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SANTA BARBARA • SANTA CRUZ

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May 31, 2002

Philip L. Chao  
Dockets Management Branch (HFA-305)  
Office of Policy, Planning and Legislation  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

Re: Advance Notice of Proposed Rulemaking Requiring Sponsors  
and Investigators to Inform IRBs of Prior IRB Reviews

Dear Mr. Chao:

On March 6, 2002, the Food and Drug Administration issued an Advance Notice of Proposed Rulemaking concerning IRB review of human subjects research. The proposed rule requires investigators and sponsors to notify an Institutional Review Board (IRB) of any prior IRB reviews. Below are the University of California's comments on this rule.

In 1998 the Office of the Inspector General (OIG) of the Department of Health and Human Services issued a report on IRBs. Among its findings, the OIG determined that sponsors or investigators sometimes apply for approval from an IRB without notifying that IRB of a prior review that resulted in disapproval of proposed research. The OIG suggested that a rule be enacted to discourage "IRB shopping" by requiring investigators and sponsors to notify any review board of previous consideration of the pertinent protocol. The OIG acknowledged that such a rule "will have particular importance for those sponsors and investigators working with independent IRBs." The FDA's proposed rule responds to the OIG's concerns.

As noted, the proposed rule has specific relevance for research that is reviewed by independent IRBs. The University of California does not employ independent IRBs; all research at UC involving human subjects must be reviewed by an institutional IRB comprised of members of UC's faculty and of the local community. The problem the rule attempts to address, therefore -- "IRB shopping" or the practice of applying to a second IRB to obtain a positive review following prior disapproval -- does not obtain at UC.

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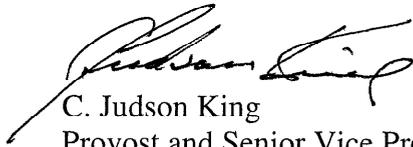
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Though the proposed rule would not modify current practice at UC, the University of California nevertheless would find it useful to be advised by a research sponsor of prior IRB reviews, particularly in multi-center studies. Notice of prior IRB reviews at other sites would permit UC's IRBs to consult with those sites if questions arise concerning the conduct of the trial. Information on prior IRB reviews in multi-center trials also would assist the University's clinical trial contract negotiators who sometimes are advised by sponsors that other research institutions have approved provisions to which UC objects. Under the proposed rule, the negotiators could evaluate more easily the sponsor's claim by contacting other organizations involved in similar trials, and by discussing the sponsor's position with contracting officers at the other research sites. In these ways, the proposed rule would benefit the community of human subjects and those charged with their protection by promoting communication and consultation between institutions that conduct research with human subjects.

Thank you for the opportunity to provide comments on the FDA's Advance Notice of Proposed Rulemaking concerning disclosure of prior IRB reviews.

Sincerely,

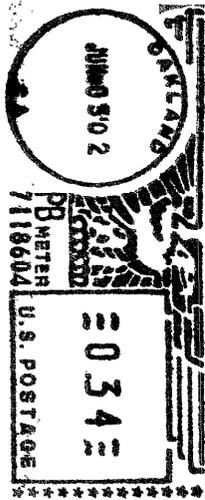


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