



May 1, 2002

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

To Whom it May Concern:

As the Chair of the Fox Chase Cancer Center (FCCC) IRB, I am writing to comment on **Docket No. 01N-0322 Institutional Review Boards: Requiring Sponsors and Investigators to Inform IRBs of any Prior IRB Reviews.**

Issue 1: "IRB shopping" is not a practice that we have encountered at either FCCC or Fox Chase Network member institutions (17 independent community hospitals). What we commonly observe is investigators and sponsors working collaboratively with an IRB to make changes in research protocols that preserve the scientific objectives and enhance protection of human subjects. The labor, time and costs (many IRBs charge a fee for review of a sponsored study) of submitting a protocol to an IRB, would generally discourage a PI from IRB shopping.

Issue 2: Since IRBs should act independently, it would not be a best practice for an IRB to notify another IRB of a decision about a specific study. Indeed, since many studies are open at multiple sites throughout the nation, it could add another burden on IRBs to receive reports about studies open at many institutions. It is already standard practice for cooperative groups and sponsors to distribute Revisions or Amendments to study protocols to all participating investigators and institutions. Such revisions often occur in response to reviews by IRBs or scientific review committees.

Issue 3: If disclosure of prior IRB reviews were to be required, then only minimum information should be reported (approved, tabled, disapproved). Our view is that such disclosures should not inhibit or prevent a thorough review at each participating institution.

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Issue 4: See response to Issue 3. We recommend limiting disclosures to:

- Date of review/decision
- Sponsor Study Number
- IRB Study Number
- Decision (approved, tabled or disapproved)
- Type of Review (Expedited or Full Board)

Issue 5: This discussion gives all the reasons for not enacting this reporting requirement or severely limiting its scope.

Issue 6: We believe the basis for prior IRB decisions should NOT be disclosed for the reasons given above. Only the final outcomes should be reported.

Issue 7: Enforcement of reporting prior IRB reviews would be extremely difficult, which is another reason for not enacting this rule.

Issue 8: We believe the best way to address this issue on a global level is to create a national database for all sponsored studies. This type of database could provide additional benefits to researchers and subjects alike. However, given the technology required and the volume of studies covered, we doubt this will happen in the near future.

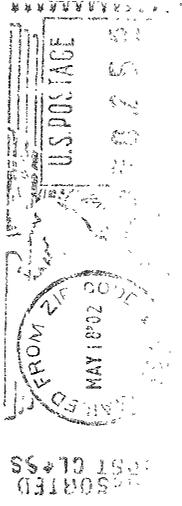
We hope you find this information helpful. Please do not hesitate to contact me with any questions.

Sincerely,



W. Thomas London, MD
Chairman, Institutional Review Board

CC: Robert C. Young, MD
R. Donald Leedy



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