Cooperative Research - Information Sheet

Guidance for Institutional Review Boards and Clinical Investigators

Cooperative research studies involve more than one institution. The Food and Drug Administration (FDA) and Department of Health and Human Services (HHS) regulations permit institutions involved in multi-institutional studies to use reasonable methods of joint or cooperative review [21 CFR 56.114 and 45 CFR 46.114, respectively]. 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.

Scope of Cooperative Research Activities

The regulatory provision for cooperative review arrangements may be applied to different types of cooperative clinical investigations. Examples include research coordinated by cooperative oncology groups and participation by investigators and subjects in a clinical study primarily conducted at or administered by another institution. Often, one institution has the primary responsibility for the conduct of the study and the responsibility for administrative or coordinating functions. At other times, multi center trials may be coordinated by an office or organization that does not actually conduct the clinical study or have an IRB.

Written Cooperative Review Agreements

The cooperative research arrangements between institutions may apply to the review of one study, to certain specific categories of studies or to all studies. A single cooperative IRB may provide review for several participating institutions, but the respective responsibilities of the IRB and each institution should be agreed to in writing.

An institution may agree to delegate the responsibility for initial and continuing review to another institution's IRB. In turn, the IRB agrees to assume responsibility for initial and continuing review. The institution delegating the responsibility for review should understand that it is agreeing to abide by the reviewing IRB's decisions. The delegating institution remains responsible for ensuring that the research conducted within its own institution is in full accordance with the determinations of the IRB providing the review and oversight.

The IRB which agrees to review studies conducted at another institution has responsibility for initial and continuing review of the research. Such an IRB, in initially reviewing the study, should take into account the required criteria for approval, the facilities and capabilities of the other institution, and the measures taken by the other institution to ensure compliance with the IRB's determinations. The reviewing IRB needs to be sensitive to factors such as community attitudes.

The agreement for IRB review of cooperative research should be documented. Depending upon the scope of the agreement, documentation may be simple, in the form of a letter, or more complex such as a formal memorandum of understanding. In the case of studies supported or conducted by HHS, arrangements or agreements may be subject to approval by HHS through the Office for Human Research Protections (OHRP) and should be executed in accordance with OHRP's instructions. Whatever form of documentation is used, copies should be furnished to all parties to the agreement, and to those responsible for ensuring compliance with the regulations and the IRB's determinations. The IRB's records should include documentation of such agreements.

When an IRB approves a study, it notifies (in writing) the clinical investigator and the institution at each location for which the IRB has assumed responsibility [21 CFR 56.109(d)]. All required reports from the clinical investigators should be sent directly to the responsible IRB with copies to the investigator's institution, as appropriate.

Multi-institutional IRB

Another form of cooperative research activity is a multi-institutional IRB, that oversees the research activities of more than one institution in a defined area, such as a city or county. Such an IRB is formed by separate but cooperating institutions and eliminates the need for each facility to organize and staff its own IRB. A variation of this is an IRB that is established by a corporate entity to oversee research at its operating components, for example, a hospital system with facilities at several locations.

Also see FDA Information Sheet: "Non-Local IRB Review" (/RegulatoryInformation/Guidances/ucm126423.htm)

More in Search for FDA Guidance Documents (/RegulatoryInformation/Guidances/default.htm)

FDA Guidance Documents: General and Cross-Cutting Topics (/RegulatoryInformation/Guidances/ucm122044.htm)

Advisory Committee Guidance Documents (/RegulatoryInformation/Guidances/ucm122045.htm)

Clinical Trials Guidance Documents (/RegulatoryInformation/Guidances/ucm122046.htm)

Combination Products Guidance Documents (/RegulatoryInformation/Guidances/ucm122047.htm)

Import and Export Guidance Documents (/RegulatoryInformation/Guidances/ucm122048.htm)

International Council for Harmonisation (ICH) Guidance Documents (/RegulatoryInformation/Guidances/ucm122049.htm)

Veterinary International Conference on Harmonization (VICH) Guidance Documents (/RegulatoryInformation/Guidances/ucm122050.htm)