

JERHRE NOTES

Skills for Solving Ethical Problems in Human Research

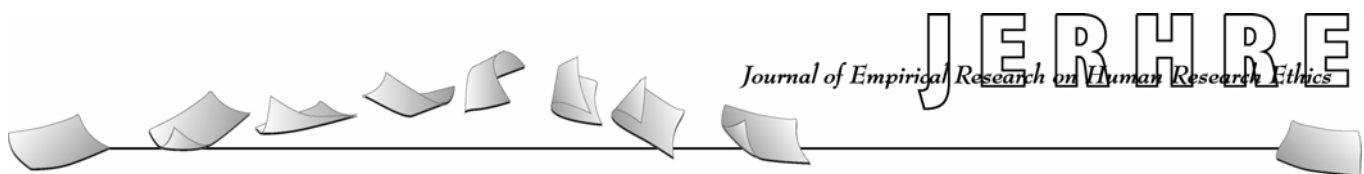
What Do Research Ethics Committees Have to do With “Ethics”?

The regulatory demands on researchers conducting studies with human subjects have increased significantly in recent years. This is the result of both researchers’ increasing awareness of regulatory requirements and of institutions’ fear of the consequences of not following default requirements of regulations (ignoring the flexibility inherent in the regulations). Recent research by Burris and Moss indicates that U.S. health researchers who are entirely committed to protecting research participants from unethical or risky research resent what they have come to regard as counterproductive requirements by research ethics committees. Hence the question: What do research ethics review boards *really* have to do with ethics?

Burris and Moss categorize the results of their interviews into eight thematic areas: (1) need for regulation, (2) satisfaction with own ethics committee, (3) policies and practices about informed consent, (4) time required to prepare protocols and receive approval, (5) minimal risk vs. risky research, (6) multiple reviews, (7) international research, and (8) impact of ethics review on researchers’ ethics. Across all eight areas, researchers strongly share the goals of regulation, but are not convinced that the regulations, as implemented, promote these goals effectively or efficiently.

Burris and Moss provide wide-ranging suggestions for responding to these problems including the following: Human research protection programs (HRPPs) within institutions should provide a feedback loop that gives researchers a voice in the process. HRPPs should also seek to develop and use an empirical basis for understanding the costs and benefits of ethical review, the nature and extent of research risk in diverse settings, and the extent to which ethics committees influence which research topics may be pursued. HRPPs should organize and educate their ethics committees so that the full flexibility inherent in the operative regulations or codes can be intelligently employed. To learn more about the problems and solutions identified by Burris and Moss, please see:

Burris, S. & Moss, K. (2006) U.S. health researchers review their ethics review boards: A qualitative study. *Journal of Empirical Research on Human Research Ethics*, 1(2), 39-58.



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