President's Response

Response to Comments

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My remarks on IRBs are anchored in three long-standing concerns of many Association members: the principles of legality; the importance of engaged, socially committed and critical scholarship; and the ability to conduct research unimpeded by unnecessary obstacles. In my address I race quickly through the first two concerns, using them mainly to frame my reflections on the third issue: problems with institutional review boards (IRBs). I deeply appreciate that each of the commentators embraces the spirit of my address. They do not take me to task for failing to present a "definitive" statement but respond graciously to my implicit invitation to engage in a discussion. The resulting product is useful: something of a mini-symposium on IRBs, or at least an introduction to some of the major problems with them. I hope that the Association will continue to find opportunities to air these important issues.

The comments converge on three issues: the scope of appropriate coverage of IRB review, how the principles of legality affect assessment of IRB functions, and ideas for ameliorating acknowledged problems with IRBs. Although their diagnoses and prognoses vary widely, the views expressed are not like ships passing in the night. They engage and they encourage still more discussion. My brief response here seeks to join issues even more securely and to further advance the discussion.

The Scope of the Problem Addressed by IRBs

Both my address and all three comments address the issue of the expanding scope of IRBs. Three of us (Feeley, Katz, & Dingwall) detect a clear and ominous expansion and complain about it; one (Stark) does not. Although those worrying about expansion cite different issues and examples, all three of us—Katz, Dingwall, and me—appear to be in considerable agreement: The scope of IRB regulation has expanded over the years, procedural restraints on IRBs have been relaxed, changes in university governance and administration have given IRBs increasing authority, and as Dingwall notes, the idea is being exported. The results:

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more scholars and more research are covered now, more hurdles have to be jumped through, and requests for exceptions are more cumbersome. Growing IRB authority coupled with decentralized and often opaque administration fosters arbitrariness and capriciousness, and even opportunity for mischief by third parties that are not subjects of research.

All the commentators agree with much of this, though when she places problems in perspective, Stark appears less concerned. In contrast, Katz uses language even more indignant than mine: IRBs stifle "potentially controversial" research (p. 801); "the historical record is clear that the IRB interpretation of regulatory requirements has changed in practice" (p. 799); "IRBs are profoundly shaping the nature of the university, repressing some lines of inquiry and encouraging others on grounds that reach far beyond perceived, much less demonstrated, consequences for research subjects" (p. 801); and "The impact of IRBs on critical social research . . . . [is] a significant turning point in American political history toward the repression of progressive inquiry and expression" (p. 805). Strong assertions. Coming as they do from one of America's leading ethnographers, who holds a position in a leading qualitative research program, his comments must be accorded great weight.

Dingwall, who teaches in Great Britain, also sees expansion—also insidious—of another sort. IRBs, he suggests, are still one more feature of American hegemony. Furthermore, he sees the rise of IRBs as another dimension of the expansiveness of surveillance in late modern society. I had not thought about it this way, but it is frightening. One wonders if those of us who have operated below the radar will have this come back to haunt us, and our past promotions and advancements questioned.

Stark is not so worried about all this. Why? Drawing on her dissertation work (2006), she thinks the critics have conveniently misread history. She too has a host of criticisms to level against IRBs (more about this below), but she takes issue with those who don the mantle of victimhood and claim that "human subjects regulations were not meant to apply to us" (p. 785). Her argument in a nutshell: IRB regulations were expansive from the outset and were meant to apply to social scientists (not just biomedical researchers) and to be a barrier to some research. She writes,

> From the outset, human subjects [reviews] protections were intended to regulate social and behavioral researchers. Recent insinuations to the contrary fail to appreciate, first, the changing meaning of "real harm" since the 1960s and, second, the extent to which human subjects regulations were never exclusively about preventing harm, but about protecting people's rights not to be

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> researched, even when everyone involved regarded the practices as harmless by any definition (p. 778).

She is not particularly sympathetic with those who complain about mission creep since, as she emphasizes, the mission was expansive from the outset.

To buttress her argument, Stark draws on foundational documentation revealing that IRB regulations were a response to a wide range of concerns: Out of frustration with behavioral science research, in 1964, the U.S. Civil Service Commission banned the use of ostensibly objective psychological tests and questionnaires because of findings of racial bias. At about the same time, members of Congress expressed alarm about research that "ask[s] our citizens to answer intimate questions about their family life, sex experience, religious views, personal values, and other subjects normally regarded as solely the private business of the individual" (p. 779); National Institutes of Health lawyers had a conviction that "human subjects protections were as much about safeguarding people's *rights* [not to be subjects of research] as about protecting them from physical or social *harm*" (p. 779; *emphasis in original*); and federal officials consciously embraced a decentralized system that minimized the likelihood that federal agencies could be "held financially responsible . . . ." (p. 780).

In sum: at the outset, some of those who had a hand in designing the human subjects protection regime ranged from being skeptical to hostile and contemptuous of social science, and they sought ways to encourage research subjects not to cooperate. In addition, one of the goals of the regime was to place the responsibility for the consequences of research at the local level. I will defer to Stark's assessment of this historical record, though the evidence she marshals hardly reveals either a set of noble concerns or clear guiding principles. But I do wonder whom she has in mind when she criticizes those who complain that the regulations "were not meant to apply to us." This sounds very much like observations I have received from IRB members who have patiently tried to explain the importance of their job to me, as if I simply did not get it. In fact, what almost every critic of IRBs does acknowledge is that there are situations in which stringent regulations make sense, such as in medical experimentation, and others where they are less compelling. Indeed, like Stark, I do acknowledge the expansiveness of IRB regulations from the outset—hence the reference to my comment to Al Reiss in 1975, and my lament that his assurance of the eventual emergence of narrow common law-like rules has not been realized. Similarly, Katz's complaints about mission creep are not couched in an appeal to a lost golden age.

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Even with its broad mandate from the outset, there are many reasons for expanded IRB authority since: IRBs' increasing institutionalization within universities, the increased salience of risk avoidance for university administrators, tighter enforcement mechanisms, vague and changing charges, and increasing sophistication of third parties who have interests in squelching critical research. In light of this, all of us would be well served to concentrate on the specifics of the complaints about IRB expansiveness made by many of our colleagues, take them seriously, and respond to their substance rather than cavalierly dismiss them. And we would be well served to explore the "social ecology" of IRBs, looking not only at the direct consequences of their decisions but also at the many indirect effects and forms of self-censorship they may produce. Of course, historical accounts of institutional practices can help us place their significance in context and perspective, but they are not likely to capture these other problems.

Principles of Legality

One of my concerns about IRBs, elaborated on by Katz, is that they contradict established principles of legality—indeed, principles that were part of the foundational concerns of this Association. This issue is serious, and more than a nuisance to be tolerated. It raises questions about the principles of legality that are at the heart of our professional concern and identity. Being required to do the impossible, being held to arbitrary and capricious standards, being judged by unreviewed and unreviewable standards, and being subjected to ill-defined and unconstrained discretion, raise fundamental questions about the rule of law and should be of concern to all of us. Stark does not see these as particularly important concerns, but simply as reflecting the well-known fact that the "application of rules is always an act of interpretation" (p. 782). This hardly constitutes a serious response to a charge of the lack of legality. These are serious charges and must be dealt with seriously.

In recent years, as Katz and others have noted, some legal scholars have begun to be drawn into the IRB review process, often when they find that their research comes within its orbit. I suggested that this development might have some beneficial by-products. Lawyers are used to speaking the language of rights and appealing to the principles of legality, and as they are drawn into contact with IRBs, they may insist upon the principle of legality. This may give new energy to those who have long complained about the over-intrusiveness of IRBs. Dingwall, no doubt correctly, warns that I may be placing too much faith in legal resistance. He

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points out that English and European law is more willing to tolerate prior restraint-like practices than American First Amendment jurisprudence. Indeed, I doubt that American prior restraint doctrine could carry the day with IRBs here. Still, with the entrance of lawyers, the debate might be sharpened and issues clarified, and practices might possibly be rolled back. More generally, as so many of our colleagues have pointed out over the past 30 years, rights discourse, even if rights are not directly realized by it, can be and is a powerful catalyst for social movement mobilization. Katz's comments here come close to being a manifesto for a new social movement. If so, can rights talk amplified by legal scholars serve as a catalyst to advance the cause? I hope so.

What Is to Be Done?

All the commentators agree that abuses occur all too frequently under the current system of IRBs. The question is, what is to be done? Like me, Katz sounds exasperated; bottom-up rethinking about nature and function is called for. In contrast, Stark seems to implicitly criticize us for adopting a victim mentality, suggesting that if we only took a broader perspective, such as the perspective of at least the most well-meaning and best-organized IRBs, we would see that on the whole IRBs perform tolerably well, and that with more effort, well-meaning people can help them do even better. Moreover, she suggests, the national regulations that established IRBs are here to stay, and the best we might reasonably hope for is incremental reform at the local level where there is considerable opportunity for change. She then points to some best practices as ways to improve what she thinks is already a pretty good system: draw more people into the review process, invite applicants to speak directly to IRB members, establish IRB subcommittees to review low-risk research, move subcommittees into departments, adopt term limits. The advantage of such a suggestion, she argues, is that it works "within the rules we already have in place," and is "more immediately feasible because it involves reforming practices at the local level rather than changing regulations at the national level" (p. 785).

Although it is clear that Katz would like to see an expansive national response, I doubt that he is adverse to Stark's suggestions. However, unlike Stark, who advocates working "within the system," he stands outside it. He advocates gonzo-like journalism: blogs that expose abuses (and as well could cite best practices). Still, there is common ground here. All agree that many of the major problems of IRBs are found at the local level. The implication: more local backbone. However, Stark does address

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the potential value of developing "local precedents." Developing such precedents is attractive, but this would take on value only if such precedents were publicized, those subjected to them had opportunity to offer proofs and reasoned arguments as to their meaning and applicability, and there was opportunity for review. Otherwise there is the language of legality without the substance.

Still, there are limits to localism and unreviewable discretion. As they are currently constituted, IRBs bear an uncanny resemblance to local censorship boards that operated under the short-lived reign of the "local community standards" test enunciated by the Supreme Court in *Miller v. California* (1973). Goodwill can only go so far, and the idiosyncrasies that yield beneficial discretion can just as easily yield lead to caprice and arbitrariness as well as good results. Defenders of IRBs might point out that unlike the *Miller* decision, relatively few IRB decisions result in outright research bans, and so the analogy breaks down. Perhaps, and I do not want to push it too far. However, those familiar with the more well-established censorship regime under the Hays Commission will appreciate how the real problem was not the number of movies banned from distribution, but the widespread self-censorship the movie industry imposed on itself. As I suggested above, to understand the scope of IRB impact one has to look outside the IRBs and to the research community. We should thus take seriously the voices of our colleagues when they speak of research they chose not to undertake because of concerns about the current IRB process.

Ironically, the most decentralized response of all would be a reactive, self-initiated tort-like regime, or a process that would trigger an administrative review in the event of complaints. I proposed this in all seriousness, but Stark only notes in passing that she is "unenthusiastic" about the idea. Presumably this is because, as she emphasizes, a well-established and elaborate regulatory system is already in place. The place to begin, she seems to suggest, is the place we find ourselves, which she believes is pretty good anyway. Improve what we have.

At the end of her comment, Stark asks, " . . . is it possible to have a forthright conversation about whether human subjects regulations actually make us angry for reasons that might be less noble than concern for academic freedom?" (p. 785). This is a disturbing question, hinting at hidden motives and defensive of IRB practices, that is most likely to be asked by someone who stands firmly within the IRB orbit. Indeed, it a version of a question that I have been asked more than once by IRB members who know my concerns. It is a question most likely to be asked by people convinced of the correctness of their position and who are impatient with those who

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do not see the situation as they do, and so seek to belittle them by changing the subject. It may also be the position of a practical person, someone who takes certain institutions and policies as immutable and given and pretty good, and who prefers to talk to practical folks who are in a position to make them even better.

A generation ago, Sarat and Silbey Sarat (1988) admonished social scientists not to be swayed by the "pull of the policy audience." They warned of the dangers of taking institutional arrangements for granted and urged researchers to be self-conscious about values and contested social visions. "We want," they assert, "to encourage movement from policy to political thinking, from the realm of technique to the realm of values" (1988:142). It is in this spirit that I raised questions about the legality and the integrity of IRBs rather than addressing ways to deal with any particularly troublesome techniques of enforcement. And it is why I could suggest an "impractical" alternative. I did not and I do not expect my proposal to carry the day, at least tomorrow; it is a nonstarter, as was suggested. But I would be content if by raising it, I stimulate wider-ranging discussion about IRBs among colleagues in the Association, one that makes value judgment and political argument more explicit, and one that is not limited by the practical pull of the policy audience.

Coda: A Modest Proposal

There is a quasi-experiment crying out to be undertaken. At least some universities are implementing the opt-out provision for IRB oversight of non-federally funded research. So far they have only announced this decision and then continued to apply the federally mandated standards to all research. One hopes that opt-out soon comes to mean opt-out. And when this occurs, one hopes that a second Stark will appear to write a dissertation on the effects of this process. Perhaps it is already underway. Does opt-out precipitate vast numbers of problems that previously had been avoided though IRB oversight? Does it produce any? Such research can yield important findings. If there are few reports of negative consequences, the research could be used to encourage still other universities to opt out. And indeed they might encourage national officials to rethink the need for such an expansive regulatory system. If so, it would not be the first time a seemingly permanent regulatory system was cut back or eliminated. On the other hand, if opt-out results in increased problems, the findings might help convince Katz, Dingwall, me, and still others of the value of IRBs.

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