

**Office of the President**

242 Garland Hall / 3400 N. Charles Street  
Baltimore MD 21218-2691  
410-516-8068 / FAX 410-516-6097

2777 '03 MAY 30 A9:21

William R. Brody  
President

May 29, 2003

Tommy Thompson, Secretary  
Department of Health and Human Services  
Dockets Management Branch (HFA-305)  
Docket Number 02N-0475  
Food and Drug Administration  
5630 Fishers Lane  
Room 1061  
Rockville, MD 20852

Re: Docket No. 02N-0475: Draft "Financial Relationships and Interest in Research Involving Human Subjects: Guidance for Human Subject Protection"

Dear Secretary Thompson:

Thank you for the opportunity to submit comments on the draft document titled "Financial Relationships and Interests in Research Involving Human Subjects: Guidance for Human Subject Protection." We endorse the principle underlying the Guidance, i.e., a robust process for identifying and reviewing potential conflicts of interest is essential to the protection of human research subjects. Careful management of conflicts of interest is critical for maintaining public trust and confidence, protecting research subjects, and preserving the objectivity of research.

We commend the Department for recognizing the complexity of conflict of interest management and for acknowledging that various rules and regulations already govern certain aspects of conflict of interest in research. Issuing additional prescriptive rules would have increased an already large compliance burden. Instead, the Department wisely proposed thoughtful guidance that will strengthen institutional policies and procedures and enhance meaningful compliance with existing regulations governing human subject protection and research integrity.

With the draft guidance, the Department proposes to bolster protection of human subjects by urging institutions to develop vigorous conflict of interest programs, including those based on case review. The document advises investigators, institutions, and IRBs to ask key questions not only about the magnitude and nature of financial interests, but also about how particular interests will impact the subjects in specific research projects. Implicit is an acknowledgement that some financial interests add risk to human subjects and some do not. In our view, a careful review of each situation – conducted in a manner consistent with the governance structure of each institution – is needed to ensure subject protection in light of financial interests. Therefore, we support the Department's approach.

02N-0475

C12



In the particularly complex area of institutional financial interests and their potential impact on human research subjects, the Guidance provides useful suggestions for policy development and implementation. Most of Section II.C.1. represents a welcome addition to recent contributions from the university and research communities. However, since the management structures of research universities vary greatly, the recommendations in bullets 11 and 12 of this Section -- that institutions engage independent entities to hold or administer their financial interests and that they engage individuals from outside the institution to oversee institutional financial interests in research -- are not necessarily feasible in all university settings. We would recommend removing these bullets from the document.

We urge the Department to issue final guidance which retains the essential structure of the draft document. We anticipate the thought-provoking questions posed in the guidance will lead research institutions to more carefully scrutinize specific conflict of interest situations in human subject research and, ultimately, to a greater degree of subject protection. Thank you for the opportunity to comment on the proposed guidance.

Sincerely,

A handwritten signature in black ink that reads "William R. Brody". The signature is written in a cursive style with a large, sweeping flourish at the end of the name.

William R. Brody