

Good Clinical Practice Q&A: Focus on IRBs

If a sponsor plans to use multiple IRBs for its multicenter study, must an Internet advertisement be approved by all involved IRBs?

When sponsors use multiple IRBs for their studies, they must adhere to the requirements of each IRB – no small undertaking at times. If an IRB requires active approval of advertising (some IRBs only require that sponsors send the advertisement to the IRB – a passive type of approval), then the sponsor must wait for the approval of each IRB that requires pre-approval before posting the advertisement on the Internet. To avoid minor changes by each reviewing IRB, the sponsor may include, with the advertisement or telephone script, information about its national use and the IRBs that have or have not granted approval.¹

Internet postings, which are not the same as advertisements, do not need IRB review, however. According to the FDA Information Sheet entitled, "Recruiting Study Subjects," "IRB review and approval of listings of clinical trials on the Internet would provide no additional safeguard and is not required when the system format limits the information provided to basic trial information, such as: the title; purpose of the study; protocol summary; basic eligibility criteria; study site location; and how to contact the site for further information. Examples of clinical trial listing services that do not require prospective IRB approval include the National Cancer Institute's cancer clinical trial listing (PDQ) and the government-sponsored AIDS Clinical Trials Information Service (ACTIS). However, when the opportunity to add additional descriptive information is not precluded by the data base system, IRB review and approval may assure that the additional information does not promise or imply a certainty of cure or other benefit beyond what is contained in the protocol and the informed consent document."²

In discussing the "local aspects" of IRB reviews, the FDA repeatedly emphasizes the need for a centralized or local IRB to consider "community attitudes." In using this term, is the FDA referring to the patient population from which study participants will be drawn or the overall population of the locality?

In a footnote appearing in its March 2006 guidance on the centralized IRB review process, the FDA acknowledges that the term could have multiple meanings. "Community attitudes is usually interpreted to refer to the attitudes of the local community where research will be conducted," says the agency. "However, it could also refer to a community of other individuals, such as a community of individuals with the same disease. For purposes of a discussion of special issues that arise in the context of central IRB review of multicenter research, when we refer to community attitudes, we are referring to any considerations that may be unique to the various communities from which research subjects will be drawn."³

How should a principal investigator and sponsor proceed if an IRB administrator refuses the principal investigator's request for a list of IRB members?

While most institutions do provide principal investigators with lists of IRB members (who, in turn, provide it to sponsors) some do not. The FDA regulations do not require that the IRB provide sponsors with a membership roster.

Some sponsors will accept a Department of Health and Human Services (DHSS) multiple project assurance (MPA) number or Federal Wide Assurance (FWA) number as evidence of

appropriate IRB membership. Institutions with OHRP assurances are listed on the OHRP web site at: <http://ohrp.cit.nih.gov/search/asearch.asp#ARUR>.

References

1. "Good Clinical Practice: A Question & Answer Reference Guide", Barnett International, 2006, pgs. 167-168
2. Ibid, pg. 170
3. Ibid, pg. 171

Source

"Good Clinical Practice: A Question & Answer Reference Guide 2005," is available for \$39.95 at <http://www.barnettinternational.com/>