Non-local IRB Review - Information Sheet

Guidance for Institutional Review Boards and Clinical Investigators

Under certain circumstances, local review by an Institutional Review Board (IRB) may not be available, e.g., research conducted by investigators unaffiliated with an institution with an IRB. Although conceptually modeled for local IRB review, the Food and Drug Administration (FDA) regulations do not prohibit review of research by IRBs in locations other than where the research is to be performed (e.g., independent or non-institutional IRB). Therefore, an IRB may review studies that are not performed on-site as long as the 21 CFR parts 50 and 56 requirements are met.

When non-local IRB review takes place, the reviewing IRB must document its role and responsibility. A written agreement should be executed between the performance site where the research is to be conducted (e.g., private practitioner's office, clinic, etc.) and the IRB or its institution. The agreement should confirm the authority of the IRB to oversee the study. While the IRB assumes responsibility for oversight and continuing review, the clinical investigator and the research site retain the responsibility for the conduct of the study.

Community Attitudes

The non-local IRB should have adequate knowledge of community attitudes, information on conditions surrounding the conduct of the research, and the continuing status of the research to assure fulfilling the requirements of 21 CFR 56.107, 56.111(a)(3), (a)(7) and (b) for each study site. The non-local IRB needs to ensure these requirements are met for each location for which it has assumed IRB oversight responsibility.

The FDA regulations require all IRBs to have membership sufficiently qualified to promote respect for the IRB's advice and counsel in safeguarding the rights and welfare of human subjects [21 CFR 56.107]. IRBs conducting non-local review need to be knowledgeable about the community from which the subjects are drawn to ensure that subject rights will be protected and that the consent process is appropriate for the subject population involved. The IRB should be sensitive to community laws and mores because state and local laws and community attitudes pertaining to research may be more restrictive than Federal regulations or the prevailing standards of the community where the IRB is located.

IRBs can obtain knowledge of community attitudes with a site visit by a representative of the IRB, by appointing an IRB member from that community, or by having a consultant from the community advise the IRB, either prior to or during the deliberations. If travel is not feasible, participation in the IRB meeting can be by video-conference or conference telephone call, or by using other technologies that allow for real-time conversational interaction between the remote member and the members at the convened location. All IRB members should receive an advance copy of the documents that are to be reviewed at the meeting. The minutes of the meeting, during which non-local research is reviewed, should document the procedures used to assure that community attitudes were adequately taken into consideration.

IRB Information Needs

IRBs should have access to a variety of information to properly conduct initial and continuing reviews. Knowledge of the conditions surrounding the conduct of the research is needed to ensure that risks to subjects are minimized [21 CFR 56.111]. An IRB should have sufficient information to judge the qualifications of the researcher conducting the study in question. The researcher's curriculum vitae, a listing of other studies conducted, letters of reference, information from the sponsor of the research, and information from licensing boards and professional societies are examples of information a non-local IRB may want to review. If the research is to be conducted in an institution, the clinical investigator should provide a description of that institution and associated medical facilities. The acknowledgment and/or the permission of the institution should also be provided. If the research is to be conducted outside an institutional setting, the IRB may request a plan for emergency medical care. Depending upon the degree of risk inherent in the study, a hospital should certify that its facilities are available.

The IRB should explicitly detail the information it needs in written reports from the researcher. In addition to scheduled continuing review of progress reports, an IRB may use other methods of obtaining information on the conduct of the study. All IRBs should have procedures that assure the IRB becomes aware of unexpected problems in ongoing studies in a timely manner. Fulfilling this requirement may call for additional efforts for non-local IRBs, such as visiting the study site, contacting the sponsor's research monitor for information on the monitor's site visits, or arranging for other oversight of the study.

IRB Contact

The FDA informed consent regulations [21 CFR 50.25(a)(7)] require that the subject be given the name of a person to contact "... for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject." Non-local IRBs should include, in the consent document, an IRB contact person and a telephone number (toll-free if long-distance). The non-local IRB may also designate an individual at the research site to be the contact and to relay reports to the IRB.

IRB Jurisdiction

When an institution has a local IRB, the written procedures of that IRB or of the institution should define the scope of studies subject to review by that IRB. A non-local IRB may not become the IRB of record for studies within that defined scope unless the local IRB or the administration of the institution agree. Any agreement to allow review by a non-local IRB should be in writing.

Also see FDA Information Sheet: "Cooperative Research." (/RegulatoryInformation/Guidances/ucm126422.htm)

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