



ABBOTT LABORATORIES

Corporate Regulatory and Quality Science

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June 3, 2002

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

RE: Institutional Review Boards: Requiring Sponsors and Investigators to Inform IRBs of Any Prior IRB Reviews [*Docket 01N-0322*]

Dear Sir or Madam:

Abbott Laboratories appreciates the opportunity to comment on the FDA's advance notice of proposed rulemaking regarding IRBs as published in the Federal Register on March 6, 2002 at 67 FR 10115. The FDA is considering whether to amend its IRB regulations to require sponsors and investigators to inform IRBs about any prior IRB review decisions.

Abbott is opposed to formal rule-making regarding notification of prior IRB reviews. The underlying assumption in this proposal is that significant differences in review standards exist among IRBs in substantive areas impacting patient safety. Rulemaking in this direction not only acknowledges, but arguably condones, IRB disparity. It effectively sends the "wrong message" to the regulated community.

FDA's role should more appropriately be directed at improving IRB standards of practice. This would ultimately do better service to public health. Such efforts could include certification, inspection and/or continuing education programs for IRBs, all of which could be administered by qualified third parties.

1. How significant is the problem of IRB shopping?

Based on our experience, we believe that "IRB shopping" as described in the document ("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") occurs very infrequently. We are aware that some sponsors may change from one IRB to another for reasons unrelated to human subject protection, e.g., IRB workload, local policy, timeliness of IRB review, etc. These cases do not connote the type of "shopping" about which the FDA is concerned.

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We are aware that some sponsors select a particular central IRB to utilize because they have established a solid working relationship with that IRB. This tends to be a prospective decision based upon prior experience with the IRB.



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2. Who should make the disclosures?

It should also be noted that several of the major central IRBs already require this type of information in their submission forms and will not process the submission unless the form is complete. These thought-leaders have already established self-regulation and standards that many will emulate. In these cases, the applicant seeking IRB approval provides the information.

3. Who should receive the disclosures?

As stated above, several major central IRBs already require this type of disclosure in their submission forms. In these cases, the IRB receives and evaluates such disclosures.

4. What information should be disclosed?

The disclosure requests we have seen are limited to studies that have been disapproved, withdrawn from, or terminated by, a prior IRB. The rationale for such action must be provided with the disclosure. This is a reasonable approach. The rationale for such actions can be of relevance to other IRBs. If the action was taken because of safety concerns, this information will help the second IRB in their decision. On the other hand, actions may have taken place due to local issues that are of no relevance to the new IRB, and which may not pose a safety or ethical concern to the new IRB.

5. If a proposal would not require disclosure of all prior IRB decisions, what information should be disclosed?

See response to # 4.

6. To permit a subsequent IRB to assess the value of a prior IRB decision, should information about the basis for the prior decision be disclosed?

See response to # 4.

The ANPR states that mandatory disclosures would help ensure that "IRBs reviewing a protocol will be aware of what other IRBs reviewing similar protocols have concluded." This is a highly inefficient and burdensome mechanism to promote information sharing among IRBs. The perceived benefits are constrained to only those IRBs reviewing a very specific protocol whereas the issues could well transcend the study in hand and be useful to other IRBs.

7. How should FDA enforce the requirement?

The IRBs that currently require such disclosure enforce the requirement by not processing any submission that fails to supply a *complete* submission form. In our experience, IRBs are very careful to preview all submission materials prior to formal Board review.



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We suggest that FDA not promulgate regulations in this area, which carry with them obligations of oversight, record-keeping and enforcement. This requirement is already emerging from major IRBs. FDA's role would be much more effectively placed at encouraging IRB harmonization and standards. Further, this could be accomplished through qualified third parties.

8. Are there any ways to deal with IRB shopping, other than disclosure of prior IRB reviews?

As acknowledged in the 1998 HHS OIG report, there were only "a few situations" where IRB shopping occurred. This echoes our understanding of the low prevalence. FDA may wish to survey those IRBs that currently require such disclosures to provide metrics on such admissions and associated rationales to gain more knowledge on the level of IRB shopping.

Again, we reiterate that FDA could play a much more effective, and overall constructive role, in fostering harmonization of IRB standards. If general standards or information sharing were promoted among all IRBs, any disparities which may encourage IRB shopping, to what little extent it does occur, would be minimized. The benefit of such efforts would extend far beyond the issue of IRB shopping and better serve public health.

Should you have any questions, please contact Jill Sackett at (847) 937-4085 or by facsimile at (847) 938-3106.

Sincerely,

A handwritten signature in cursive script that reads "Doug Sporn / jws".

Douglas L. Sporn
Divisional Vice President
Corporate Regulatory Affairs, Abbott Laboratories

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