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May 30, 2003

Dockets Management Branch (HFA-305)
Docket Number 02N-0475
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville MD 20852

SUBJECT: Docket No. 02N-0475

The University of California, Berkeley is a member of the Council on Governmental Relations (COGR) an association of 150 research intensive universities in the United States that works with federal agencies to develop a common understanding of the impact that policies, regulations and practices may have on the research conducted by its membership. On behalf of the Berkeley campus, I am writing this letter through the Dockets Management process in support of the comments submitted to you by COGR. In addition, we have comments to include specifically for our institution.

The Berkeley campus shares with the COGR, the Department of Health and Human Services' goal of upholding the highest ethical standards for all research activities. As a major research institution in the United States we understand how important it is to maintain objectivity in research and we are aware that conflicts of interest may undermine objectivity and compromise the protection of human research subjects. For those reasons, without imposed federal guidelines, we have already taken steps to manage financial conflicts of interest in human subjects studies.

Our campus guidelines include reviews of financial conflicts of interest for all participants on a research study that involves the use of human subjects. We do not limit our review only to investigators who are Berkeley campus employees, faculty or students. We also ask that conflicts be disclosed for non-Berkeley collaborators. Once a conflict is disclosed it is referred to the faculty committee that addresses financial conflicts. This committee will review the disclosure, determine the appropriate actions and make recommendations to the IRB on language to include in the subject consent forms. In our judgment, IRBs must be aware of a potential conflict but they must not divert their attentions to try to manage them. Research institutions are already mandated to review financial conflict of interests and have established procedures to do so, therefore it seems both inappropriate and redundant for the IRBs to take on this role as well.

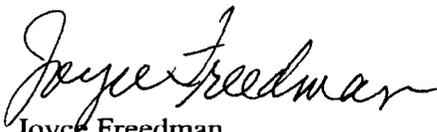
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The University of California, Berkeley has gone out in front of federally or state mandated regulations to management financial conflicts of interest in human subjects studies because we believe that it is fundamentally the right thing to do. We urge the Department of Health and Humans Services to issue these guidelines allowing for institutions to implement them in a matter that is consistent with the unique characteristics and culture of that institution.

I appreciate the chance to comment on the draft guidance on behalf of the University of California, Berkeley.

Sincerely,

A handwritten signature in cursive script that reads "Joyce Freedman".

Joyce Freedman
Assistant Vice Chancellor,
Research Administration and Compliance