



Investigator Dissatisfaction with the IRB Approval Process

Author(s): Steven Pennell, MBA, MA; Dr. Ronald Maio; James Lepkowski, PhD

Affiliation: University of Michigan

Funding: University of Michigan

Topic: IRB Operations

Problem/Issue Statement

Little empirical data, but much anecdotal information, characterize researcher experience with the human subjects regulatory system. The 2002 Institute of Medicine report, the 2003 National Research Council report, the 2005 Illinois White Paper, and the associated 2006 editorial in Science recommend collection of empirical data to guide HRPP operations, yet more progress is needed. Empirical data that reflect investigator experience with the regulatory system are important because: 1) the approval process is the core service IRBs provide to researchers; 2) perceived or real difficulty strictly following approved protocols may lead to disrespect, noncompliance, or scofflaw behavior; 3) IRBs facilitate the research mission of Universities and collectively affect the nation's research enterprise. This research contributes to advancing knowledge about how researchers experience the human subjects regulatory system by asking: 1) what is the relationship between time to approve an application and researcher dissatisfaction with the IRB's core service; 2) what are other correlates of dissatisfaction with the IRB approval process; 3) are these correlates system-related, characteristics of researchers, or both; and 4) what is the strength of the relationship among these correlates and investigator dissatisfaction?

Description of Research

To answer these questions the University of Michigan's Institute for Social Research conducted an IRB-approved scientific survey among 1,800 Ann Arbor campus investigators in late Fall, 2007. The overall response rate for the web-based survey was 46%. Extensive focus groups preceded the survey to develop topic domains. A separate analysis indicated no nonresponse bias. Results from multivariate logistic regression modeling indicate several statistically significant outcomes: 1) investigators support the concept of ethical/regulatory review of research but take exception with how IRBs operationalize it; and 2) dissatisfaction with the IRB approval process is significantly associated with system-related outcomes and attitudes shaped by those outcomes. The time to approve applications is a key determinant of dissatisfaction: the odds ratio of dissatisfaction increases dramatically when approval times exceeds 4 weeks when controlling for other covariates in the model. Other significant system-related correlates are unanswered investigator inquiries to the IRB; IRB-required application changes; and difficulty using the application system. Attitudes like the perceived usefulness of IRBs and whether IRBs are regarded as allies also are important predictors. Investigator demographics are unrelated to dissatisfaction. The results suggest that reducing dissatisfaction with the IRB approval process will require recalibration of system-related features of HRPPs, above all reducing the time to approve applications. Examples will be provided. Repeated surveys will begin in Fall, 2009 to monitor system changes and their affect on key outcomes, including dissatisfaction with the IRB approval process.

Additional Information

A national survey is planned.