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Good Clinical Practice Q&A: Focus on Informed Consent

FDA regulations do not seem to directly address "screening" informed consent forms, which are administered to study candidates prior to the study screening process used to determine if a subject will qualify for a study (i.e., before the study's formal informed consent process). In the FDA's view, when are screening informed consents required and under what circumstances?

While FDA regulations do not speak to screening informed consents directly, the FDA Information Sheet entitled, "Screening Tests Prior to Study Enrollment," discusses situations that warrant such consents. "For some studies, the use of screening tests to assess whether prospective subjects are appropriate candidates for inclusion in studies is an appropriate pre-entry activity," it notes. "While an investigator may discuss availability of studies and the possibility of entry into a study with a prospective subject without first obtaining consent, informed consent must be obtained prior to initiation of any clinical procedures that are performed solely for the purpose of determining eligibility for research, including withdrawal from medication (wash-out). When wash-out is done in anticipation of or in preparation for the research, it is part of the research."

The agency notes that the informed consent process should address the complexities and confusion that the practice of medicine and pre-existing doctor-patient relationships can present to the prospective clinical trial participant. "Procedures that are to be performed as part of the practice of medicine and which would be done whether or not study entry was contemplated, such as for diagnosis or treatment of a disease or medical condition, may be performed and the results subsequently used for determining study eligibility without first obtaining consent," the Information Sheet says. "On the other hand, informed consent must be obtained prior to initiation of any clinical screening procedures that is performed solely for the purpose of determining eligibility for research. When a doctor-patient relationship exists, prospective subjects may not realize that clinical tests performed solely for determining eligibility for research enrollment are not required for their medical care. Physician-investigators should take extra care to clarify with their patient-subjects why certain tests are being conducted." [1]

Reference

1. "Good Clinical Practice: A Question & Answer Reference Guide", Barnett International, 2008, #5.4 pp. 114-115

Source

"Good Clinical Practice: A Question & Answer Reference Guide 2008," is available for $45.95 at http://www.barnettinternational.com/