

**CONSORTIUM OF  
INDEPENDENT  
REVIEW BOARDS**

**CIRB**

**CIRB**

May 23, 2002

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

**Re: Comments on FDA ANPRM Regarding Prior IRB Review Information (Docket No. 01N-0322)**

Dear Sir/Madam:

The Consortium of Independent Review Boards ("CIRB") submits these comments in connection with the Food and Drug Administration's ("FDA") notice that it is considering amendments to its human subject protection regulations. See 67 Fed. Reg. 10,115 (March 6, 2002). The amendments under consideration would require sponsors and investigators to inform institutional review boards ("IRBs") about prior IRB review decisions. CIRB is a consortium of independent IRBs with a central mission of assuring the protection and rights of human research subjects, while promoting an understanding of how independent IRBs support this goal. Approximately 40% of clinical research in the United States is conducted in non-academic settings, and independent IRBs review a majority of this research. Therefore, CIRB has a significant interest in any change in the human subject protection regulations.

CIRB supports the implementation of a regulation that will require sponsors and investigators to report a prior IRB review of a study protocol where the prior review resulted in disapproval. The individual members of CIRB already request such information from investigators and sponsors, and believe that the information is helpful to the IRB review process. CIRB does not believe that one IRB's disapproval of a protocol should necessarily result in disapproval by a second IRB. However, honest and complete disclosure on the part of the investigator and the sponsor is an important factor in determining whether human subjects will be vigorously protected during the conduct of a study. In addition, although CIRB does not believe that "IRB shopping" is a significant issue in the clinical research community, it does believe that a reporting requirement will decrease the possibility of such behavior.

CIRB supports a carefully crafted regulation that avoids overburdening the IRB with unnecessary information. Therefore, CIRB recommends limiting the reporting requirement to (1) final written IRB disapproval of a protocol, and/or (2) sponsor or investigator withdrawal of a protocol from an IRB's jurisdiction. In these cases, the sponsor or the investigator should provide the new IRB with the name and address of the prior reviewing IRB. The new IRB then would have the necessary contact information in order to explore the matter further as necessary.

01N-0322

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Consortium of Independent Review Boards  
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CIRB recognizes the reasons for proposing amendments to 21 C.F.R. part 56 and suggests similarly amending 21 CFR parts 312 and 812. These drug/device regulations specifically set forth the sponsor and investigator reporting responsibilities in connection with the conduct of a clinical investigation. CIRB believes that amendment of the relevant sections would increase the likelihood of compliance. Additionally, amending the drug/device regulations appropriately places the reporting burden on those parties with actual knowledge about the prior IRB reviews. For example, where a multi-site study is involved, the sponsor may be the only party with full information on prior IRB disapprovals or withdrawals.

As noted above, CIRB supports a proposed regulation that will require the reporting of prior IRB disapprovals and sponsor/investigator study protocol withdrawals from IRB review. CIRB hopes these comments are helpful to FDA as it considers how to proceed in this matter.

Sincerely,

A handwritten signature in black ink that reads "John Isidor" followed by a circled monogram "JH".

John Isidor  
Chair

cc: CIRB Membership  
David Lepay, M.D., Ph.D.

**Kirkpatrick & Lockhart LLP**

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May 23, 2002

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

**Re: Docket No. 01N-0322**

Dear Sir/Madam:

Enclosed find 1 original and 2 copies of comments submitted by the Consortium of Independent Review Boards in connection with the Food and Drug Administration's notice that it is considering amendments to its human subject protection regulations.

Sincerely,

  
Gary Yingling

Enclosures

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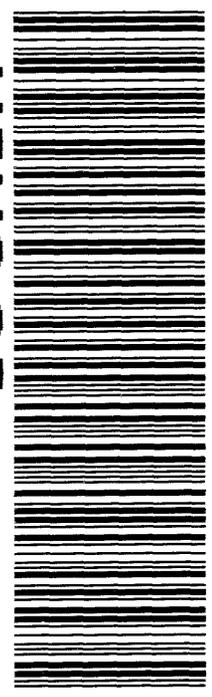
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