ANALYZING RISKS AND BENEFITS

A regulatory criterion for approval of research is that risks to participants are reasonable in relation to anticipated benefits, if any, to participants, and the importance of the knowledge that may reasonably be expected to result.

When reviewing a proposal, the IRB should evaluate whether research submitted for review satisfies this criterion.

We should regularly assess the likelihood and magnitude of harms and benefits, and understand the importance of the knowledge reasonably expected to result.

We should consider the range of harms, including physical, social, economic, psychological, and legal harm when reviewing specific protocols.

We should also be cognizant of the range of benefits. Benefits can take the form of therapy, education, information, resources or empowerment. Benefits can be directed at participants or the community at large.

Assessing the adequacy of the plan for monitoring data

A regulatory criterion for approval of research is that when appropriate, the research plan makes adequate provisions for monitoring the data to ensure the safety of participants.

When reviewing a proposal, the IRB should evaluate whether research submitted for review satisfies this criterion.

For clinical research involving no more than minimal risk and for most behavioral and social science research (because most involves no more than minimal risk), specific detailed provisions for data and safety monitoring are not usually needed to protect participants. Usually, confidentiality protections are the primary focus.

For research that involves more than minimal risk, we should consider the research and its potential risks and determine whether or not the data and safety monitoring plan is adequate; remembering that there are a number of approaches that are acceptable. (Data and Safety Monitoring Boards review sheet, 5/06). Such approaches might include monitoring by the investigator, the sponsor (e.g., sponsor medical monitor with access to all sites' data) a safety monitoring committee, or by an independent monitoring board.

References: AAHRPP guidance
PHRC educational sheets June 2007