

EMPIRICAL RESEARCH ON IRBs AND METHODOLOGIES USUALLY ASSOCIATED WITH MINIMAL RISK

RECENTLY THERE HAS BEEN A STREAM of papers on problematic aspects of some ethics committees. These papers have focused on issues such as preoccupation with procedures and documentation at the expense of thoughtful consideration of ethical and safety issues for protection of human subjects. Issues discussed in most of these papers include understanding what constitutes risk and benefit for research participants, what kinds of consent procedures actually inform and result in sound decisions by subjects, and what policies and practices harm (or benefit) science and the careers of investigators.¹ All of these reports raise important and somewhat related questions that cannot adequately be answered without empirical research.

In this editorial, we focus particularly on the most recent of these papers which juxtaposes academic freedom and human subjects protection, and may seem to suggest that the advancement of one is *necessarily* at the expense of the other. While the complaint about infringement on the rights of some investigators is based in fact, we believe that empirical research can help to reframe the issue so that neither science nor human subjects are placed in jeopardy. The American Association of University Professors (AAUP) released a report entitled "Research on Human Subjects: Academic Freedom and the Institutional Review Board" on Sep. 13, 2006.² As noted by the AAUP, "... the report takes issue with aspects of the federal government's regulations for research on human subjects that constitute a threat to academic freedom. The application of the federal regulations to research methodologies that present no serious risk of harm to research subjects has long been of concern to Committee A, which will continue to keep this matter and other troubling features of the regulations on its agenda."

The AAUP report, like other such reports, prominently reflects university faculty's concern that review of minimal risk human subjects research encroaches on faculty autonomy to pursue their research interests. The report is a symptom of resistance to and frustration with human research protection programs (HRPP) at many universities that seem to be more about regulating scholarly behavior than about protecting human subjects.

It is common to confuse the IRB (a committee) with the HRPP (the administrative policies and program that specify the role of the IRB and other elements of the system such as education of investigators, students and IRB members). By doing so, there is a failure to

¹Some recent papers include: Burris, S & Moss, K (2006) United States health researchers review their ethics review boards, *Journal of Empirical Research on Human Research Ethics*, 1(2), 39-58; Green, LA, Lowery, JC, Kowalski, CP, & Wyszewianski, L (2006) The impact of Institutional Review Board practice variation on observational health services research *Health Services Research*, 41(1), 214-230; Gunsalus, CK, et al., (2006) Mission creep in the IRB *World Science*, 312(5779), 1441; National Research Council (2003) *Protecting participants and facilitating social and behavioral sciences research* Washington, DC: The National Academies Press; Wagner, TH, Bhandari A, Chadwick GL, & Nelson DK. (2003) The cost of operating institutional review boards (IRBs) *Academic Medicine*, 78(6):638-644.

²See (<http://www.aaup.org/AAUP/About/committees/committee+repts/CommA/ResearchonHumanSubjects.htm>). This report was drafted by a subcommittee of the AAUP's Committee A on Academic Freedom and Tenure. The subcommittee was comprised of Judith Jarvis Thomson, chair, Massachusetts Institute of Technology, Philosophy; Catherine Elgin, Harvard Graduate School of Education, Philosophy; David A. Hyman, University of Illinois at Urbana-Champaign, Law and Medicine; Philip E. Rubin, Yale University School of Medicine, Surgery, and Haskins Laboratories; and Jonathan Knight, AAUP staff.

recognize and acknowledge the flexibilities inherent in the regulations which call upon institutions to develop efficient systems of research oversight (HRPPs). Such a system may mandate that the IRB not review minimal risk research or exempt research. Rather, these may all be reviewed within the process set forth by the HRPP, but outside the IRB.

This editorial seeks to reframe the issue in terms of improving universities' HRPP so that its IRB(s) can function more efficiently, and so that methods, contexts and any risks involved in proposed research are quickly and expertly evaluated in a collegial setting, and research is thereby improved and advanced, rather than discouraged, delayed or prevented.

This editorial has three tasks in mind: (1) to call for empirical research so that we know more about the forms of human research review that cause faculty to frame the issues as violations of academic freedom, (2) to distinguish between normally low-risk methods and their uses in high-risk contexts (e.g., focus groups or interviews of 18-year-old college students about their injection drug use), and (3) to urge better dissemination of information about the intent of the U.S. Federal regulations (45CFR46), and the flexibility they offer so that well-designed HRPPs can protect human subjects without infringing on academic freedom. We suggest that if university administrators were to press for reform of their own HRPP and take a responsible role in the conduct and administration of those systems as a formal feature of their legally constituted HRPP (not as casual delegation of responsibility for oversight and education) the abuses of authority by IRBs would be avoided, or at least observed, reviewed, and corrected. The federal agencies to which the institutions and HRPPs respond, particularly the Office for Human Research Protections, could facilitate meaningful progress by more actively encouraging such reform and offering constructive guidance on how to achieve it.

The AAUP report included three main recommendations. The first recommendation, made to policy makers, was "... that research on autonomous adults whose methodology consists entirely in collecting data by surveys, conducting interviews, or observing behavior in public places, be exempt from the requirement of research ethics committee (IRB) review—straightforwardly exempt, with no provisos, and no requirement of IRB approval of the exemption." The second recommendation, made to academic institutions, was "... that colleges and universities take the opportunity that the regulations make available to them and formulate a separate set of procedures for research that is not federally funded." Finally, the subcommittee recommended that its parent organization, the AAUP, serve a coordinating role across academic disciplines to consider further opportunities for future, joint action. As noted "... unless a focused strategy is adopted, and concrete steps taken, nothing will change." It should be emphasized that the AAUP recommendations were limited to minimal risk research with autonomous adults.

Underlying these recommendations was the desire to develop a meaningful approach to remedy apparent systemic problems in a portion of the human subjects system. As noted, institutional oversight in its present form, while well-intentioned and beneficial in most instances, can produce a variety of unintended consequences that could, potentially, put important research and subjects at greater risk. One such concern is that, due to limited IRB resources, increased IRB attention to minimal risk research could lead to reduced oversight for higher-risk research. The report also called for greater consideration of the costs and benefits of alternatives to IRB review when dealing with methodologies that involve minimal risk or that are specifically exempt from IRB review. It has been claimed by some that IRBs are absolutely necessary to protect institutions, investigators, and research participants. However, there is often a failure to consider the balance of the costs and benefits of IRBs as compared with other forms of research oversight that can be accommodated in institutional HRPPs.

It is our view that the AAUP report, like similar articles that preceded it, raises a number of important issues and questions that could be better considered with the benefit of empirical research. As is common in such reports, the AAUP document relays a number of complaints based on anecdotal information. Responses to such reports often provide examples of problematic situations with what are usually fairly benign research methodologies. But what is the reality behind these stories and scenarios? It would be useful to see systematic research on the incidence and nature of harm to participants of research related to specific methodologies, such as surveys, interviews, public observation, cognitive and perceptual tests, linguistic studies, etc., and how these compare with "higher risk" methodologies in other areas of research. It would also be essential to separate whether potential risk is inherent in the methods being utilized or in a combination of the issues under study, the contexts of the research, and the research participants. What are the burdens placed on researchers by current regulations and practices?³ How real are these, how frequent,

³Levine, Robert J. (2006). Empirical research to evaluate ethics committees' burdensome and perhaps unproductive policies and practices: a proposal. *JERHRE*, 1(3), 1-4.

and how can they be measured? How do the presumed risks and benefits on which IRBs base their decisions compare with research participants' perceptions of what is a risk and what is a benefit? Do institutions with separate biomedical and social-behavioral-humanities IRBs do a "better" job at protecting research participants than institutions with integrated IRBs that consider the spectrum of research? What does "better" mean, in this instance, and how can it be measured? What are the benefits of IRB review? Does IRB review suffer in any way because of the consideration of minimal risk research? How could various alternatives to IRB review be structured and assessed?

One approach to improving HRPPs and identifying alternatives to the typical IRB review would involve research-based reforms such as the augmentation of ethical problem-solving skills among investigators. By this, of course, we do not mean studying success at recitation of federal regulations. Neither authoritarian political regimes nor authoritarian child-rearing are known to produce wise or responsible decision makers. Rather they tend to produce manifest rule-following or deviant behavior designed to skirt the rules. Research has already demonstrated that this principle of (negative) moral development applies to researchers as well.⁴ What institutional environments, including those at peer consultation, teaching, departmental, and higher institutional levels, can be created to produce mature ethical decisions and behavior in the design and conduct of human research? Might requirements of peer review by colleagues be the way to build ethical infrastructure in research institutions? How can such environments be developed in conjunction with departmental and HRPP oversight? What institutional policies and practices could be developed to deal with the occasional errant investigator who will do something foolish and harmful irrespective of what HRPP policies are in place? How can we institute such reforms, encourage their articulation, and study them experimentally? In 1969, Donald Campbell explained how reforms can be initiated as experiments that evaluate their efficacy; manifold articles and books have ensued which demonstrate methods by which this could be achieved.⁵

The Federal Regulations offer much flexibility, such as permitting expedited review by experienced IRB members within their own discipline or department,⁶ which provides a great incentive for each department to nominate to the IRB those of its members who have extensive and up-to-date methodological expertise and research experience. In turn, those members could assist faculty who teach methodology to include critical curriculum at the intersection of ethics and methodology. For this service, they should be compensated with release time from teaching and recognition in promotion decisions. With an emphasis on proactive ethics education, early consultation with the department's resident IRB member, and very rapid turn around for expedited and exempt review, most objections to ethics review may vanish.

We believe that responsible and competent IRB members, in such a departmental role, would be ideally situated to understand the contextual factors that can result in high risk when using normally low-risk methods, and to help investigators design rigorous and ethical research. However, since the devil is in the details, evaluations of such reforms and comparative case studies of such departmental or disciplinary endeavors would be highly informative. We note that such "bottom-up" departmental activities can gain traction only if institutional officials commit "top down" those resources needed to fund, recognize and reward such proactive department-level roles. In turn, well-documented evaluation of effective ethical socialization within departments would provide a blueprint for other institutions to follow.

This call for empirical research is not intended to be independent of the call for reform. Within the framework of their HRPPs, institutions can examine problems, introduce innovative approaches to the review of research, and commit to responsibly evaluating those reforms. The readers of JERHRE can help to play a significant role in this process both as researchers and as rich sources of ideas on how empirical research can help inform this process. A review of JERHRE's web page on experiments within IRBs provides a model for inexpensive research on the IRB

⁴DeVries, R., Anderson, M. S. & Martinson, B. C. (2006) Normal misbehavior: Scientists talk about the ethics of research. *JERHRE*, 1(1), 43-50. Keith-Spiegel, P., Koocher, G. P., & Tabachnick, B. (2006) What scientists want from their research ethics committee. *JERHRE*, 1(1), 67-81.

⁵Campbell, Donald T. (1969). Reforms as experiments. *American Psychologist*, 24, 409-429.

⁶Research activities involving human subjects that are exempt from IRB review are identified in 45CFR46.101 (b)(1)-(6). Institutions and IRBs may not create new categories of exempt research. Institutions should have a clear policy in place on who shall determine what research is exempt under 46.101(b). Those persons who have authority to make a determination of what research is exempt are expected to be well-acquainted with interpretation of the regulations and the exemptions. In addition, the institution should be prepared to reinforce and review, as necessary, the method of determining what is exempt. . . . investigators should not have the authority to make an independent determination that research involving human subjects is exempt, and should be cautioned to check with the IRB or other designated authorities concerning the status of proposed research or changes in ongoing research.

process; see: <http://www.csueastbay.edu/JERHRE/experiments/index.html>. Ultimately, it falls to those who will empirically study problems arising from ethical review, create reforms based on the knowledge gleaned, and evaluate those reforms to improve both the protection of participants in research, and the ability of researchers to add to our knowledge and to the overall well-being of our society.

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Thanks are due C.K. Gunsalus, Greg Koski, Felice Levine, and Robert Levine for their helpful comments on drafts of this editorial.