



OFFICE OF THE PROVOST AND SENIOR VICE PRESIDENT—  
ACADEMIC AFFAIRS

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June 4, 2003

Secretary Tommy G. Thompson  
U.S. 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: Draft "Financial Relationships in Research Involving Human Subjects:  
Guidance for Human Subject Protection" [Docket No. 02N-0475]

Dear Secretary Thompson:

On behalf of the University of California (UC), I am submitting comments on the Department of Health and Human Services' Draft "Financial Relationships in Research Involving Human Subjects: Guidance for Human Subject Protection," published in the Federal Register on March 31, 2003 (68 FR 15456) [Docket No. 02N-0475].

The University of California strongly supports the Department's efforts to craft guidance on conflict of interest in human subject research. The increasing complexity of relationships among investigators, research institutions, and research sponsors require robust internal review processes that will ensure the objectivity of research decisions. In the arena of human subject research, biased research decisions cannot be tolerated – the safety of individuals who volunteer to participate in research must not be compromised.

The University of California has long-established policies for identifying and managing conflict of interest in human subject research. The University's policies and practices are consistent with many of the approaches recommended by the Department in the Draft Guidance. Each campus at the University of California has a Conflict of Interest Committee whose sole charge is to review financial and other interests that may affect the integrity of research. Each UC campus also has one or more institutional review boards (IRB). The University of California's Conflict of Interest Committees and IRBs work together to ensure that human subject research is not inappropriately influenced by financial relationships.

The Draft Guidance recommends that institutions establish clear channels of communication between the two functions of conflict of interest review and human subject protection. In line with this recommendation, UC policy requires IRBs and Conflict of Interest Committees to coordinate operations and to communicate information so that investigator financial interests in sponsors are considered by the IRB and are disclosed where required in the informed consent process.

We appreciate the Department's approach of providing institutions with questions designed to prompt appropriate consideration and management of conflicts, rather than mandating a set of specific requirements. We believe the questions are useful guides when examining conflict of interest in human subject research. This is particularly so in light of the diversity of institutions that conduct human subject research and the fact that many of these

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institutions already have processes for reviewing conflict of interest in human subject research, as described above. Since each research institution has its own structure, organization, and culture, the Department's guidance is most useful in that it does not attempt to impose a preconceived process onto an existing structure.

In the Draft Guidance, the Department recommends that research institutions establish criteria to determine what constitutes an institutional conflict of interest. The University of California is in the process of establishing a Task Force on Institutional Conflict of Interest in Research that will develop criteria and a process for identifying and managing institutional conflict of interest. Although several organizations have recently discussed this issue (as listed in footnote 6 of the Draft Guidance), there are few concrete guidelines on what constitutes an institutional conflict of interest and how to manage it. We appreciate that the Draft Guidance provides institutions with the flexibility to determine their own specific standards and procedures for handling conflicts, but look forward to additional guidance the Department may provide on this issue.

Concerning IRB operations, the Department suggests that the research institution poll and record IRB members' conflicts of interest for every protocol at every meeting. The University of California agrees that IRB members' financial interests must be considered when a protocol is being reviewed. However, this type of conflict is already addressed in federal regulations, at 45 CFR 46.107(e). That section prohibits IRB members from reviewing a study in which they have a conflicting interest. IRB members at the University of California are trained in the responsibilities and requirements of IRB membership, they are familiar with the regulation concerning conflict of interest, and they disqualify themselves when they have a conflict of interest. We do not think that a new procedure that records IRB member conflicts for every protocol would add substantively to the protection of human subjects beyond the recusal rules currently in place. Indeed, such a practice would distract the IRB from its central function and would consume valuable time that should be devoted to human subject protection.

Thank you for the opportunity to provide comments on DHHS's Draft "Financial Relationships in Research Involving Human Subjects: Guidance for Human Subject Protection."

Sincerely,

A handwritten signature in black ink, appearing to read "Lawrence B. Coleman". The signature is fluid and cursive, with a long horizontal flourish extending to the right.

Lawrence B. Coleman  
Vice Provost for Research

cc: Provost King  
Interim Director Auriti  
Principal Analyst Landes