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Good Clinical Practice Q&A: Focus on Screening Logs

Suppose a clinical research center develops a generic preliminary screening log that is not study specific and will be used to collect general information on prospective subjects, such as name, age, gender, address, telephone number, medical history, current symptoms, and where the person heard about the study/research center. Since the screening log is not study specific, would it require IRB review and approval?

In a response to this question, the FDA noted that, "the Institutional Review Board (IRB) has the authority and should review the method and material(s) that investigators propose to use to recruit subjects. Telephone screening is a form of recruitment for subjects that should be viewed as the start of the informed consent and subject selection process. As such, it is subject to IRB review either as part of its initial review of the specific research study or as its responsibility for oversight of all research under its jurisdiction. If the site uses a specific format or script for screening subjects to determine basic eligibility for a study, the IRB should assure the procedures followed adequately protect the rights and welfare of the prospective subjects.

"FDA's IRB regulations require the IRB to maintain 'copies of all research proposals reviewed, scientific evaluations, if any, that accompany proposals, approved sample consent documents, progress reports submitted by investigators, and reports of injuries to subjects' (see 21 CFR 56.115(a)(1)). If the screening log is part of the research proposal then it would need to be submitted to the IRB."

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.