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Institutional Review Boards: Bureaucratic Roadblock or Knowledgeable Resource

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For many clinical research trials, the Institutional Review Board (IRB) has the power to determine whether or not the research will be conducted and, if conducted, certain of the parameters under which the clinical research must be performed. IRB approval and continuing review is, with certain exceptions, required by law for clinical research that is performed on human subjects and funded by a federal agency. IRB review and monitoring is also required for clinical research that involves drugs, devices or biologics that are regulated by the United States Food and Drug Administration (FDA). IRB review may be required pursuant to other regulatory requirements, or non-regulatory requirements such as the policies of the institution in which the research will be conducted.

The primary purpose of IRB review is to protect the rights and welfare of human subjects participating in clinical research. Although protection of human research subjects is of mutual interest to the IRB, research sponsor and clinical investigator, the relationship between those parties is not always a positive collaboration. IRB review is sometimes viewed more as a bureaucratic requirement that impedes research and scientific progress than an educational process through which study methods and procedures may be constructively challenged and improved.

Clinical investigators who are mindful of the issues outlined below may find the process of IRB review to be more pleasant, efficient and beneficial to the proposed research and the parties involved.

Be Familiar with the Regulations by which the IRB is Bound

Like clinical research itself, IRBs are constrained by a variety of regulatory requirements and restrictions. It is helpful to understand the IRB's mandate, and the standards to which it is held. For instance, both FDA regulations and the Common Rule require specified elements to be included in the written informed consent form. Understanding these and other parameters under which the IRB operates can help clinical investigators anticipate and proactively address issues that may otherwise impede IRB approval.

Review the IRB's Policies and Procedures

Although the legal requirements applicable to IRBs are, aside from state law differences, substantially the same, the manner in which those legal requirements are implemented may vary from one IRB to another. Familiarity and compliance with the timelines, deadlines, reporting and information requirements of the reviewing IRB can prevent unnecessary or unexpected delays in IRB review and approval.

Submit Complete and Consistent Forms and Documents

Before the IRB approves a clinical trial, its members, some of whom are necessarily non-clinical, must review and comprehend a variety of complex and inter-related documents including the protocol, investigator's brochure, informed consent and HIPAA authorization. Submission of documents that are clear, concise and consistent with the other documents to which they relate can facilitate efficient review and avoid delays due to the need for clarification of ambiguities.

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Maintain Active Communication and Involvement with the IRB

The relationship between the clinical investigator and IRB does not end upon approval of a study. Continuing review, monitoring, follow-up and future studies may necessitate ongoing interaction between them. An investigator's early and active involvement in the process, such as presenting the protocol and related study documents in person if given the opportunity, can set a positive tone for future relations.

Working collaboratively, the IRB and clinical investigator can effectively serve their differing purposes toward the same end of promoting and facilitating research and scientific progress.

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