Sponsor - Investigator - IRB Interrelationship - Information Sheet

Guidance for Institutional Review Boards and Clinical Investigators

The interrelationship and interaction between the research sponsor (e.g., drug, biologic and device manufacturers), the clinical investigator and the Institutional Review Board (IRB) may be very complex. The regulations do not prohibit direct sponsor-IRB contacts, although, the sponsor-IRB interaction customarily occurs through the investigator who conducts the clinical study. The clinical investigator generally provides the communication link between the IRB and the sponsor. Such linkage is agreed to by the sponsors and investigators when they sign forms FDA-1571 and FDA-1572, respectively, for drug and biologic studies or an investigator agreement for device studies. There are occasions when direct communication between the IRB and the sponsor may facilitate resolution of concerns about study procedures or specific wording in an informed consent document. The clinical investigator should be kept apprised of the discussion.

Sponsor Assurance that IRBs Operate in Compliance with 21 CFR Part 56

FDA regulations [21 CFR 312.23(a)(1)(iv)] require that a sponsor assure the FDA that a study will be conducted in compliance with the informed consent and IRB regulations [21 CFR parts 50 and 56]. This requirement has been misinterpreted to mean that it is a sponsor's obligation to determine IRB compliance with the regulations. This is not the case. Sponsors should rely on the clinical investigator, who assures the sponsor on form FDA-1572 for drugs and biologics or the investigator agreement for devices that the study will be reviewed by an IRB. Because clinical investigators work directly with IRBs, it is appropriate that they assure the sponsor that the IRB is functioning in compliance with the regulations.

An IRB must notify an investigator in writing of its decision to approve, disapprove or request modifications in a proposed research activity [21 CFR 56.109(e)]. This correspondence should be made available to the sponsor by the clinical investigator. In the Agency's view, this required documentation provides the sponsor with reasonable assurance that an IRB complies with 21 CFR part 56 and that it will be responsible for initial and continuing review of the study. Also, the sponsor and, in fact, anyone who is interested, may obtain an Establishment Inspection Report from an FDA inspection of an IRB. These reports summarize the conditions observed during the IRB inspection. FDA, however, does not certify IRBs.

Sponsor Access to Medical Records

The IRB is responsible for ensuring that informed consent documents include the extent to which the confidentiality of medical records will be maintained [21 CFR 50.25(a)(5)]. FDA requires sponsors (or research monitors hired by them) to monitor the accuracy of the data submitted to FDA in accordance with regulatory requirements. These data are generally in the possession of the clinical investigator. Each subject must be advised during the informed consent process of the extent to which confidentiality of records identifying the subject will be maintained and of the possibility that the FDA may inspect the records. While FDA access to medical records is a regulatory requirement, subject names are not usually requested by FDA unless the records of particular individuals require a more detailed study of the cases, or unless there is reason to believe that the records do not represent actual cases studied or actual results obtained. The consent document should list all other entities (e.g., the sponsor) who will have access to records identifying the subject. The extent to which confidentiality will be maintained may affect a subject's decision to participate in a clinical investigation.

Confidentiality of Sponsor Information

The IRB's primary responsibility with respect to protecting confidentiality is to the research subject. IRBs should, however, respect the sponsor's need to maintain confidentiality of certain information about products under development. IRB members and staff should be aware that information submitted for review may be confidential, trade secret, and of commercial interest and should recognize the need for maintaining the confidentiality of the review materials and IRB records. It is advisable for IRBs to have policies that address this issue.

Nonsignificant Risk Device Studies

"A sponsor's preliminary determination that a medical device study presents an NSR is subject to IRB approval." The effect of the IRB's NSR decision is important to research sponsors and investigators because significant risk (SR) studies require sponsors to file an Investigational Device Exemption (IDE) with FDA before they may begin. NSR studies, however, may begin as soon as the IRB approves the study. The sponsor, usually through the clinical investigator, provides the IRB with information necessary to make a judgment on the risk of a device study. While the investigational plan and supporting materials usually contain sufficient information to make a determination, the IRB can request additional information if needed [21 CFR 812.150(b)(10)]. If the IRB believes that additional information is needed, it may contact the sponsor directly, but it should keep the clinical investigator apprised of the request. While making the SR/NSR determination, any of the three parties may ask FDA to provide a risk assessment. See FDA Information Sheet: "Significant Risk and Nonsignificant Risk Medical Device Studies" for further information.

Disagreements

The sponsor may choose not to conduct, to terminate, or to discontinue studies that do not conform with the sponsor's wishes. For example, the sponsor, clinical investigator, and IRB may reach an impasse about study procedures or specific wording in an informed consent document. The FDA

will not mediate such disagreements. The Agency's policy of decentralized ethical review of clinical investigations allows such decisions to be made by local IRBs, and any disagreements between a sponsor, IRB, and clinical investigator should be resolved through appropriate communication among those parties.

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