

**CONSORTIUM OF
INDEPENDENT
REVIEW BOARDS**

CIRB

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May 27, 2005

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

Re: Comments on FDA's Draft Guidance for Industry on Using a Centralized Institutional Review Boards Process in Multicenter Clinical Trials (Docket No. 2005D-0103)

Dear Sir/Madam:

The Consortium of Independent Review Boards ("CIRB") is pleased to provide comments on the issues addressed in the Food and Drug Administration's ("FDA") Draft Guidance for Industry entitled "Using a Centralized IRB Process in Multicenter Clinical Trials ("Draft Guidance")."¹ CIRB is a consortium of independent institutional review boards ("IRB") located in the United States and Canada. The membership has a central mission of promoting the protection and rights of human research subjects, while providing 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. CIRB's individual members frequently perform the function of "Central IRB," as that term is defined in the Draft Guidance, and thus, CIRB has a significant interest in this matter.

CIRB commends FDA for issuing this Draft Guidance because it provides clarification to the various parties that use, or are considering using, central IRBs for IRB review. In supporting the recommendations set forth in the Draft Guidance, CIRB notes that the Draft Guidance principles represent current practice of its members. CIRB provides the following comments.

I. Addressing Local Aspects of IRB Review

The Draft Guidance provides a thoughtful and complete explanation of how Central IRBs are able to address local issues. We agree that the diversity of IRB membership provides a meaningful way to address local conditions such as cultural backgrounds. Such diversity also allows for a thoughtful process for addressing ethical standards of the local community. Clearly, Central IRBs can implement mechanisms that assure meaningful review of relevant factors.

¹ 70 Fed. Reg. 15,635 (March 28, 2005).

CIRB commends FDA for providing clarifying language in the Draft Guidance that recognizes the concept of “community attitudes” as extending beyond those considerations arising in connection with the physical location where the research is conducted.² While in the past, participants in clinical research were largely drawn from the communities directly proximate to the clinical site, this is no longer the case. It is not uncommon for human subjects to travel great distances in order to participate in a clinical trial at a particular site. This is especially true in connection with clinical studies testing new treatments for serious or life-threatening conditions. Further, geographic mobility and mass media are beginning to diminish the differences between the different geographic communities, especially those of North America.

II. IRB Records; Documenting Agreements for Central IRB Review

CIRB agrees with the Draft Guidance recommendation providing for documentation of agreements between institutional-based or local IRBs and Central IRBs, and documentation of agreements between Central IRBs and unaffiliated clinical sites. Such written agreements delineating responsibilities between the parties are imperative to assuring appropriate IRB review and continuing review.

III. Written Procedures

Further, CIRB agrees that written IRB procedures are useful for ensuring adequate IRB review in the Central IRB review context. CIRB notes that because its members are not affiliated with research institutions, all sites are “geographically remote” and thus, the members’ standard procedures describe the initial and continuing review process for remote sites.

CIRB also acknowledges that Central IRB procedures need to be aware of and sensitive to the “local community” aspects associated with IRB review.³ CIRB supports the Draft Guidance mechanisms listed, which include maintaining a diverse IRB membership and obtaining written documentation from the sites.

IV. Definitions

Finally, CIRB finds useful the Draft Guidance’s distinction between “centralized” IRB review, in which a central IRB assists in or assumes the review of sites under the jurisdiction of a local IRB, and “central” IRB review, in which a Central IRB assumes the review of unaffiliated sites.

² See Draft Guidance, footnote 10.

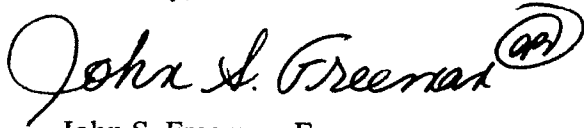
³ 21 C.F.R. 56.107

Dockets Management Branch
May 27, 2005

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CIRB again wishes to express its appreciation to FDA for the creation of this Draft Guidance and for providing CIRB with the opportunity to comment.

Sincerely,

A handwritten signature in black ink that reads "John S. Freeman" with a circled "99" at the end.

John S. Freeman, Esq.
Chair

cc: CIRB Membership