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Good Clinical Practice Q&A: Focus on IRBs

In reviewing a study, how do central (national) IRBs fulfill their obligation to consider local community standards and concerns?

"Non-local IRBs," as the FDA calls them, must have adequate knowledge of community attitudes, information on the conditions relevant to the conduct of the research, and the study's continuing status. In its Information Sheet entitled, "Non-local IRB Review," the FDA states that "IRBs conducting non-local review need to be knowledgeable about the community from which the subjects are drawn to ensure that subject rights will be protected and that the consent process is appropriate for the subject population involved. The IRB should be sensitive to community laws and mores because state and local laws and community attitudes pertaining to research may be more restrictive than Federal regulations or the prevailing standards of the community where the IRB is located."

To ensure that it can fulfill FDA requirements at 21 CFR 56.107 and 56.111 (criteria for IRB approval of research) for each study site, the non-local IRB should have adequate knowledge of community attitudes, information on conditions regarding the conduct of the research, and the continuing status of the research. The non-local IRB must ensure that it meets these requirements for each location at which it has assumed IRB oversight responsibility.

The FDA agrees that these non-local IRBs can attain knowledge of community attitudes through a variety of means, including written materials and site visits by a representative of the IRB, by appointing an IRB member from the community in which a study is to be conducted, or by having a consultant from the community advise the IRB either prior to or during the deliberations.

The FDA's most recent discussion of the "local aspects" of IRB review appears in the agency's March 2006 final guidance entitled, "Using a Centralized IRB Review Process in Multicenter Clinical Trials." "IRB review, through its membership, is intended to provide meaningful consideration of various local factors in assessing research activities, including the cultural backgrounds (e.g., ethnicity, educational level, religious affiliations) of the population from which research subjects will be drawn, community attitudes about the nature of the proposed research, and the capacity of the institution to conduct or support the proposed research. Inter-community differences could influence, among other things, assessments of whether mechanism of subject selection will be equitable, whether adequate provision is made to minimize risks to vulnerable populations, and the adequacy of the informed consent process... Where a centralized IRB review process is used.., the review should consider the ethical standards of the local community. Therefore, a centralized IRB review process should include mechanisms to ensure meaningful consideration of these relevant local factors. Possible mechanisms include:

- Provision of relevant local information to the central IRB in writing by individuals or organizations familiar with the local community, institution and/or clinical research.
- Participation of consultants with relevant expertise, or IRB members from the institution's own IRB, in the deliberations of the central IRB.
- Limited review of a central IRB-reviewed study by the institution's own IRB, with that limited review focusing on issues that are of concern to the local community.

"Other mechanisms may also be appropriate. IRB meeting minutes or other records should document how relevant community issues were considered in the review…" [1]

Reference

1. "Good Clinical Practice: A Question & Answer Reference Guide", Barnett International, 2008, #8.44 p. 236-237

Source

"Good Clinical Practice: A Question & Answer Reference Guide 2008," is available for $45.95 at http://www.barnettinternational.com/.