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Docket Number 02N-0475  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

**RE: Docket Number 02N-0475**

The Association of American Medical Colleges welcomes this opportunity to provide comments as requested to the Draft *“Financial Relationships and Interests in Research Involving Human Subjects: Guidance for Human Subject Protection”* (68 Federal Register, 15456, March 31, 2003). The AAMC represents the nation’s 126 allopathic medical schools, over 400 major teaching hospitals and health systems, and 96 academic societies.

The AAMC strongly supports scrupulous oversight, management, reduction, and when possible, elimination, of financial conflicts of interest in research, as demonstrated in its two reports addressing individual and institutional financial interests in human subjects research *“Protecting Subjects, Preserving Trust, Promoting Progress: Policy and Guidelines for the Oversight of Financial Interests in Human Subjects Research,”* published in December 2001 and October 2002, respectively. These reports build on earlier AAMC efforts to encourage comprehensive institutional policies for identifying, disclosing, and managing conflicts, with vigorous enforcement and oversight mechanisms.

We note that the DHHS March 2003 Guidance replaces the Draft Interim Guidance issued in January 2001. The AAMC and other groups expressed concerns about the January 2001 draft, particularly with respect to the involvement of the IRB as the primary source for overseeing and managing financial interests, and the lack of flexibility in the standards. The AAMC welcomes the new draft Guidance that reinforces the centrality of the institution’s role in developing or improving the system of oversight of research, emphasizes the creation of conflicts of interest committees, and encourages promulgation of guidelines for identifying and managing institutional conflicts of interest.

The new draft Guidance reflects many of the AAMC Task Force’s recommendations for oversight of individual and institutional financial interests and represents a reasonable and thoughtful approach to enhancing protections for human subjects in research, without unduly encumbering or obstructing that research.

## **I. Guidance for Institutions, IRBs and Investigators**

### **INSTITUTIONS**

The AAMC endorses the emphasis on the primacy of the institution in devising a system for the effective oversight and management of financial interests in human subjects research. The draft Guidance appropriately focuses on several key principles for institutions to consider when creating policies to support a system of management and oversight of financial interests in research: separating responsibility for financial decisions and research decisions, establishing conflict of interest committees (COICs), establishing criteria to identify institutional conflicts of interest, supporting meaningful communication and interaction between COICs and IRBs, and undertaking training efforts.

The AAMC also supports the principle embodied in the Department's Guidance that effective oversight of financial interests requires an integrated effort on the part of institutions, investigators, and IRBs. This approach necessitates clearly defined roles and responsibilities of each party involved in the research process.

### **IRB OPERATIONS**

The AAMC believes that the provisions set forth in this section of the Guidance will assist IRBs in promoting the integrity of the review process and the disclosure of conflicts among IRB members. The points mentioned in the draft Guidance establish a discipline that, if followed, will serve to promote the independence and accountability of IRB review.

Nevertheless, caution should be exercised in imposing any new duties on IRBs. Therefore, the AAMC suggests that the last bullet point ("*Developing educational materials about the regulations' requirements for IRB members*") be revised as follows:

"Develop educational materials for IRB members to ensure their awareness of federal regulations and institutional policies regarding financial relationships and interests in human subjects research."

### **IRB REVIEW**

The AAMC supports those provisions that assure that COICs communicate with IRBs their findings and recommendations with regard to the management or elimination of financial interests in human subjects research.

In order to clarify the respective roles of the COICs and IRBs, it would be useful to acknowledge the function of the COIC in evaluating financial interests, while affirming the ultimate decision-making authority of IRBs in protecting human research subjects.

Accordingly, the AAMC suggests merging the first point (“*Determine whether methods being considered or used for management of financial interests of parties adequately protect the rights and welfare of human subjects*”) with the second bullet point (“*Determine when an IRB needs additional information to decide wither financial interests could affect subjects*”), and issuing a revised recommendation as follows:

“Determine whether the analysis and recommendations of the COIC for management of the financial interests of investigators and the institution adequately protect the rights and welfare of human research subjects.”

## **II. Assessing the Impacts of Conflicts of Interest Guidance**

The notice in the Federal Register solicits ideas and views “*as to how to best assess any impacts of this guidance, as well as related non-Federal recommendations on enhancing the protection of human subjects.*”

Consistent with the recommendations of the AAMC Task Force, the AAMC has undertaken a project to assess the extent to which institutional policies incorporate the principles and recommendations articulated in the AAMC Task Force reports on individual and institutional financial interests in research. We expect to receive informative responses regarding individual financial interests, but recognize that the universities may well require more time to grapple with the much more difficult issues of institutional financial interests. Accordingly, we will conduct another survey in Spring 2004 to assess the extent to which institutional conflicts of interest policies have been developed and the extent to which they are consistent with the Task Force’s recommendations.

By conducting this assessment and evaluation of institutional policies, the AAMC expects to offer a detailed picture of institutional efforts to respond to new recommendations regarding comprehensive oversight and management of financial interests in research.

The AAMC welcomes the new approach taken by the Department and supports the draft Guidance as a useful tool for institutions to enhance protections for subjects when financial interests exist in human subjects research. We thank you for the opportunity to comment on this matter.

Sincerely,

Jordan J. Cohen, M.D.