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Good Clinical Practice Q&A: Focus on Informed Consent

The members of the IRB for our hospital do not agree as to whether fasting, from midnight to the morning of the blood draw at the screening visit, is even a study-related intervention and, therefore, whether a consent is needed in advance. In some sense, isn't this more of a convenience offered to prospective study participants (so they will not have to return to the site a second time for the blood draw) than it is a study-related activity for screening purposes?

Ultimately, this is an IRB decision, a staffer in the FDA's Good Clinical Practice Program emphasized in a recent informal response. "I can understand how people would have different conclusions for the need for consent in the situation you've described," the staffer noted. "In many of these tests, where fasting is needed prior to lab work, it seems to me that one could view it is a convenience to the patient to let him or her know that if they want to be considered for the study, fasting could be done prior to coming back in and signing the form (and having the test done at that time). I would think that this would depend upon the nature of the study, condition, etc. To me, one of the benefits of the IRB system is that people discuss these issues. I think that discussion furthers our dialogue of what should or should not be done in particular situations. What is important is what the IRB decides, with the specific information before it…"[1]

Reference

1. "Good Clinical Practice: A Question & Answer Reference Guide", Barnett International, 2011, #5.24 p. 163

Source

"Good Clinical Practice: A Question & Answer Reference Guide 2011," is available for $45.95 at http://www.barnettinternational.com in electronic and paper form.