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OFFICE OF THE PROVOST AND SENIOR VICE PRESIDENT—
ACADEMIC AFFAIRS

OFFICE OF THE PRESIDENT
1111 Franklin Street
Oakland, California 94607-5200

October 4, 2004

Division of Dockets Management
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Attn: Philip L. Chao, Office of Policy and Planning (HF-23)

Re: Institutional Review Boards; Registration Requirements, Docket No. 2004N-0242

Dear Mr. Chao:

This letter sets forth the comments of the University of California on the Proposed Rule published in the Federal Register on July 6, 2004 concerning registration of Institutional Review Boards. The proposed rule will require Institutional Review Boards (IRB) to register with the Department of Health and Human Services (HHS) and to provide information concerning active protocols involving FDA-regulated products.

An IRB registry will meet certain essential needs in the area of human subject protection. It will provide the FDA with information that can be used for oversight and compliance monitoring and for educational purposes. It will also improve communication between institutions and human subject protection programs in that they can turn to the registry for contact information for peers and counterparts at other IRBs to discuss common studies.

However, we believe that the proposed data collection includes a required element that will not contribute significantly to the ability of the FDA to effectively assess an IRB's compliance. Among the information that the FDA proposes be submitted is the accreditation status of the human subject protection program. We recommend that the registry not include this information. Information on accreditation status is publicly available from the accrediting organizations. Also, accreditation information on the HHS registry would not be reliable since the registry will be updated only every three years. Finally, the accreditation process for IRBs is relatively new, and only a small number of human subject protection programs are accredited. Accreditation status, therefore, does not accurately represent a measure of compliance with human subject protection regulations for the hundreds of IRBs that have not yet undertaken the accreditation process. A lack of accreditation could be mistakenly construed as a reflection on the quality of the human subject protection program.

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FDA, Division of Dockets Management
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We believe that the FDA should revise the proposed Rule before final publication to require reporting of only those data elements that contribute significantly to the Department's oversight and monitoring efforts. Thank you for the opportunity to provide comments on the FDA's Proposed Rule concerning registration of IRBs.

Sincerely,

A handwritten signature in black ink, appearing to read "L. Coleman", with a long horizontal flourish extending to the right.

Lawrence B. Coleman
Vice Provost for Research

cc: Provost Greenwood
Executive Director Auriti
Coordinator Landes