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Good Clinical Practice Q&A: Focus on Screening

In its review of the proposed screening form, what types of assessments would the IRB be expected to make with regard to the nature of the information/data being collected, and what the study site will do with the information?

"It is the IRB's responsibility to review how subjects will be screened for an individual study," the agency notes in an informal response to this question. "Thus, if certain information is going to be collected for screening purposes, the IRB should review the information that will be collected, as well as the method of collection, to ensure that each is consistent with FDA's informed consent regulations. Thus..., the information collected and the method by which it will be collected should be reviewed and approved by the IRB."

The agency also emphasizes that the IRB should consider how the information will be handled and protected after it is collected. "In some cases, personal and sensitive information is gathered about the individual," the agency notes. "The IRB should have knowledge of the procedures that will be used to protect confidential information about the subject to assure that the information will be appropriately handled. A simple statement such as 'confidentiality will be maintained' does not adequately inform the IRB of these procedures. Examples of issues that are appropriate for IRB review include: What happens to personal information if the caller ends the interview or simply hangs up? Are the data gathered by a marketing company? If so, are names or other information sold to others? Are names of non-eligible subjects maintained in case they would qualify for another study? Does maintaining such records for potential subjects constitute a breach of confidentiality? Are paper copies of records shredded, or are readable copies put out as trash?

"The acceptability of the procedures will depend on the sensitivity of the data gathered, including personal, medical and financial information. Further, if part of the screening process involves providing the potential subject with information about the trial, the IRB must ensure that information is balanced and not misleading."

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.