



Center for Clinical Trials

Department of Biostatistics  
Department of Epidemiology  
Department of International Health

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Department of Medicine  
Department of Ophthalmology  
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Tuesday, 9 April 2002

**Memorandum**

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

**Fr:** Curtis L. Meinert, PhD *Curtis Meinert*  
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**Re:** Comments on proposal requiring sponsors and investigators to inform IRBs of any prior IRB reviews

The "cure" is worse than the disease and especially when there is a lack of evidence of "shopping". It seems unreasonable to construct a flood of paper to address a problem that even the OIG characterizes as rare and where the only evidence cited is hearsay (the OIG has "heard of a few situations where" ...).

The ability to shop for an IRB is not an option for investigators at institutions with standing IRBs. One submits to his IRB or he does not do the research.

Largely, the action of other IRBs has no bearing on the reviews or actions taken by another IRB. IRBs are constituted to be autonomous. Efforts to make them interdependent seem ill-advised and at odds with the tenets underlying IRBs.

Taken at its face, sponsors or investigators would be required to provide a running, almost day by day count of "prior actions" as investigators clear their respective IRBs. Further, since most of those "prior actions" would be favorable, there are, at least some IRBs, that would regard getting counts of approvals as mildly coercive. In any case, the only thing that can be reliably tracked is when and if approvals are obtained. IRBs rarely disapprove, they simply fail to act. Hence, there is no reliable way to track adverse actions.

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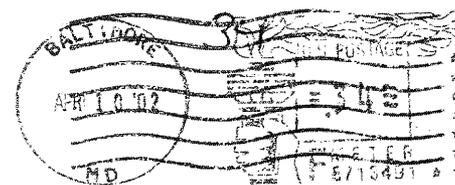
If the concern is with shopping, then the simplest "fix" is for the FDA to require that investigators not affiliated with institutions having IRBs indicate whether their submissions have been reviewed and disapproved by another IRB, and if so, the reason for the disapproval.

**Distribution**

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