



February 25, 2001

National Human Research Protection  
Advisory Committee (NHRPAC)  
Attn: Dr. Greg Koski  
6100 Executive Boulevard, Suite 3B01  
MSC-7507  
Rockville MD 20892-7507

Dear Dr. Koski:

I am responding to the request for comment on the OHRP "draft interim guidance" document entitled, "*Financial Relationships in Clinical Research: Issues for Institutions, Clinical Investigators, and IRBs to Consider when Dealing with Issues of Financial Interests and Human Subjects Protections.*" The University of Iowa is committed to processes and procedures that assure both the protection of human participants in research as well as objectivity in research.

The University of Iowa agrees with statements made in Section 1.1 of your draft interim guidance that a Conflict of Interest Committee is an appropriate institutional body to develop expertise in such matters and determine when and how conflicts can appropriately be managed in the context of the specific research project. We also agree that the decisions of this Committee should be shared with IRBs on projects involving human subjects. Such a system of coordination and communication accomplishes several objectives. First, it recognizes the special contributions each group can make to the process of the appropriate performance of research. Second, this division of labor reduces the burden on individual committees at a time when the complexities of regulatory compliance are already placing an enormous strain on these systems.

Given our apparent agreement with OHRP on statements in Section 1.1, we are concerned with the degree of prescription contained in the remainder of the document regarding the IRB's role in reviewing and managing conflict of interest. In the absence of such requirements, the University of Iowa has, for several years, operated a system of communication and coordination between these two committees. We believe that subject protection is best left to the IRB, and objectivity of research and the management of conflicts is best in the hands of the Conflict of Interest Committee. It is clear that final decisions and management plans that affect the involvement of human subjects must be communicated to the IRB. In spite of the very appropriate starting point in Section 1.1, your guidance document is comprised of extensive, specific procedures for the IRB to follow when reviewing the conflict of interest. Your document not only strays from the

starting point of recognizing the appropriateness of a division of effort, but it also adds a significant amount of duplicative work to the already over-burdened IRB process.

This document states that the guidance provided is based on information presented at the HHS August 15-16, 2000 conference and comments to that conference. While we applaud HHS for facilitating discussion of these difficult issues, we believe that much of the information provided was the personal opinion of the speaker or anecdotal evidence of deficiencies. We believe that a more systematic review of policies and procedures that currently exist and work should also be a component of any deliberations. We encourage OHRP to coordinate its efforts and interests in the area of conflict of interest with organizations such as AAMC and AAU that are also studying these issues and soliciting the insight and experience of their constituent institutions. Through these organizations, we hope that a set of recommended practices may emerge based on the experience of institutions that have spent the past several years developing procedures to implement appropriate practices and protections based on their actual experiences.

This draft also addresses the issue of institutional conflict of interest. Given the absence of any definition or regulation, we believe that addressing this issue is premature.

We appreciate the opportunity to provide commentary.

Sincerely,

David J. Skorton  
Vice President for Research