



May 27, 2005

*VIA ELECTRONIC SUBMISSION*

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

**Re: Docket No. 2005D-0103  
Comments of Biotechnology Industry Organization on Draft  
Guidance for Using a Centralized Institutional Review  
Board Process in Multicenter Clinical Trials**

To Whom It May Concern:

The Biotechnology Industry Organization (“BIO”) is pleased to have the opportunity to comment on the Food and Drug Administration’s (“FDA’s” or the “agency’s”) draft guidance on using a centralized institutional review board (“IRB”) process in multicenter clinical trials (herein “Draft Guidance”).<sup>1</sup> BIO is the largest trade organization to serve and represent the biotechnology industry in the United States and worldwide. BIO represents more than 1,000 biotechnology companies, academic institutions, state biotechnology centers, and related organizations in the United States. Our members are involved the research and development of healthcare, agriculture, industrial and environmental biotechnology products, with over 300 biotech drugs in clinical development addressing a host of diseases. Although we support comments to the Draft Guidance by our various members, BIO writes separately regarding specific concerns to us as an industry organization.

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<sup>1</sup> Notice for Solicitation of Comments by FDA on Draft Guidance for Industry on Using a Centralized Institutional Review Boards Process in Multicenter Clinical Trials, 58 *Fed. Reg.* 15635 (March 28, 2005).

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BIO applauds the time and effort the agency has devoted to developing this Draft Guidance. We recognize the importance of providing adequate human subjects protections while ensuring that the IRB review process can be performed in an efficient manner. BIO believes this Draft Guidance will be an important resource for the industry with regard to multicenter clinical trials. We are also encouraged by the recommendations that the FDA has set forth in the Draft Guidance thus far. We believe that overall, this guidance will help to fulfill the goal of reasonable joint review and eliminate unnecessary duplicative review processes.

After careful consideration and review of the Draft Guidance, BIO is pleased that the guidance is aimed at lessening the burden of delays, duplications and or conflict/comments for the sponsors and Investigators. We urge the FDA in finalizing the Draft Guidance to continue to provide the industry flexibility with regard to its recommendations for carrying out certain aspects of centralized review processes. We provide some general comments below regarding these concerns.

#### **A. Central IRBs Should be Afforded Flexibility in Addressing Local Aspects of IRB Review**

BIO is pleased that the Draft Guidance highlights the importance of addressing issues related to the local community as required under the FDA's human subjects and IRB regulations. We agree that that an IRB should have a diverse membership so that meaningful consideration of various local factors is provided and that the ethical standards of the local community are observed. BIO appreciates that the FDA has provided several possible mechanisms (e.g., participation of consultants, experts, or local IRB members in central IRB deliberations; limited review of a central IRB-reviewed study by the local IRB), rather than listing prescribed mechanisms for ensuring that local factors are considered.

BIO urges the agency to continue to allow central IRBs the flexibility to address local issues through mechanisms that are relevant to the proposed research and tailored to a particular central IRB's review process. Indeed, in its discussion on mechanisms for ensuring consideration of relevant local factors, the FDA states that "[o]ther mechanisms may also be appropriate."<sup>2</sup> We hope that the final guidance continues to offer suggested mechanisms, but also provides IRBs the opportunity and flexibility to determine their own mechanisms for addressing local aspects of IRB review that would also satisfy regulatory human subjects and IRB requirements.

#### **B. IRB Recordkeeping & Documentation**

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<sup>2</sup> "Guidance for Industry: Using a Centralized IRB Review Process in Multicenter Clinical Trials," *Draft Guidance*, p. 5, FDA, January 2005.

BIO recognizes the importance of maintaining adequate documentation of IRB activities, as required under 21 C.F.R. 56.115(a). We agree with the agency that local and central IRBs should clearly delineate the specific responsibilities of each IRB for initial and continuing review of clinical studies. We urge the FDA to allow central IRBs the flexibility in developing their own agreements with local IRBs. While we recognize the importance of documenting such agreements and outlining responsibilities, we believe that IRBs should have flexibility in designing their own instruments to avoid overly-burdensome requirements.

### **C. The Role of Sponsors in Multicenter Clinical Research**

Under the Draft Guidance, the agency lists one model for defining the rules and responsibilities of the various parties involved in a centralized IRB review process. With regard to sponsors, BIO urges the FDA to emphasize that sponsors may have some oversight and control over who reviews clinical drug and biological product studies. The agency explains that 21 C.F.R Part 312 provides that the sponsor is responsible for obtaining a commitment from each investigator that all requirements relating to IRB review and approval will be met. The Draft Guidance further states that “[s]ponsors can also initiate plans for use of a centralized IRB review process and facilitate agreements and other necessary communications among the parties involved.”<sup>3</sup> We hope that the final guidance will consider the unique role of sponsors in research whose studies may be conducted under centralized review and that such sponsors will be encouraged to use this efficient method of review while also ensuring that human subjects protections and IRB procedures are maintained.

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BIO appreciates the opportunity to comment on the Draft Guidance and applauds the FDA in its efforts thus far. We hope the agency will take into consideration these specific comments as it finalizes the Draft Guidance.

Respectfully submitted,

/s/

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Director of Bioethics,  
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<sup>3</sup> *Id.* at p. 3.