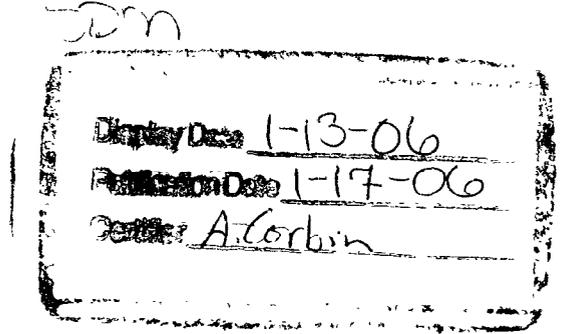


DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 56

[Docket No. 2001N-0322 (formerly 01N-0322)]



Institutional Review Boards: Requiring Sponsors and Investigators to Inform Institutional Review Boards of Any Prior Institutional Review Board Reviews; Withdrawal

AGENCY: Food and Drug Administration, HHS.

ACTION: Advance notice of proposed rulemaking; withdrawal.

SUMMARY: The Food and Drug Administration (FDA) is announcing the withdrawal of an advance notice of proposed rulemaking (ANPRM) entitled “Institutional Review Boards: Requiring Sponsors and Investigators to Inform IRBs of Any Prior IRB Reviews” that published in the **Federal Register** of March 6, 2002 (67 FR 10115).

DATES: The ANPRM is withdrawn [*insert date 30 days after date of publication in the Federal Register*].

FOR FURTHER INFORMATION CONTACT: Patricia M. Beers Block, Good Clinical Practice Program (HF-34), Food and Drug Administration, 5600 Fishers Lane, rm. 9C24, Rockville, MD 20857, 301-827-3340.

SUPPLEMENTARY INFORMATION: In 1998, the Department of Health and Human Services, Office of the Inspector General (OIG) issued several reports on institutional review boards (IRBs). The OIG sought to identify the challenges facing IRBs and to make recommendations on improving Federal oversight of IRBs. One recommendation was that sponsors and clinical investigators be

required to notify IRBs of any prior review (see OIG, Department of Health and Human Services, "Institutional Review Boards: A Time for Reform," p. 14, June 1998; <http://oig.hhs.gov/oei/reports/oei-01-97-00193.pdf>). The OIG report stated that the OIG had:

* * * 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. This kind of IRB shopping deprives the new IRB of information that it should have and that can be important in protecting human subjects. The ground rules should be changed so that sponsors and investigators have the clear obligation to inform an IRB of any prior reviews (footnote omitted). The obligation should be applied to all those conducting research funded by HHS or carried out on FDA-regulated products. It will have particular importance for those sponsors and investigators working with independent IRBs.

Id.

After reviewing the OIG's recommendation, FDA published an ANPRM on March 6, 2002 (67 FR 10115) (see <http://www.fda.gov/OHRMS/DOCKETS/98fr/030602a.pdf>) announcing it was considering whether to amend its IRB regulations to require sponsors and investigators to inform IRBs about any prior IRB review decisions. We invited public comments on: (1) The frequency of IRB shopping and under what circumstances IRB shopping has occurred; (2) what information about prior IRB review should be disclosed, where should it be disclosed, and who should disclose it; and (3) what methods, other than disclosure of prior IRB reviews, might prove to be valuable for dealing with IRB shopping.

In response to this ANPRM, FDA received 55 comments. The majority of the comments reported they had little or no first hand knowledge of instances of IRB shopping, and did not believe IRB shopping presented a significant

problem. Many comments expressed concern about the logistics of maintaining a system that would enable the exchange of information among IRBs, especially when studies involved multiple study sites. There was concern that maintaining such a system would substantially increase the IRBs' workload and not provide any additional human subject protection. There was also concern that waiting for information from other IRBs prior to the review of research proposals within a particular institution might contribute to delays in the review of these proposals.

The Office for Human Research Protections (OHRP) also informed FDA that it considered the OIG's recommendation to require sponsors and investigators to notify IRBs of any prior IRB review of a research plan. OHRP concluded that it had no reason to believe that IRB shopping was occurring with any regularity in the review of HHS conducted or supported human subjects research.

Based on these reasons, FDA concluded that IRB shopping either does not occur or does not present a problem to an extent that would warrant rulemaking at this time.

In a letter dated February 26, 2005, FDA advised the OIG of these findings and conclusions. FDA is now withdrawing this ANPRM. A withdrawal does not prevent the agency from taking action in the future. Should FDA decide to undertake rulemaking sometime in the future, the agency will provide new opportunities for comment.

Dated: 1/4/06
January 4, 2006.

oc05261


Jeffrey Shuren,
Assistant Commissioner for Policy.

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