Principal Investigator Views of the IRB System

Simon N. Whitney, Kirsten Alcser, Carl E. Schneider, Laurence B. McCullough, Amy L. McGuire, and Robert J. Volk

1. Department of Family and Community Medicine, Houston Center for Education and Research on Therapeutics, Baylor College of Medicine, Houston, TX 77098-3926, USA 2. Survey Research Center, Institute for Social Research, University of Michigan, Ann Arbor, MI, USA 3. University of Michigan Law School, Ann Arbor, MI 48109-1215, USA 4. Center for Medical Ethics and Health Policy, Baylor College of Medicine, Houston, Texas 77030, USA 5. Department of Family and Community Medicine, Houston Center for Education and Research on Therapeutics, Baylor College of Medicine, Houston, TX 77098-3926, USA

Abstract:

We undertook a qualitative e-mail survey of federally-funded principal investigators of their views of the US human subjects protection system, intended to identify the range of investigator attitudes. This was an exploratory study with a 14% response rate. Twenty-eight principal investigators responded; their comments were analyzed to show underlying themes, which are here presented along with supporting quotations. There was consensus that it is important to protect human subjects from research abuse, but disagreement over how well the IRB system is functioning. Some researchers felt that the system is effective and serves its purpose well. Of those who support the system, some endorse its methods, purpose, and daily functioning, as they experience it, without reservation. Others, while expressing some frustration, feel that the purpose is important and their local IRB does its best to make a difficult system work well. Those investigators who were more harshly critical commented on multiple flaws in the system, including (1) consent forms that are inappropriate and incomprehensible, (2) an emphasis on minutiae, and (3) concern with protecting the institution more than research subjects. Respondents told us that the IRB system is a particular burden for research in neurology, emergency medical conditions, repositories, and social sciences in general; a more comprehensive study might identify other problematic areas. Significant concern was expressed about the cost, inefficiency, and irrationality of IRB review. The IRB system works well for some researchers, but our results indicate that other investigators feel the costs outweigh the benefits.

Key Word:
Ethics Committees, Research, Questionnaires, Attitude

Volume 5, Number 2, - 2008, ISSN 1449-1907