are the principles that guided the February 2008 Report from the AAU and AAMC entitled "Protecting Patients, Preserving Integrity, Advancing Health: Accelerating the Implementation of COI policies in Human Subjects Research." That Report included an extensive set of policy recommendations, implementation strategies, and educational tools, and it significantly extends the strong 2001-2002 recommendations of both Associations.

That Report begins as follows:

The vitality and integrity of biomedical research are critical to the health of the public and to finding the keys to addressing some of society's most compelling and difficult challenges. In the United States, universities and medical schools, the dominant source of this research, are now more than ever key components of the social, economic and scientific forces that empower our nation in a globalized economy. The academic research community is increasingly aware of pressures created by these changed societal expectations, particularly those associated with its relationships with industry. A principled partnership between the academic community and industry is essential if we are to realize the promise of biomedical research, but such collaboration can also create serious conflicts of interest. These pressures compel academic institutions to reaffirm their highest values of protecting the integrity of their research, the wellbeing of the human subjects who participate in it, and the trust of the public.

[The Report] strongly advocates the adoption of more consistent policies and practices across academic institutions . . . [and] also asserts that time is of the essence with respect to fully implementing comprehensive conflicts of interest programs in human subjects research.

Our comments on the ANPRM follow its format.

### I. Expanding the Scope of the Regulations and Disclosure of Interests

- a. *Should the regulations be expanded so that they also apply to Phase I SBIR/STTR research applications/proposals for PHS funding?*

The Associations believe that any and all applications and proposals for NIH funding should be subject to the Regulations for Promoting Integrity in Research for Which PHS Funding is Sought. The Associations do not favor continuing to exempt from the definition of "significant financial interest" those ownership interests in the institution where the institution is an applicant under the SBIR Program (including the STTR Program). Successful implementation of Bayh-Dole does not depend on the exemption of SBIRs and STTRs from the regulatory requirements. Indeed, greater transparency, consistency and ease of implementation for universities and medical schools could be achieved by removing this exemption.

- b. *Would expanded disclosure allow the Institution to better determine which of these Significant Financial Interests constitute a FCOI?*

In their February 2008 Report, the Associations recommended that Investigators should report to their institutions all of their financial interests directly or indirectly related to their research responsibilities (as well as their other institutional responsibilities), regardless of amount. However, to respond fully to the ANPRM question, it is necessary to distinguish two entirely different concepts that are often conflated in addressing the issue of what should be revealed to whom in terms of financial interests. The original 2001 AAMC recommendations usefully and meaningfully distinguished between "reporting" and "disclosing" financial interests and conflicts. "Reporting means the provision of information . . . by a covered individual to responsible institutional officials and to the institutional COI committee, or the transmission of such information within institutional channels (e.g., from the COI committee to the IRB)."

"Disclosure means a release of relevant information about significant financial interests in human subjects research to parties outside the institution's COI review and management processes. . . ." We believe it is important that this distinction be preserved, and that NIH should make a distinction in its own policies and in

regulatory provisions between what should be reported to one's institution and what should be routinely disclosed to NIH. Our discussion will use this distinction. Of course, we recognize that NIH on occasion may require additional information based on its review of disclosures or other oversight requirements.

The 1995 regulations indicate that institutions must “[r]equire by the time that an application is submitted to PHS each Investigator who is planning to participate in the PHS-funded research has submitted to the designated official(s) a listing of his/her known Significant Financial Interests (and those of his/her spouse and dependent children) . . . that would reasonably appear to be affected by the research for which PHS funding is sought. . . .” This formulation permits investigators to determine for themselves those interests “that would reasonably appear to be affected”, and in so doing places a difficult burden on them to distinguish those interests that would be affected from those that would not. This provision almost certainly creates the potential for inconsistencies and misunderstandings on the part of the investigator community as to which of several interests might or might not be reportable. Experience has shown that to promote consistency and accuracy, the responsibility for determining which financial interests are relevant to a determination of conflict of interest should shift to the institution. This is reflected in the Associations’ 2008 Report, which recommends that:

Covered individuals . . . should be required to report all of their outside financial interests directly or indirectly related to their professional responsibilities to the institutions, including their dollar amount, regardless of whether or not the individual believes these financial interests might reasonably appear to be affected by the individual’s current or anticipated human subjects research.

Thus with respect to the requirement for reporting to their institutions, the Associations support NIH’s extending the regulation to require covered individuals to report to their institutions all financial interests directly or indirectly related to their research responsibilities, regardless of amount, excluding reasonable reimbursement for travel and excluding sponsored research agreements between a sponsor and the institution. Institutions may choose to extend this requirement to include reporting of all interests related to their professional responsibilities, consistent with the AAMC-AAU recommendation. That requirement reflects the fact that many of those with research-related responsibilities also have other responsibilities, including those relating to clinical practice, teaching, and administrative duties.

Moreover, the regulatory requirement concerning reporting to institutions should be extended to eliminate any *de minimis* thresholds for such reports, as is more fully explained, below.

## II. Definition of “Significant Financial Interest” (SFI)

### *a. Should the current exemptions be maintained?*

- *If so, are the current de minimis thresholds reasonable? If not, how should the de minimis thresholds be changed? Should these thresholds be the same for all types of research?*

The 1995 regulations define “Significant Financial Interest” as “anything of monetary value, including but not limited to, salary or other payments for services (e.g., consulting fees or honoraria); equity interests (e.g., stocks, stock options or other ownership interests); and intellectual property rights (e.g., patents, copyrights and royalties from such rights).” This SFI definition is used in the regulations to define not only what must be reported to one’s institution but also what must be disclosed to PHS. These two actions – reporting and

disclosure -- must be distinguished, as previously discussed. With respect to the question of whether the current exemptions should be retained for purposes of disclosing to the awarding component, the following comments are offered.

The 1995 regulations provide in Section 50.604(g)(2) that the institution must certify 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 (but not the nature of the interest or other details) found by the Institution and assure that the interest has been managed, reduced or eliminated in accordance with this subpart...” Practically speaking, many awardee institutions have adopted the Regulations’ existing financial thresholds (more than \$10,000 income or more than \$10,000 stock plus more than 5% ownership interest) as the threshold for disclosing to the awarding component. The Associations believe that the following changes in the *de minimis* thresholds are necessary for disclosing to the awarding component in order to increase consistency across institutions, enhance transparency, and remove the potential for misunderstanding.

To explain their position, the Associations again reiterate their support for the principles articulated in the ANPRM and affirm that the value of integrity in research is fundamental and does not differ in character depending on the nature of the research, with or without human subjects. Accordingly, the Associations believe that the existing thresholds of more than \$10,000 income or more than \$10,000 stock plus more than 5% ownership interest should be lowered for purposes of disclosing to the PHS awarding component potential conflicts to more than \$5,000 income, more than \$5,000/more than 0.1 percent stock, options, or other ownership interest in a publicly traded entity, and stock, options, or other ownership interest of any value in a non-publicly traded entity.

The Associations have carefully considered a zero threshold for purposes of disclosing to the PHS awarding component. Although the Associations would not be opposed to such a threshold, it would clearly create a huge volume of disclosures and would diminish PHS’s ability to focus on conflicts with the potential to affect PHS-funded research. A zero disclosure threshold will generate an enormous volume of noise in the system rather than focus on the important signals. Accordingly, we recommend above the \$5,000 income, \$5,000/0.1 percent ownership in a publicly-traded company, and zero threshold for ownership interests in a non publicly-traded company instead. In this connection, the Associations support changing the designation of those financial interests that must be routinely disclosed to the PHS from “significant financial interests” to “disclosable financial interests”.

Finally, the word “report” in Section 50.604(g)(2) should be changed to “disclose”, for the reasons indicated above.

- *If not, which exemptions should be reconsidered, and why?*

Currently, the regulations exempt from the definition of Significant Financial Interest the reporting of royalties from the applicant institution. The Associations support the elimination of this exemption. Such royalties should be examined by the institution for their potential to create conflicts of interest and thus should be reported to it. As indicated previously in our response, the Associations also believe that “ownership interests in the institution, if the institution is an applicant under the SBIR Program” should also be removed from the list of exemptions from the definition of SFI.

The Associations support retaining the exemption for “[i]ncome from seminars, lectures, or teaching engagements sponsored by public or nonprofit entities,” and they support retaining the exemption for “Income from service on advisory committees or review panels for public or nonprofit entities”. These activities are part of an individual’s professional commitment to the institution, they redound to the benefit of the institution, and should not be considered personal financial interests subject to scrutiny under the PHS regulations.

With respect to equity interests that institutions should require covered individuals to report to their institutions, the existing exemption should be removed for “equity interests that when aggregated for the Investigator and the Investigator’s spouse and dependent children, meets both the following tests: Does not exceed \$10,000 in value as determined through reference to public prices or other reasonable measures of fair market value, and does not represent more than a five percent ownership interest in any single entity.” Similarly, for purposes of reporting to one’s institution, the exemption should be removed for “Salary, royalties or other payments that when aggregated for the Investigator and the Investigator’s spouse and dependent children over the next twelve months, are not expected to exceed \$10,000”, for the reasons specified above.

- b. Should certain SFIs (i.e. from specific sources or related to certain types of research) be automatically considered FCOI under the regulations? If so, what types of SFIs?*

As noted previously, the Associations recommend including equity, options, or other ownership interests in a privately-held company as a SFI, regardless of amount. Whether it constitutes a financial conflict of interest depends on an examination of the facts and circumstances of the particular case.

### III. Identification and Management of Conflicts by Institutions

- a. Should large Institutions (defined as greater than 50 employees) be required to establish an independent committee to review financial disclosures, and require that committee to report to an organizational level within the Institution that is not conflicted by the short-term financial interests of the Investigator or Institution? Would a 50 employee threshold reasonably balance the risk of a more relaxed requirement for small Institutions against the burden imposed by requiring an independent panel for these evaluations?*

The Associations support a requirement that large institutions (defined as greater than 50 employees) that receive one or more PHS research grants be required to establish an institutional committee to review financial reports from investigators. However, the question regarding whether the committee should be required “to report to an organizational level within the Institution that is not conflicted by the short-term financial interests of the Investigator or Institution” is ambiguous and lacking in any external definition. Such a requirement can reasonably be interpreted differently under different conditions, could obviously change from project to project, depending on particular financial interests, and could subject institutions to extensive second-guessing.

Moreover, the phrasing may imply that the conflicts committee must itself be a decision-maker. In many institutions, including some public institutions, committees in general do not themselves have administrative, decision-making authority but only the authority to recommend to an individual with administrative authority. Individuals with delegated administrative authority may be the only authorized decision-makers in the institution.

The Associations propose as an alternative that NIH consider requiring that the committee be required to report to a designated institutional official consistent with other committees of similar scope and importance, and that its members themselves be subject to the institution's conflict of interest policies. In this manner, any potential conflicts can be reviewed and managed, reduced, or eliminated, depending on the circumstances.

- b. *For certain types of research, should the Institution be required to develop a conflict management plan when an Institution decides to manage or reduce, rather than eliminate, the conflict? If so, for which types of research? Should there be prescribed standards for conflict management plans? Should the Institution be required to submit this plan to the PHS funding component when it reports the existence of a conflict to the component?*

The Associations' 2008 recommendations indicate that for any research that involves a significant financial interest, there should be a management plan. Thus for any disclosable conflict (see the response to question II.a. regarding disclosure thresholds to NIH, above), the Associations support extending the disclosure requirement by the institution to the funding component to include a brief description of the type of conflict involved, the amount of the financial interest, and the key features of the institution's management plan, rather than a requirement that the management plan itself be submitted, because it may include information that does not directly relate to the PHS funding. However, PHS would, of course, have the right to request the management plan in the event of questions or need for additional information. For routine reporting, NIH should develop a standard electronic format for submitting such additional information to the funding component.

The Associations strongly oppose prescribed standards for management plans because of the enormous variety of potential conflicts and research projects. Prescribed standards could not possibly anticipate the myriad facts and circumstances encountered by Associations' members. The Associations' 2008 Report provides as follows:

Strategies for management of potential conflicts of interest range from highly specific conditions for researcher participation in the research project to more abstract assurances of compliance, but all are directed at ensuring integrity, protection of subjects, and public trust. The examples provided in this section do not represent a complete list of all management techniques and strategies, but rather a collection of approaches that academic institutions have used to mitigate the challenges posed by potential conflicts. They are intended to provide a range of options from which institutions might choose, depending on the circumstances of a particular case. There is no formula that dictates which strategies "fit" which conflicts. The final determination is dependent on an individualized assessment at the local institutional level of the totality of the circumstances that need to be taken into account. Each institution is best positioned to make this assessment on its own behalf, consistent with the framework for federal regulation of conflicts of interest and with the institution's responsibility for the quality and integrity of the research conducted under its auspices.

- c. *Should Investigators who are involved in participant selection, the informed consent process, and clinical management of a trial, be prohibited from having a Significant Financial Interest in any company whose interests could be affected by their research or clinical trial? If so, what special circumstances would justify waiving this condition, if any?*

The Associations' 2008 Report recommends a "rebuttable presumption" standard that institutions should adopt when dealing with financial interests in human subjects research (with thresholds as indicated previously in

these comments). However, an *a priori* prohibition against involvement in particular components of human subjects research would fail to take into account the enormous variety of circumstances, stages, and types of research that must be accommodated in any set of regulatory provisions on this topic. Therefore, the Associations urge the NIH to adopt a more nuanced approach, consistent with the following from the 2008 Report:

It is critically important for institutions to develop specific policies for protection of human subjects in the presence of conflicts of interest. When the COI Committee devises any conflicts management plan, special attention must be paid to focusing its strategies on the protection of subjects. Interactions between a conflicted researcher and the subjects participating in the proposed research must receive the strictest scrutiny because the interactions are fraught with ethical dilemmas and carry potential for harm. The restriction of a conflicted investigator's role in the research project, adjusted to the level of anticipated risk, is the principal strategy for protection of subjects. Accordingly, the following questions should be addressed by the COI Committee in determining what role, if any, a conflicted investigator should play in interacting with subjects.

1. Under what circumstances, if any, should a conflicted individual be allowed to participate in subject recruitment?
2. Under what circumstances, if any, should a conflicted individual be allowed to participate in subject selection, including prescreening for inclusion/exclusion criteria?
3. Under what circumstances, if any, should a conflicted individual be allowed to participate in the consent process?
4. Under what circumstances, if any, should a conflicted individual be allowed to participate in clinical treatment of subjects, separate from the research interventions or procedures?
5. Under what circumstances, if any, should a conflicted individual be allowed to participate in clinical evaluation of subjects during the research, separate from the research interventions or procedures, including adverse event evaluation and reporting?

*d. Should the regulations prescribe specific approaches for the management, reduction, or elimination of particular types of FCOI? If so, for which types of FCOI? Which approaches?*

As indicated above in our response to Question III.b, and in light of the enormous range of types and levels of research projects as well as financial interests and other circumstances, the Associations strongly urge that PHS not prescribe specific standards for the management, reduction, or elimination of particular types of FCOI. Because of the large contextual variation in circumstances in which conflicts of interest may arise, such an approach would almost always be either excessive, misdirected, or inadequate, depending on the circumstances. The facts and circumstances that can be involved encompass a very broad range of academic research.

The Associations advocate an array of management, elimination, and reduction options, as spelled out in great detail in their February 2008 Report. These options, or management techniques, are arrayed under key headings that include: a list of options relating to disclosure; a list of options relating to human subjects; a list of options relating to students, trainees, and colleagues of the conflicted individual; a list of options relating to research and data integrity; a list of options relating to financial interests themselves (including reduction and elimination); a list of special considerations relating to start-up companies and small ventures; and a list of special considerations for conflicted administrators and supervisors. This "menu" approach is far more likely to

serve both to better protect the integrity of the research and the subjects involved in it than any pre-ordained specific approach.

- e. Should specific requirements related to the identification, management, and reporting of FCOI be established for subrecipients (i.e., sub-grantees, contractors, subcontractors, collaborators)?*

The freedom to contract between prime awardees and subawardees increases the capacity of research institutions and is a valuable tool in integrating research effort across institutions, establishing research partnerships and consortia, and extending individual institutional capacity and resources, all for the good of the public. This capacity to contract between prime and subawardees must be preserved in a way that provides appropriate assurance to PHS regarding objectivity in research, that does not unduly burden prime awardees, and that emphasizes the responsibilities of the subawardee for its own employees and agents.

Practically speaking, it is impossible to require that a grantee evaluate the COI program of its subrecipients. If a subrecipient certifies to the grantee that its FCOI program conforms to applicable federal regulations, that should be sufficient insofar as the grantee is concerned (absent clear and substantial evidence that the certification is false). If a subrecipient cannot provide a certification that its own conflicts program complies with PHS standards, then the grantee must require that those from the subrecipient's institution that will be involved in the project in question must subject themselves to and comply with the grantee's policy with respect to the sub-award in question. Anything else puts the grantee in the untenable position of evaluating another entity's FCOI program according to standards, the interpretation of which it does not control.

- f. Should amounts received by Investigators from certain kinds of organizations be limited to certain maximum thresholds if an Investigator is supported with PHS research funds? If so, which kinds of organizations?*

The Associations oppose financial thresholds for investigators. Institutions are and should be held accountable for FCOI programs that are fully compliant with applicable regulations. The Associations believe that the standards recommended in this response provide a rigorous and transparent framework for the evaluation, management, reduction, or elimination, as appropriate, of any identified conflict in PHS-supported research. This framework preserves integrity, protects subjects, and affirms the value of principled relationships with industry. To attempt to impose artificial caps on investigators would impose a penalty on those undertaking PHS funded research, without corresponding benefit to accountability and integrity. It could also inhibit useful relationships with industry that aid in the translation of research to public benefit. This would damage the productive academic-industry partnerships that are essential for the health of the public and for maintaining the primacy of the United States' role in scientific and biomedical research.

Moreover, to do as suggested by this question would conflate the receipt of PHS support by the institution with the possession by the investigator of personal financial interests. PHS, NIH, and the Associations' institutions have taken great pains to establish that PHS funding is awarded to institutions, not to investigators, and that it is the institution, not the investigator, that has the direct relationship with the awarding component and is accountable for the expenditure of federal funds. That relationship would be distorted by imposing maximum limits on personal financial interests and create enormous problems in implementation, given the number of projects with both PHS and support from other funding sources.



#### IV. Assuring Institutional Compliance

*a. Should the regulations enhance existing enforcement options in the event of noncompliance?*

Section 50.606 of the current regulations cites strong tools for the awarding component, and the Associations believe that the enforcement options in that Section provide a robust enforcement framework and communication process between the awarding component and the awardee institution. Awardee institutions also have an array of enforcement options currently available. The Associations will be pleased to respond to any specific additional suggestions that NIH proposes.

*b. Should Investigators be required under the regulations to complete routine FCOI training?*

The Associations support NIH adding a requirement that Investigators receiving PHS funding be required by their institutions to complete routine FCOI training as part of their routine research training, provided that the content is institutionally-determined. The Associations request that NIH offer a suggested training module or modules, but the NIH module should not serve as a standard or a requirement in terms of content.

*c. Should independent confirmation of an Institution's compliance with the regulation be required? If so, what should this confirmation look like (e.g., accreditation by an outside body, an independent audit)?*

Academic institutions as well as many other types of institutions are facing complex issues involving conflicts of interest as historical boundaries between sectors of society blur in an increasingly interdependent society and world. Immense challenges confront academic institutions in particular to preserve their fundamental values of integrity, protection of human subjects, and preservation of the public trust, while nurturing vitally important, principled relationships with industry. These challenges extend beyond the research domains into those associated with education, clinical practice, and administrative activity. The Associations and its members are committed to addressing all of these challenges responsibly, fully, and in a timely manner.

As a first step, the Associations have supported legislation now pending in Congress to require pharmaceutical, device, and medical supply companies to disclose payments of various kinds to physicians. Such legislation, if enacted, would for the first time provide academic institutions a tool with which to audit conflicts of interest reporting forms that are already required under existing regulations. The Associations believe that such a public reporting system would have an immediate and salutary effect on conflicts of interest programs, provided that a distinction is made in reporting categories among varieties of industry payments, and perhaps most importantly, a distinction is made between sponsored research directed to institutions, not individuals, and other forms of industry payments. Similarly, the AAMC also supports related efforts by the Medicare Payment Advisory Committee regarding disclosure of industry payments to physicians and others. Some member institutions have already undertaken comprehensive public disclosure programs of financial interests, and others have announced plans to do so.

With respect to accreditation, the Associations have strongly supported the highest standards in human research protection programs and are founding institutions of The Association for the Accreditation of Human Research Protection Programs, Inc. (AAHRPP), the sole U.S. accrediting body for human research protection programs. Under existing human research protection regulations, there are provisions relating to conflicts of interest. The Associations support AAHRPP's prerogative to determine appropriate standards and elements insofar as they relate to the existing human research protection regulations' requirements on conflicts of interest, but not to the

PHS regulations with respect to “Promoting Objectivity in Research” generally. This position is consistent with the Associations’ acknowledgement of the compelling considerations associated with the participation of human subjects in PHS-funded research, yet it does not impose unreasonable burdens, financial and otherwise, on other types of research.

On the other hand, the regulatory framework for conflicts of interest is different in kind and degree from that associated with human research protection programs. The PHS conflicts of interest regulatory framework necessarily must accommodate different state laws relating to financial interests, different administrative structures relating to oversight of personnel matters (of which conflicts regulation is often one aspect), and different policy considerations governing conflicts of interests in settings other than PHS funded research (for example, in privately-funded FDA-regulated research, in the education setting, in purchasing, and in financial aid to students). The Associations are strongly opposed to any requirement relating to accreditation of conflicts of interest programs generally, beyond their above-referenced support of AAHRPP’s prerogative to select appropriate accreditation standards as they relate to the existing human research protection regulations’ requirements on conflicts of interest.

#### V. Requiring Institutions to Provide Additional Information

- a. *Should Institutions be required to submit to the PHS funding component additional information on any identified conflict? If they should not be required to submit additional information for all conflicts, should they be required to submit additional information for identified conflicts involving certain types of research? If so, for which types of research? What kind of information would provide valuable data to the PHS funding component in evaluating these reports and the potential risk of bias in the conduct of research?*

As indicated earlier in this response, the Associations support a requirement that additional information be submitted to NIH. The information should include at a minimum the name of the investigator, the name and number of the award, the nature and amount of the financial interest and conflict, and a summary of the management activities imposed. For research involving multi-site clinical trials, the information should include a designation that it is part of a multi-site study and an indication of the coordinating site and PI, if different from the investigator who is the subject of the management plan about which information is being submitted. The Associations request that NIH develop a standard electronic format for submitting such information.

This formulation would provide evidence to the awarding component that the awardee institution is complying with its regulatory responsibilities. It would also provide a convenient mechanism to identify certain research areas where the presence of financial interests can be especially problematic, and it would enable the awarding component to exercise its existing authority under Section 50.606(b) to review all actions regarding conflicting financial interests in particular PHS-funded research projects and all records pertinent to compliance with existing regulations.

#### VI. Institutional Conflict of Interest

- a. *How would Institutional conflict of interest be defined?*

The challenges associated with identifying and managing or eliminating institutional conflicts of interest are so complex and difficult that the Associations and NIH have attempted to address them appropriately for years.

The Associations made recommendations in 2001 and 2002 about managing institutional conflicts, and HHS, in its 2004 “Points to Consider” (69 FR 26393), offered additional guidance that reflected extensive dialogue with our community. Institutional conflicts of interest, the vulnerability of human research subjects, the integrity of the science performed on our campuses, and the reputational threats arising from perceived conflicts in institutional decision-making prompted the biomedical research community to request that the Associations address it extensively in their 2008 report.

AAMC’s 2002 Report on institutional conflicts indicated that institutional conflicts are of two types. There is the conflict associated with financial holdings by an institution where research is being performed; and there is the conflict associated with the activities and financial holdings of institutional officials. AAMC’s 2002 Report recommended a definition of institutional conflict of interest that the Associations saw fit to quote in their 2008 Report.

An institution may have a conflict of interest in human subjects research whenever the financial interests of the institution, or of an institutional official acting within his or her authority on behalf of the institution, might affect—or reasonably appear to affect—institutional processes for the conduct, review, or oversight of human subjects research.

*b. What would an Institutional conflict of interest policy address in order to assure the PHS of objectivity in research?*

Drawing upon the definition of institutional conflict offered above, any meaningful policy must assure that the conflicts of both institutions and institutional officials are systematically reviewed, managed and, where necessary, eliminated. The NIH, the Associations and the biomedical research community have formulated principles and recommendations to guide institutions and administrators in developing and implementing their own policies. The Associations 2008 report synthesizes and refines these principles and recommends that institutions develop and implement comprehensive institutional conflict of interest policies within two years of the report’s issuance and, for the first time, they offer a template that can be used in developing such institutional policies. A copy of the template can be found in Appendix A of the Associations’ 2008 Report at [https://services.aamc.org/publications/index.cfm?fuseaction=Product.displayForm&prd\\_id=220&prv\\_id=268&cfd=1&cftoken=83D0D0B8-B0FA-D4FC-9B0F5F99EC958B8A](https://services.aamc.org/publications/index.cfm?fuseaction=Product.displayForm&prd_id=220&prv_id=268&cfd=1&cftoken=83D0D0B8-B0FA-D4FC-9B0F5F99EC958B8A).

The Associations believe that the complexity of the issue of institutional conflict of interest, the extensive differences among grantee institutions in administrative structure, and the level of difficulty institutions have faced in putting these policies into place while still complying with national, state, and local imperatives for economic development and active partnerships with industry all suggest that institutional conflict of interest is not a matter for federal regulation at this time. Such a regulation would impose enormous burdens on affected institutions in terms of evaluations and disclosures to PHS without corresponding gain in PHS’s oversight capability. We believe that research institutions are already moving to address their institutional conflicts, in no small part due to the existing guidance provided by NIH and the strong recommendations and timetable of the Associations, and that regulation is unwarranted and impracticable.

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The AAU and the AAMC appreciate the opportunity to comment on the questions posed in the ANPRM and are committed to rigorous implementation by awardee institutions of PHS standards for protecting the integrity of

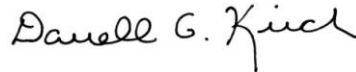
research. The record shows that the overwhelming majority of our institutions and affected investigators take their responsibilities under the regulations seriously, and well-functioning, costly systems are in place and are constantly expanding and improving to oversee the integrity of their research. Nonetheless, in any human system, imperfections will occur regardless of the rigor of oversight and enforcement, and however stringent the standards and supervision, violations of conflicts of interest policies will continue to occur. But reacting by imposing over-zealous regulations could disrupt productive partnerships to the detriment of science and the public. The Associations believe that the active and committed partnership among the NIH, the awardee institutions, and the Associations collectively can achieve the necessary and appropriate level of oversight and the requisite degree of accountability while still fostering productive and principled relationships among universities, academic medicine, and industry.

The Associations appreciate the opportunity to comment on this ANPRM. Any questions should be directed to Patrick White at AAU, [pat\\_white@aau.edu](mailto:pat_white@aau.edu), and Susan Ehringhaus at AAMC, [sehringhaus@aamc.org](mailto:sehringhaus@aamc.org).

Sincerely,



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