



APPLIED RESEARCH ETHICS  
NATIONAL ASSOCIATION

The Applied Research Ethics National Association (ARENA),  
PRIM&R's membership division, is the professional home for those whose  
responsibilities include the protection of human or animal research subjects

October 1, 2004

Food and Drug Administration  
Attn: Philip L. Chao, Office of Policy and Planning (HF-23)  
Division of Dockets Management  
5630 Fishers Lane  
Rm. 1061  
Rockville, MD 20852

Re: Proposed Rule: Institutional Review Boards; Registration Requirements  
Docket No. 2004N-0242

Dear Mr. Chao:

On behalf of the Applied Research Ethics National Association (ARENA), we appreciate the opportunity to comment on the proposed rule on the federal registration of Institutional Review Boards (IRBs) published in the Federal Register on July 6, 2004. ARENA is a division of Public Responsibility in Medicine and Research (PRIM&R), and shares with that organization a commitment to advance the highest ethical standards governing research and to foster their consistent application. ARENA's members include administrators, chairs and members of Institutional Review Boards (IRBs) and Institutional Animal Care and Use Committees (IACUCs), representing organizations across the nation with varying volumes and complexities of research.

We have the following comments to offer on this proposed rule:

1. We support the concept of voluntary accreditation. We hope that FDA and OHRP will use this information to better target educational and outreach efforts and inspections. However, it is important to remember that institutions are accredited, not IRBs. Therefore, this question should be revised appropriately.
2. We request that FDA and OHRP maintain one common registration site that will automatically include currently registered IRBs and allow them to retain their currently assigned numbers. We are concerned about this issue because although this intention is stated in the proposed rule, the information provided states that the registration site address will be provided after the rule is final.
3. We disagree with the statement in the introduction to the proposed rule that there has not been an accurate list of IRBs. FDA requires sponsors to identify IRBs, and OHRP has kept a list of IRBs with Assurances for over twenty years. The past record-keeping appears to have been sufficient for the purposes of inspection. We hope that the combined registration will be used for education and support as well as for monitoring purposes.
4. We urge that the information required from registered IRBs be the same for both FDA and OHRP. For example, the FDA rule does not appear to require that IRBs submit a roster of members. We believe that the FDA rule should be revised to include a roster.

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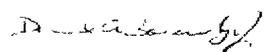
5. We are concerned about sanctions for not registering. The sanctions suggested (clinical holds or withholding drug approval) are more appropriate for sponsors or researchers than for IRBs. Sanctions, if any, should be more appropriate for IRBs and could include sanctioning or warning letters to the IRB or notices to sponsors.
6. It is not clear from the proposed rule if 520(g) of the act is limited to IDEs or will be applied to all investigational devices in clinical investigation (e.g., abbreviated IDE or exempt from IDE etc.). This should be made clear in the final rule.
7. We are concerned about the timing of registration. In some cases, it is possible that the requirement to register 30 days in advance of reviewing regulated research will interfere with an expedited approval process or a full review process that takes fewer than 30 days. We suggest that the rule state that IRBs may not issue a determination on regulated research until they have registered. Tying registration to review may penalize researchers and sponsors unnecessarily.
8. Likewise, we have concerns about reporting the closure of an IRB within 30 days. This process may take longer than 30 days and would put an undue burden on the IRBs and the institutions that support them.
9. We have a concern about the request for specific numbers of protocols reviewed since it is unclear how useful or accurate the data reported would be in light of:
  - The varying complexities of IRB review and protocol driven research activities (e.g., social and behavioral, biomedical, phase 1, 2, or 3 studies, gene therapy);
  - the level of IRB review (i.e., full committee review or expedited review process) required for research protocols (e.g., chart reviews, interventions, survey research, continuation review, etc.); and,
  - the frequent and daily changes in the number of protocols reviewed by an IRB.

We suggest that this question be made optional.

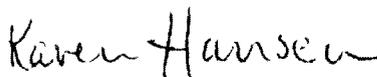
10. The rule should make clear what of the required information is available through a Freedom of Information Act (FOIA) request.

We are grateful for the opportunity to comment on the proposed rule. Please contact us if you need more information or have questions about our comments.

Sincerely,



David Borasky  
President



Karen Hansen  
Co-Chair, ARENA Public Policy Committee

Cc: Bernard Schwetz, DVM, PhD - OHRP  
David LePay, MD, PhD - FDA  
Helen McGough, ARENA - IRB Registration Subcommittee