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Good Clinical Practice Q&A: Focus on Screening

Does the FDA provide guidance on the minimum amount of information an investigator should maintain for subjects who are screened for their eligibility for a clinical trial, in particular for those who fail screening?

In a recent informal response, a staffer in the FDA's Good Clinical Practice Program stated, "I am not aware of any FDA guidance that specifically addresses what information an investigator should maintain on individuals who fail screening. The ICH E6 Good Clinical Practice Consolidated Guidance…, an FDA endorsed guidance document, includes screening logs in the list of essential documents to permit evaluation of the conduct of a trial, but FDA regulations do not specifically identify such logs... If screening logs are used, they are considered study-related documents and need to be maintained in accordance with 21 CFR 312.62(c) for drug and biologic studies…"

"In general, the information maintained on individuals screened for a study should be sufficient to demonstrate that the study screening was appropriately conducted per the investigational plan. I believe the information needed to demonstrate compliance with the investigational plan may depend on the specific study. If screening is based solely on procedures and tests that are the standard of care for such patients (that is, would be performed whether or not study entry was contemplated, such as for diagnosis or treatment of a disease or medical condition), then specific records on screen failures may not be needed unless the sponsor requires such records (in which case you should contact the study sponsor to determine the minimum information needed). In the case where screening involves procedures/tests that are performed solely to determine study eligibility, however, I believe records need to be maintained because these activities are directly related to the research. At a minimum, the records should include signed and dated consent forms for the screening procedures/tests, the results of those procedures/tests and any other documentation, such as a physician's or nurse's notes, documenting the reason for screening failure. Of course, for individuals who pass screening, records demonstrating that the screening criteria are met would be part of the case histories required to be maintained for the study."

Source

"Good Clinical Practice: A Question & Answer Reference Guide", Barnett International, 2012, #6.22. The Guide is available at http://www.barnettinternational.com in electronic and paper form.