

THE UNIVERSITY OF IOWA



May 23, 2002

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MC 20852

Re: Requiring Sponsors and Investigators to Inform IRBs of Any Prior IRB Reviews

I am writing on behalf of the University of Iowa in response to the 6 March 2002 Federal Register Advance Notice of Proposed Rulemaking (vol. 67, no. 44, pp. 10115-10116) entitled "*Institutional Review Boards: Requiring Sponsors and Investigators to Inform IRBs of Any Prior IRB Reviews.*"

The Notice cites a 1998 DHHS OIG report and states that the OIG, "...heard of a few situations where sponsors and/or research investigators who were unhappy with one IRB's reviews switched to another without the new IRB being aware of the other's prior involvement." Aside from hearsay, no specific information is provided. The University of Iowa has no firsthand knowledge of such situations and believes that, if such a problem exists, it is unlikely to exist within academic medical centers. We come to this conclusion because most, if not all, academic medical centers have written policies regarding the review of human subjects research to be conducted by investigators within their institution. These policies specify the use of an internal IRB or a designated external IRB with which the institution has a standing agreement. Therefore, no possibility exists for the investigator to "shop" for an IRB if s/he or the sponsor is not satisfied with the first IRB review.

If the FDA believes that this concern warrants investigation/action, this could be accomplished by requiring investigators to list on Form FDA 1572 all IRBs that reviewed the protocol on behalf of that investigator. The FDA could then, as a part of the marketing approval process for drugs and devices, ascertain if investigators are using multiple IRBs. The agency could also follow-up with the specific cases to determine the reason for and nature of each IRB review.

If the FDA is concerned that sponsors are "shopping" for positive IRB reviews by switching investigators, the FDA could require sponsors to provide a listing of all IRBs that reviewed the protocol but are not included in the 1572s submitted with the marketing approval application.

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Multiple reviews, as is the case in many multi-center trials, may result in different IRB outcomes. However, in the absence of documented instances, it is impossible to speculate as to whether these are more or less appropriate IRB reviews. Differences may reflect the local context within which the study is considered. One IRB may determine that the resources available at one institution may make the trial inappropriate for that site, while the resources at another site may result in the opposite IRB outcome. The best protection against this concern is to assure that each IRB conducting reviews for FDA clinical trials is appropriately constituted and educated in the application of 21 CFR Parts 50 and 56.

We strongly advise against establishing a system whereby each IRB reviewing a protocol for a multi-site trial is burdened with having to sort through prior reviews from other IRBs. The time required to review these materials (of undetermined value) would be compounded by the time an IRB would have to spend to produce minutes that could stand alone and provide clear, meaningful information to all other IRBs without the accompanying IRB- and institution-specific application materials (which are available to the FDA for inspection).

In summary, the required reporting and sharing of IRB deliberations contemplated by this Advance Notice of Proposed Rulemaking would represent a significant burden to IRBs, which is a well-documented issue of concern in the OIG Report. Rather than impose this burden when a documented “shopping” problem has not been shown to exist, we suggest that a minor revision in Form 1572 as well as a change in reporting requirements for sponsors could provide the necessary information for the FDA to address this concern.

Sincerely,

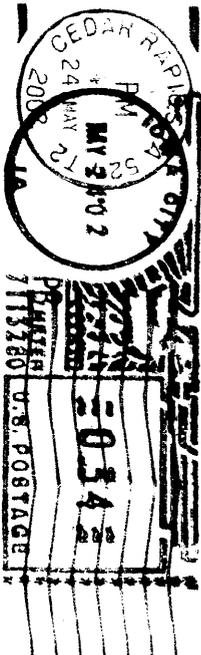


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