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Good Clinical Practice Q&A: Focus on Television News

If a principal investigator is going to participate in a television news interview that may very well generate patient interest in enrolling in the clinical study, would the investigator have to gain IRB approval before participating in the interview?

The FDA information sheet titled, "Guidance for Institutional Review Boards and Clinical Investigators" (1998 update) provides guidance to sponsors and investigators on topics like media advertising and news stories. The FDA considers direct advertising for study subjects to be "the start of the informed consent and subject selection process" and contends that advertisements be reviewed and approved by the IRB as part of the package for initial review. News stories, on the other hand, are not considered direct advertising and are not included in the FDA's guidance on direct advertising for clinical trials.

An IRB has no jurisdiction over a news interview. It cannot interfere in a bona fide news interview and its free distribution in the public media. It can, however, control the duplication of the interview and the paid distribution of the interview to prospective subjects.

Prospectively, investigators should be reminded of the type of language that can be used in the interview. Language should be consistent with that used in the consent form (e.g., "may provide," "is untested," "experimental"). Since the investigator's language could affect recruitment, he/she should be particularly careful not to overstate possible benefits or understate risks. Generally, large research institutions have a media relations officer and staff who can advise and coach investigators in preparing for the interview.

While press coverage of "new science" is important, care must be taken to avoid creating false hope among patients that an investigational product will provide relief or a cure. The investigator should attempt to provide a fair, accurate and balanced discussion of the science.

What amount to "infomercials" that appear, only on the surface, to be news interviews with a principal investigator represent an entirely different category of communications. These are paid commercial, scripted venues whose expressed purpose is to recruit subjects. As such, these require IRB approval.

If the subject's noncompliance continues, site staff should contact the sponsor for advice as to how to proceed. The sponsor may decide that this subject should be dropped from the study because of protocol noncompliance and questions about data integrity and reliability.

Source

"Good Clinical Practice: A Question & Answer Reference Guide", Barnett International. The Guide is available at http://www.barnettinternational.com in electronic and paper form.