

Subject: Draft Interim Guidance on Financial Relationships in Clinical Research

Dear Dr. Koski:

Colorado State University is responding to the request for comments on the "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 Protection". We concur with the concern expressed and the comments made by the Association of American Universities (AAU), the Council on Governmental Relations (COGR) and the National Association of State Universities and Land-Grant Colleges (NASULGC) in their joint letter to you.

We affirm the importance of human subjects protection and the obligation to protect the integrity of the research process, both of which are currently subject to two different sets of regulations, issued under the authority of different statutes, with no overarching regulation that combines both. While universities are currently reviewing their existing systems for compliance with both of these issues, we have experienced increased confusion and uncertainty due to DHHS' process for promulgating regulations versus guidance, and the fact that the administrative transition has placed some of these regulations on hold pending review.

In the important area of protecting human life and managing financial conflicts, it is very important that there be consensus between the community and the government, and that the government, if possible, speak with one voice. Intense high-level discussions are underway in the university community. The AAU and the AAMC have committed to developing principles to help guide member institutions in this delicate area. In light of this, we believe that the OHRP draft should support the debate rather than attempt to direct it prematurely. We believe the objectives of the OHRP effort would be better served by withdrawing the current guidance and replacing it with a DHHS-issued document of "points for consideration" which would build on the current momentum of university review of these issues, and provide a broader fact basis upon which to gauge what is required to build community consensus prior to advocating policy changes or revised rules. This approach, rather than the prescription contained in the current draft interim guidance, would supplement rather than complicate the ongoing Presidential level initiatives underway by the AAU and other leaders in the academic community.

We appreciate the opportunity your office has provided for universities to comment on this important issue.

Sincerely,

Anthony A. Frank
Vice President for Research and
Information Technology
Colorado State University