



## Corporate Regulatory and Quality Science

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

**RE:** Institutional Review Boards; Registration Requirements  
[Docket No. 2004N-0242]

Dear Sir or Madam:

Abbott Laboratories (Abbott) submits the following comments regarding FDA proposed rule, "Institutional Review Boards; Registration Requirements," published in the Federal Register on July 6, 2004 at 69 FR 40556.

Thank you for the opportunity to provide these comments. In general, Abbott agrees with FDA's proposal to require institutional review boards (IRBs) to register at a site maintained by the department of Health and Human Services. Our comments pertain to FDA's specific requests for comments on certain topics.

### **Proposed Rule**

#### **Who must register?**

In response to FDA's request for comment on foreign IRB registration, we believe there is a benefit to inviting the registration of foreign IRBs participating in studies supporting FDA-regulated products. Registration would afford foreign IRBs the same benefits that are intended for IRBs located in the United States (e.g., educational opportunities, early notification alerts). However, consideration should be given to local (foreign) privacy laws outside the United States, which may impact the ability of foreign IRBs to comply with all the requirements of a United States registration.

#### **What information must an IRB provide when registering?**

The proposed registration information required for IRB submission is appropriate. Further, Abbott considers the inclusion of the IRB's accreditation status, as well as the identity of the accrediting body to be a valuable element of registration. Accreditation implies a certain standard has been achieved. We agree this information will help FDA evaluate the value of IRB accreditation.



**What sanctions, if any, should be used against sponsors and investigators who utilize unregistered IRBs?**

Because the focus of this proposed rule is administrative and does not establish requirements pertaining to IRB qualifications the use of sanctions against sponsors due to use of an unregistered IRB is not appropriate. Actions, such as a clinical hold, are imposed when the rights and/or safety of subjects are in jeopardy or other material non-compliant concerns are evident (see 21 CFR 312.42). Noncompliance with registration, under the proposed rule, does not mean improper study oversight by an IRB or sponsor.

**Are additional changes to FDA regulations necessary?**

No, it is not necessary to change additional FDA regulations. Part 56 describes requirements pertaining to IRBs. Sponsors rely on Part 56 for IRB requirements. Amendment of any other regulations seems unnecessary. Thus, FDA can best ensure sponsor use of registered IRBs by amending Part 56 only.

**Are there other ways to ensure the use of registered IRBs?**

Regarding measures to ensure the use of registered IRBs by sponsors and investigators, Abbott recommends FDA establish a link to the publicly accessible information via its own "Good Clinical Practices in FDA-Regulated Clinical Trials" located at [www.fda.gov/oc/gcp/default.htm](http://www.fda.gov/oc/gcp/default.htm). We also recommend that in addition to making the name of the institution operating the IRB and the IRB name publicly accessible that FDA also include the name, address, and telephone number of the IRB contact and, for accredited IRBs, information pertaining to the accreditation. Through these measures, sponsors and investigators will have a single source for obtaining pertinent information regarding registered IRBs.

Should you have any questions, please contact me at (847) 937-8197 or by facsimile at (847) 938-4422.

Sincerely,

/s/

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