

On behalf of the University of Illinois at Urbana-Champaign, I am writing to comment on the document "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".

Many universities are currently subject to two different sets of regulations, issued under the authority of different statutes. In our situation as a state institution, one covers the protection of human subjects, the other addresses the management of financial conflicts of interest in order to protect the research enterprise and ensure that faculty and staff fulfill their obligations to the State of Illinois. We favor an approach that would strengthen linkages between existing IRB's and committees or officers responsible for conflict of interest review. Many universities, including the University of Illinois, have been working to build such internal connections in recent years.

Financial conflicts are an inevitable result of many diverse activities within the university. We favor the approach taken by current HHS regulations, which focus on detecting and managing financial conflicts, or, should that prove impossible, rejecting a proposed project altogether. We believe that the existing division of expertise between IRB's and conflict of interest processes helps to ensure objective evaluation of conflicts. At the same time, it would be reasonable to incorporate disclosure of potential financial conflict of interest into the research protocol and the informed consent process, as well as ensuring that they are included in existing conflict evaluation processes.

In order to both protect human subjects and guard against financial conflicts, a consensus of the research community and the government is needed. We would like to see further discussion on these issues. We endorse the suggestion by NASULGC, COGR, and AAU that HHS convene a conference, in the summer or fall of 2001, in conjunction with other interested federal agencies and others in the academic community. The agenda for such a conference could be prompted by points of consideration from OHRP developed jointly with other affected parties within HHS (e.g., ORI and NIH). At the conference, the academic community could report on changes in policy and procedures, which it has considered or implemented since the beginning of the intensive debate on human subjects protection that has been ongoing for a year or more. This conference, with the goal of assessing the degree of consensus on required protections, could be an important milestone in the dialogue among all parties towards further policy development in the area of financial conflicts of interest and human subjects protection. To encourage attendance from a broad cross-section of the human subjects research community, such a conference should have a low registration fee and be held in an inexpensive location. High registration fees and hotel costs typical of medical conferences have limited our ability to participate in other recent conferences and symposia on human subjects protection. We appreciate this opportunity to offer our comments, and thank you for your attention to the needs and opinions of the research community.

Sincerely,

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