

Where the Rubber Meets the Road: Aligning IRBs and Research Practice

In recent years, there has been increased discussion and even debate about how to reconcile a commitment to the ethical conduct of research in the social and behavioral sciences with a regulatory apparatus for the protection of human subjects that seems too often to fall short of its own aspirations and ideals. The gap between regulations and their implementation whether at the federal, state, or local levels is typically grist for the mill in political science. When, however, the issues are more in our own backyard—in our academic and research institutions—insight, interventions, and even empirical study are harder to come by. The purpose of this essay is neither to applaud what is right nor to decry what is wrong with the current system for the protection of human subjects as practiced. Our goal is to help further catalyze through this *PS* symposium a conversation about the need to produce system reform, illustrate some readily doable steps for doing so, and entice social science colleagues to work at their own institutions and at a national level for system change.

Institutional Review Boards in Context

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Federal attention to the review of human research, including in the social and behavioral sciences, has a long history—dating back to 1966 and U.S. Public Health Service (PHS) policy that required review for all PHS awards. Over the

ensuing years, the scope of this commitment broadened to the then entire Department of Health, Education, and Welfare (HEW preceded Health and Human Services—HHS), which issued guidance for institutional review of HEW human research. Title II of the National Research Act of 1974 (P.L. 93-348) took steps to raise the profile of human research protection issues even further. This act established the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (National Commission) and charged it with examining the existing HEW system and the ethical underpinnings for human research protection. In addition the act mandated that HEW require any entity applying for a grant or contract involving human subjects to provide assurance that it has established a board to be known as an institutional review board (IRB) and that HEW also take

steps to codify its policy into federal regulations. (See Levine and Skedsvold 2008.)

The National Commission identified three basic ethical principles—respect for persons, beneficence, and justice—for research involving human participants and issued a report addressed both to these principles and how they apply to requirements of informed consent, risk/benefit assessment, and the selection of subjects of research (National Commission 1979). Known as the Belmont Report, these principles and related applications guided the process that led to passage of the Code of Federal Regulations for the Protection of Human Subjects (45 CFR 46) in 1981. By 1991, 15 other federal departments and agencies joined HHS to adopt Subpart A as the Common Rule.

One of the defining features of the Belmont Report is a motivating philosophy that ethically sound research requires flexibility and a balancing of factors in decision making (Levine and Sieber 2007). From the very outset of the report the framers make that clear: “These principles cannot always be applied so as to resolve beyond dispute particular ethical problems. The objective is to provide an analytical framework that will guide the resolution of ethical problems arising from research involving human subjects” (National Commission 1979). As Levine (1979) pointed out, the National Commission saw local committees as preferable to national or regional review committees. The commission expressed the view that local IRBs can “work closely with investigators to assure that the rights and welfare of . . . subjects are protected and . . . that the application of policies is fair to the investigators.”¹ While at that time commentators recognized that the protection of research subjects through a decentralized peer-review system was not without its risks and that the rights of investigators needed to be well articulated (see, e.g., Robertson 1979), there was strong support for a local peer-review system that provided for flexibility and discretion and for IRB and investigator engagement.

Contemporary Challenges and Opportunities for Change

The variability of IRB review processes and of investigator experiences across institutions and over time makes it hard to assess the magnitude and extent of the fault lines in the human research protection system in practice. Empirical research is sparse, but both earlier (e.g., Gray, Cooke, and Tannenbaum 1978; Bell, Whiton, and Connelly 1998) and recent (e.g., Keith-Spiegel, Koocher, and Tabachnick

2006; Ashcraft and Krause 2007) studies point not only to a range of investigator experiences, but also to an overall concern about the fairness and respectfulness of the process and especially the relationship between IRB implementation of requirements in relation to minimal risk research. It almost goes without saying to a social science readership that perceptions of fairness and the trust from those governed by a regime are central to the legitimacy and viability of authoritative institutions. Thus culture change in the operations of the human research protection system with an emphasis on cooperation, education, and prevention can benefit IRBs and investigators as well as support the advancement of the ethical conduct of research.

So why are IRBs and research practices not adequately aligned, and is the situation more acute than in the past? While both investigators and IRBs are responsible for protecting the rights and welfare of human participants, the two bring different role perspectives to the overall human research protection system. IRBs operate in a strong legal and regulatory framework because they serve as the institution's body for ensuring compliance with human subjects laws and regulations. Additionally, because the penalties for violations can be severe, IRBs often take a risk-averse approach in reviewing protocols or are called upon by their institutions to take on tasks outside of assessing the ethical implications of research with human subjects (e.g., reviewing in-class teaching of interview skills). Investigators, on the other hand, are a step or two removed from the legal and regulatory forces, and, in preparing protocols, they rely on disciplinary ethics codes, learned norms of workable practices, and their own moral compass to ensure that human research participants are protected. Unfortunately federal regulations, professional ethics codes, and research practice may have shared goals but tend to speak with different languages—creating frustration and skepticism in a system that could potentially work quite well if transformations are made.

It should be pointed out that the current situation is not only challenging to investigators. IRBs are often strapped for resources, mired in paperwork, provided with insufficient staff support, or delegated with tasks that are a distraction from what they are intended to do. There is also great variability in training and institutional rewards for such service and a defensiveness or frustration that can be experienced by IRB members knowing how their colleagues perceive their roles or define the situation. In 1999, after a few high-profile tragic incidents in biomedical research and the suspension of research at a number of institutions, the regulatory climate became more pervasively bureaucratic and mechanistic in approach for social science as well as biomedical research (see, e.g., Singer and Levine 2003; Sieber, Plattner, and Rubin 2002; Gunsalus et al. 2007; Fost and Levine 2007). In the last several years since, there is increased focus on how best to improve the human research protection system (for excellent treatment of this issue in the social sciences, see Citro, Ilgen, and Marrett 2003); good ideas, however, are yet to be tested or implemented on a wide scale.

The benefit of high-profile system change can have a positive impact on all of the actors seeking to promote ethical problem solving in social and behavioral science research (see Sieber 2004). Accountability and discretion for IRBs are not just implied, but are integral to 45 CFR 46 and explicitly noted by the HHS Office for Human Research Protections (OHRP), which is responsible for oversight of institutional compliance with the federal regulations on human research protections. According to OHRP, "an institution may use an alternative approach if the approach satisfies the requirements of the HHS regulations at 45 CFR part 46."² Since institutions indeed have flexibility, the challenge is how to use it effectively and responsibly. The opportunities to do so are present—achieving that ambition is where the rubber meets the road.

Models for Reform

Below we describe four pathways for change in the human research protection system and the role of IRBs in reviewing social and behavioral science research. These suggestions are concrete and plausible ways to introduce change in human research protection systems, and all, we believe, can be accomplished within the current regulatory framework. The goal in presenting these examples is to show how creative use of the flexibility within the current system might resolve some of the pressing concerns of social and behavioral science investigators while ensuring adequate oversight of research involving human participants.

Decentralizing the IRB

Two of the most frequent complaints from social and behavioral scientists are that: (1) IRBs do not thoroughly understand the methods and approaches of investigators in these fields, and (2) expedited review of minimal risk research takes much longer than is warranted. An alternative model of IRB review could address these concerns as well as reduce the burden on already overworked IRBs.

The proposed alternative would allow for the establishment of decentralized departmental or research unit review committees. At present, all or most research that an institution agrees to review under the Federalwide Assurance (FWA) is centralized under one, two, or perhaps three IRBs depending upon the size and complexity of a major university or other institution. We recommend a further decentralization of the IRB function and responsibilities, especially for the review of minimal risk research, while ensuring accountability. Essentially the current regulations that apply to IRBs—in terms of membership, functions and operations, review of research, and criteria for approval—would be transferred to a number of human research review committees. A central IRB may still be tasked with more than minimal risk proposals and could have an oversight and audit function related to the decentralized IRBs. Agreements could also be developed between a central IRB and decentralized review committees within an institution to ensure that the division of responsibility and the authority are clear, the quality of the review process remains intact, and potential conflicts of interest are anticipated with well-specified procedures to ensure that they are fully addressed.

Under the decentralized model, the IRB for a departmental or research unit would be comprised of persons who possess the characteristics required under the federal regulations: individuals with professional competence, including persons of diverse and varying backgrounds; representative(s) from other departments or research units; at least one member whose concerns are non-scientific as well as one who is not affiliated with the institution or department; individuals familiar with vulnerable populations as needed; and persons knowledgeable about institutional policies and regulatory issues on human research protections. These criteria capture the definition of IRB membership under the federal regulations and still allow for a decentralized review process. Although the regulations state that "no IRB may consist entirely of members of one profession," the regulations still provide latitude for institutions interested in developing new models for a local human research protection system to do so (see 45 CFR 46.107[b]). Other regulatory requirements for IRB review and approval of research could also be transferred to decentralized committees, creating more flexibility for institutions that seek different models without running afoul of federal regulations.

This decentralized model is compatible with the theory underlying the delegation of human subjects protection to institutions.

In contrast to when IRBs were first established, colleges and universities today are larger and more complex organizations with many more human subjects protocols to review (irrespective of whether or not the research is federally funded). Therefore further decentralization allows for more relevant expertise, more interaction around ethical issues and problem solving, and a more educative approach to review and approval of protocols. Outside of the academy, many research institutions in the social and behavioral sciences have their own IRBs (e.g., the Rand Corporation and the American Institutes for Research)—indicating the feasibility and potential utility of review committees that have similar methodological expertise and substantive knowledge.

Simplifying and Expediting Expedited Review

Under federal regulations, IRBs may use expedited review procedures for: (1) categories of research that appear on the HHS approved list and have been found by the reviewer to involve no more than minimal risk, or (2) minor changes in previously approved research if it occurs during the period approved for the research. Review may be conducted by the IRB chair or an experienced member of the IRB who is designated by the IRB chair. This process, while well intentioned, has proved frustrating for even the most experienced social and behavioral science researchers—even those who have served on an IRB.

Under a decentralized IRB model, this minimal risk research could be reviewed by departmental or research unit committees. While a review is still required by the regulations, allowing it to occur at several places within the overall local human research protection system could significantly improve the processing of protocols for minimal risk research. A centralized IRB unit might collect information and track the number of requests for expedited review, the number of protocols approved under expedited review, the time from submission to decision, and may even periodically audit the records for purposes of accountability and to ensure responsible conduct, but, in a decentralized system, the workload could be distributed to other review groups.

Even without a decentralized review, the expedited review process could still be enhanced under the current structure, and OHRP could facilitate improvements. Through the assurance process, OHRP can encourage institutions to put in place a mechanism to track and improve the processing of protocols under expedited review. A key system change would be to maintain records and report on expedited review. Through the FWA, institutions could describe the expected timeframe for completing expedited review and provide an annual report regarding, for example, the number of applications submitted and approved for expedited review, the number that were ultimately taken to full review, and the time span between filing for expedited review and action by the expedited review official. By taking reasonable steps to collect information about the expedited review process and by encouraging continuous improvement, OHRP can facilitate immediately accelerating the review process and making for greater efficiency in reviewing and implementing ethically responsible research. No change in the regulations is needed.

Limiting Review of Public Use Data Files

In the social and behavioral sciences, investigators are encouraged to share or archive their data and create public use files that can be widely analyzed by other investigators. The sharing of data that has been de-identified is seen as a way to advance knowledge and promote the public good by making maximum use of limited resources through secondary analysis.

Investigators can then test new or alternative hypotheses using the same data.

Before being made available to the public an IRB must determine that the data file contains only data collected in anonymous form or that has been stripped of direct and indirect identifiers. The data are then classified as a public use data file, and no further review by an IRB should be needed. Indeed the regulations specifically exempt public use data files from IRB review under 45 CFR 46.101(b)(4). Nevertheless many IRBs continue to require review of studies that use public use data files.

At the federal level, OHRP could provide much more leadership and guidance to institutions regarding public use data files. Specifically, in 2002, the National Human Research Protections Advisory Committee recommended that public use data files that have been vetted through an IRB by the data producer or provider should not need to undergo further review.³ The National Research Panel (NRC) on Institutional Review Boards, Surveys, and Social Science Research further fleshed out a parallel recommendation (Citro et al. 2003, 72–3) as did the NRC Panel on Data Access for Research Purposes. The latter NRC Panel (2005, 72–3) recommended that OHRP work with statistical agencies, data archives, data producers, and other entities so that a certificate could be linked to all data vetted for public use—“such a system would permit IRBs to exempt secondary analysis with such data from review as a matter of standard practice.” Exempt public use files would include those prepared by investigators or data suppliers such as the Interuniversity Consortium for Political and Social Research as well as federal statistical data collections. With such a process in place, local IRBs would no longer need to determine that the use of the file by an investigator meets the criteria for exemption from IRB review. Public data files such as the National Election Study or General Social Survey that have been so classified would be readily available to investigators or faculty for training students without further review. Under circumstances where an investigator sought to merge public data files or enhance a file such that individuals could potentially be identified, IRB review would be needed to ensure that any new data are properly protected.

This illustration is characteristic of the system-wide thinking that should be encouraged. By identifying procedures that can avert multiple or repeated IRB review, OHRP can raise the overall quality of determinations (that is, IRBs with appropriate expertise undertake the review in the first instance) and reduce the variation and inconsistency across institutions that lead to confusion and mistrust in the IRB system. Also, IRBs and investigators will benefit from the efficiency of eliminating unnecessary repeated review. Institutions may still implement a tracking system so that they know which investigators are using which public use data files, but IRB approval to use such files would not be needed.

Enhancing the Educative Function of IRBs

Perhaps one of the simplest ways to align IRBs and research practice is to enhance the role of IRBs in assisting investigators to develop protocols that meet human research protection guidelines. For example local IRBs could sponsor a monthly open meeting to answer questions about federal regulations, local policies, and/or issues relating to specific protocols. Developing opportunities for education and advisement could assist institutions in creating a positive climate for improving human research protections. While educating investigators about the overall system, IRB members and investigators can discuss ideas about, for example, reducing risk or enhancing confidentiality protections as researchers are developing protocols. Also, the sessions could be planned as opportunities for feedback and

occasions for interaction about practices or procedures used by IRBs that could be modified to better meet the objective of undertaking ethically responsible research. Changing the culture of the human research protection system from one focused on compliance to one focused on education and prevention could better align IRBs and research practice.

Taking such steps could not only impart knowledge but also establish a more open, accessible, and collaborative climate between IRBs and investigators (including students). For the human research protection system to be effective, it needs the support of investigators. While IRBs have an oversight role in ensuring compliance with federal regulations, they must be seen as legitimate by researchers in order to engender and maintain compliance. Indeed cumulative knowledge from procedural justice research indicates that people are more willing to accept decisions of authorities when they view the process as fair (Thibaut and Walker 1975; Lind and Tyler 1988; Tyler 1988; Tyler 2004). And at least three relational processes are important in this judgment: respectfully considering group members' views, treating group members with dignity, and demonstrating neutrality in decision-making processes (Tyler and Lind 1992; Tyler 2004).

By increasing opportunities for researchers and IRB members to discuss issues surrounding human research protections, the overall system becomes more transparent, and the groundwork is laid for building trust in the process.

Consistent with this recommendation, a panel of the National Academies called for improved communication between IRBs and researchers:

Clear, open communication between IRBs and investigators is needed to facilitate the preparation of research protocols that adequately describe participant protection procedures and the timely review of research protocols by IRBs. To the extent that researchers better understand the functions of and constraints on IRBs and IRBs better understand researchers' concerns for maintaining the integrity of their research design and reaching closure

on a timely basis, the smoother the research process is likely to be. (Citro et al. 2003, 172)

Indeed, drawing upon procedural justice research and theory, Keith-Spiegel and Koocher (2005) contend that the IRB paradox may be that the likelihood of distrust or dishonesty in interaction with an IRB is greater when investigators perceive that they are not operating in a climate that is collegial and fair.

Concluding Thoughts

We are at a good time to press for change. Since the period of high tension in the early part of this decade, there has been both important empirical research and some serious efforts toward rethinking IRB practice. For example, in the fall of 2004, the Secretary's Advisory Committee on Human Research Protections suggested that OHRP sponsor a workshop to look into the issues involved in using alternatives to local IRBs. This workshop was held in November 2005,⁴ followed by a conference in November 2006. Our strategy for reform urges an emphasis on aligning IRB and research practices within the contours of the current regulatory framework. While making progress will require thinking outside the box, fortunately the regulations provide flexibility to do so.

OHRP, for its part, could provide a supportive framework for positive change. By acknowledging that there are multiple ways to protect human research participants within the parameters of the federal regulations, OHRP would provide needed reassurance for institutions and investigators. Furthermore, to promote new ideas in this area, OHRP could develop a call for reform models and thereby signal to institutions its support for change. The mutual responsibility of all actors—local IRBs, investigators, and the federal government—for building a sound human research protection system and facilitating sound social science commends our doing so. There are enough good ideas and recommendations being generated that it is wise to take the high road and press for moving ahead.

Notes

1. At a national conference co-sponsored by OHRP in 2006, Levine reiterated the commission's view on the role of IRBs. See "National Conference on Alternative IRB Models: Optimizing Human Subject Protection," available at: www.aamc.org/research/irbreview/irbconf06rpt.pdf.

2. U.S. Department of Health and Human Services' Office for Human Research Protections, "Human Research Questions and Answers" available at: www.hhs.gov/ohrp/faq.html.

3. See the report "Recommendations for Public Use Data Files" approved by the National Human Research Protections Advisory Committee (2002) available at: www.hhs.gov/ohrp/nhrpac/documents/dataltr.pdf.

4. See "Alternative Models of IRB Review: Workshop Summary Report" (2005) available at: www.aamc.org/research/irbreview/irbreviewsummary.pdf.

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