The IRB Paradox: Could the Protectors Also Encourage Deceit?

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The efforts of some institutional review boards (IRBs) to exercise what is viewed as appropriate oversight may contribute to deceit on the part of investigators who feel unjustly treated. An organizational justice paradigm provides a useful context for exploring why certain IRB behaviors may lead investigators to believe that they have not received fair treatment. These feelings may, in turn, lead to intentional deception by investigators that IRBs will rarely detect. Paradoxically, excessive protective zeal by IRBs may actually encourage misconduct by some investigators. The authors contend that, by fostering a climate in which investigators perceive that they receive fair and unbiased treatment, IRBs optimize the likelihood of collegial compliance with appropriate participant protections.

The primary function of institutional review boards (IRBs) is to ensure the protection of the rights and welfare of human research participants. It may seem ironic in that context to suggest that IRBs can, in some instances and under certain conditions, facilitate irresponsible science. We explored the thesis that one antecedent to deceitful action by scientific investigators arises in response to perceived biases and unjust actions by IRBs.[1]

Historically, the blame for questionable or dishonest scientific practices has focused on pressures to publish, competition for funding and other limited resources, excessive ambition, looming deadlines, character flaws, and giving into deceitful means of retaining or advancing one's career. The role of the IRB in investigators'

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[1]Perceptions of organizational injustice can be based on decisions and actions that others might judge as fair but that are perceived of as unfair by the recipients.

decisions to disobey the rules has not heretofore been proposed. However, consider these scenarios, adapted from actual incidents.[2]

An investigator regards her IRB as unresponsive and arrogant. Now she purposely collects most of her research data as "regular educational assignments" carried out in the classroom or as required homework. When a data set looks interesting enough to publish, she submits a protocol requesting use of data already collected for nonresearch purposes.

An investigator became frustrated because her institution's IRB took extended periods of time to render decisions on her protocol submissions, even when they fell into an "exempt" category. In response, she routinely begins data collection before the IRB has rendered a decision.

An investigator has experienced numerous problematic interactions with the IRB, most involving what he perceives as demands for picky changes that compromise the quality of his designs. He now writes, in elaborate detail, content he knows will likely bore readers and make no waves, while omitting or distorting elements of his projects that he believes might cause his IRB to balk. He has used this technique for his last seven proposals, and every one gained approval without question.

An investigator's institution imposes strict requirements for consent and allowable risks that considerably exceed federal guidelines. The investigator believes his proposal will fail to gain approval by this IRB, so he does not seek it. He reasons that he has no moral obligation to obey the dictates of what he regards as "a rigid and antiscientist authority." As a prolific publisher, he willingly takes the chance that a publication based on a protocol never submitted to the IRB will pass unnoticed.

An investigator felt badly mistreated when, even after two appeals to the IRB, his research proposal could not gain approval without what he and several colleagues with whom he consulted believed were unnecessary and time-consuming changes. He needs another publication to bolster his upcoming tenure review, but the IRB has taken over 4 months to review his appeals. Despite guilt-ridden qualms, he submits a paper for publication, reporting his procedure as conforming to IRB mandates using data he contrived.

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[2]These disguised incidents were conveyed to the first author by colleagues at another university and served as the impetus for this line of inquiry.

These incidents reveal behavior patterns that may well continue unabated. It is also revealing that the risk extends well beyond investigators themselves. The researcher in the first case, for example, appears to have less concern with what her students learn and more interest in exploiting them as unwary research participants. Harm to research participants could also result from using inadequately reviewed study methods, as evidenced in the second, third, and fourth cases. Any subsequent discovery could lead to federal sanctions, especially if risks materialize and become known. The last case corrupted the research record. Although we hold investigators responsible for their misbehavior, organizational justice theory and research may prove helpful in understanding, minimizing, and preventing some instances of deceitful and dishonest actions.

THE THEORETICAL PERSPECTIVE

Organizational justice theory predicts the elevated potential for employee misconduct whenever management is perceived as behaving in an unfair, arbitrary, or biased manner. A considerable body of research demonstrates strong associations between perceptions that an employer applies just and fair policies and employees' good citizenship behaviors and organizational commitment (e.g., Cropanzano, Byrne, Bobocel, & Rupp, 2001; Folger & Cropanzano, 1998). Conversely, management perceived as unfair or unjust often leads to negative reactions from employees, including the commission of dishonest acts (e.g., Folger, 1992; Robinson & Bennett, 1995; Youngblood, Trevino, & Favia, 1992). When people feel disrespected, they become disinclined to comply with authorities (Miller, 2001).

Two types of organizational justice have particular relevance to our thesis. First, *procedural justice* involves the appraisal of the process used to make decisions. If a decision-making procedure seems biased or unfair, the level of employee commitment declines, the amount of theft or other forms of retaliation rises, and some employees seek work elsewhere (Cropanzano & Greenberg, 1997; Skarlicki & Folger, 1997). Because people care deeply about how they are treated on the job, perceptions of fair decision-making procedures determine, in large measure, their relationships with employers (Folger & Cropanzano, 1998). Perceptions of procedural justice associate strongly with a belief by the recipients that those with decision-making authority have worked from a clear policy, applied evenly, without bias or prejudice, and is understood by all parties (Tyler & Lind, 1992). Procedural justice holds special importance for individuals with other sources of conflicts or stress in their lives (Siegel, Post, Brockner, Fishman, & Garden, 2005).

Levanthal (1976, 1980) generated a list of process characteristics that can elevate the perception of procedural fairness. These include consistency, lack of bias,

accuracy, correctable mechanisms in case of error, representativeness, and adherence to basic ethical standards. It is significant to note that a large, national sample of biomedical and social–behavioral investigators rated these same characteristics applied to IRBs as the most important to them (Keith-Spiegel, Koocher, & Tabachnick, 2004). Thus, it would appear that the scrupulous application of procedural justice could mitigate against negative reactions to decisions that researchers do not welcome.

A common complaint about IRBs focuses on inadequate opportunity to appeal negative decisions. Thibaut and Walker (1975) described a significant property of procedural justice as *voice*. People are more willing to accept a negative outcome when they have an opportunity to present their case (i.e., have their views considered in making the decision) *and* that the decision makers both listened to and heard their concerns (Bies, 1987). This opportunity mitigates against loss of self-esteem caused by a negative outcome because the individual's views gain at least implicit acknowledgment (Folger & Cropanzano, 1998).

The second type of organizational justice of interest here is *interactional justice*, having to do with how people are treated by decision-makers. Interactional justice has been divided into two subtypes (Colquitt, Conlon, Wesson, Porter, & Ng, 2001). *Interpersonal justice* would be evidenced in IRBs by treating the investigator whose submitted protocol received a negative decision in a sensitive and dignified manner that preserves self-regard. Any evidence of caring will alter the impact of the perceptions of the decision makers, even when a negative outcome follows. *Interpersonal injustice* pertains when an investigator receives dismissive, disrespectful, or arrogant treatment with little respect or empathy. *Informational justice* would be evidenced by providing a sincere and reasonably complete explanation regarding the bases of the adverse decision. Explanations, even including making excuses, promote perceptions of fairness (Shaw, Wild, & Colquitt, 2003). *Informational injustice* pertains when IRBs offer investigators inadequate explanations regarding required changes or rejections to a protocol and no opportunity to appeal. Without a full explanation people will ascribe their own motives and intentions to decision makers, and these will often be distinctly negative.

Perceivers of both forms of interactional injustice create more marginalized, hostile, and punishing feelings toward the source of the unsatisfying outcome (Tyler & Lind, 1992). In fact, perceptions of interactional injustice have been shown to more strongly predict deviant reactions than procedural injustice (Aquino, Lewis, & Bradfield, 1999). Applied to IRBs, angered or insulted investigators might dismiss the IRB members as incompetent or biased and may disregard or circumvent IRB rulings in the future. (For in-depth coverage of organizational justice theory and research, see Beugre, 1998; Folger & Cropanzano, 1998; Greenberg, 1996; Greenberg & Colquitt, 2005; Greenberg & Cropanzano, 2001; Vardi & Weitz, 2004.)

WHY IRBS BECOME EASY TARGETS
FOR PERCEIVED UNFAIRNESS

The vast majority of organizational justice field research takes place in factories, businesses, government, or service agencies where organizational structures have a clear chain of command and continuous supervision of employees. IRBs most commonly function within institutions of higher education and research institutes or hospitals associated with universities. Investigators' work typically takes place without close supervision or monitoring, with most enjoying considerable freedom to determine the nature of their professional activities. One could argue, then, that previously studied populations differ substantially from professionals in research settings, making the application of organizational justice theory and research findings suspect. However, we propose that characteristics of investigators and the settings in which they work make IRBs *exceptionally* susceptible to being perceived as unfair.

Common Complaints About IRBs

Though recognizing that local IRBs often must function with insufficient resources and inadequate staff, criticisms regarding how they operate abound. The list of complaints about IRBs includes superficial and hasty reviews of protocols, favoritism toward protocols of selected colleagues, leniency in the hopes of receiving similar consideration when their own proposals come up for review, conflicts of interest, and poor training (Ferraro, Szigeti, Dawes, & Pan, 1999; Hayes, Hayes, & Dykstra, 1995; Palca, 1996; Silberner, 1998). Concerns raised at the Summit of Psychological Science Societies (Cohen, 1999) included censorship of research topics, harassment of certain researchers, lack of accountability, biases, ineffective communication with investigators, lack of knowledge about research, inability to accurately assess research risks, lack of appeal mechanisms, inconsistency, wide variations in the interpretation of federal regulations, and an overweening focus on protecting participants in ways that unnecessarily diminish scientific validity. Social and behavioral scientists decry being subjected to regulations that seem more applicable to biomedical research, causing them unnecessary delays that do not add meaningful protection for participants (Azar, 2002; DeVries, DeBruin, & Goodgame, 2004). Other criticisms include unreasonable demands for consent, impractical requirements for the protection of confidentiality (Devries et al., 2004), excessive dwell time before deciding on protocols, arrogant and dismissive treatment of investigators, using the "local standards" loophole as a justification to make idiosyncratic decisions, and taking overly conservative stances to protect the institution (Keith-Spiegel et al., 2004). It is significant to note that almost all of these criticisms could fall under the rubric of procedural or interactional injustice.

Scientists' Self-Image and Personal Needs

The conduct of research fulfills a variety of personal and professional needs. Therefore, IRB decisions have momentous importance because IRBs stand guard as keepers of the gate, allowing or denying projects to move forward. Because investigators depend on research productivity to define their professional lives, IRBs may have particular intrinsic susceptibility to criticism of unfairness, even if objective others would judge their decisions to deny or substantially alter a protocol to be fair. Furthermore, people do not often attribute negative outcomes to their own shortcomings (e.g., Weiner, 1995), which further fans the potential for perceptions of IRBs as unfair. Whenever investigators perceive their work as "shot down," a powerful sense of righteous indignation and moral outrage may follow. According to Folger and Cropanzano (1998), if the insult feels very strong, people will even act against their own economic self-interests and become heavily emotionally invested in punishing those who treated them unfairly. Research has shown that expressing anger and retaliation actually facilitates the restoration of self-image (Miller, 2001).

Poorly delivered negative feedback constitutes a source of perceived unfairness (Baron, 1993), and those charged with communicating IRB decisions may not deliver bad news effectively. For example, a colleague told us that her IRB delivers bad news in a generic form letter, with an *X* in a box next to "DISAPPROVED."

No Limits on Approvals

The usual settings in which organizational research takes place typically allocate finite resources, such as salaries or other benefits. How these resources are dispersed is important to employees. However, *distributive justice* is not at issue in our theoretical application because an IRB could conceivably approve every protocol coming before it. That realization may actually constitute an additional source of perceived injustice. Because no protocol "acceptance quotas" exist, heightened resentment may follow any protocol rejection.

Clamping Down on Investigators Because of Fears From Federal Regulators

IRBs operate under policies set at the federal level. Because of rare but highly visible instances of harm to participants, such as the death of Jesse Gelsinger during a 1999 gene therapy trial (Couzin & Kaiser, 2005), considerable external demands placed on IRBs have progressively increased (see, e.g., the *Compliance Oversight Procedures* issued by OHRP/OPPR, 2000). IRB managers know that failure to comply with what they perceive as federal requirements could result in suspension or withdrawal of their institution's Assurance of Compliance or result in suspen-

sion of investigators and institutions from participation in federally funded research. The IRB response to such concerns might involve intrusive vigilance and overly conservative decision making, which in turn would most likely be poorly received by investigators.

A related and paradoxical source of pressure on IRBs, leading to another source of perceived unfairness, arises from the flexibility permitted under the existing regulations, allowing the IRB to interpret these rules to better fit the scientific and ethical requirements of the specific research context and justify that decision in their official minutes. In the current environment—in which IRBs may fear falling out of compliance more than they fear violating the conditions that make research feasible, ethical, and valid—they may err on the side of extreme risk avoidance, dither over imagined hazards, and impose requirements inappropriate to the protocol before them. Investigators whose work should have been given the green light may highly resent the stumbling blocks and seek alternative ways around them. A better IRB model would be to first decide what is ethical and then use the flexibility to justify the investigation (Sieber, 2004).

Clamping Down on Investigators Due to Fears From Within

IRBs may face pressures from inside the institution itself that lead to actions that heighten the potential for generating perceptions of injustice. A few complaints—even minor ones—to the administration may generate significant internal pressures to avoid future incidents. In addition, some excessively risk-averse institutions may shy away from approving projects in sensitive topical areas to avoid unwanted publicity. Imposing limits more stringent than what federal policies require likely makes IRBs more susceptible to investigators' perceptions of unfairness. To the extent that IRBs exercise more restrictions than required, investigators may feel disadvantaged and seek ways to circumvent the system. To the extent that disgruntled investigators complain to their peers, urban legends about the IRB may depict it as more draconian than reality warrants.

Questionable Respect for Some Decision Makers

In most organizational justice research, the ladder of command and status in terms of who makes the decisions is clear. IRB membership, however, can include people junior in position and status relative to the investigators whose proposals they must evaluate. Thus, IRBs may have greater vulnerability to perceptions of injustice whenever investigators do not hold all of the decision makers IRB members in high esteem. Investigators may have a greater inclination to feel insulted and resentful when handed negative outcomes by those they deem scholarly inferiors to themselves. Such outrage may fuel direct or indirect responses against the IRB or IRB members.

Research has also shown that people care a lot about whether their treatment is fair because it indicates their status in their peer group (Miller, 2001). Thus, if they perceived themselves as treated unfairly, they may also infer a sense of diminished reputation and importance. Furthermore, people feel entitled to more respect from their own group than from an out-group (Miller, 2001; Tyler, 1994). To the extent that investigators see the institution, the IRB, and its members as all part of a unit, they may feel especially disadvantaged when they perceive disrespectful treatment coming from among their own. In what we hope is an extreme case, one investigator, sitting on the university personnel committee, became instrumental in voting down a candidate for promotion who had sat on the IRB that disapproved his protocol. This investigator confided with a degree of smugness that revenge tastes sweeter served up cold.

POSSIBLE CONSEQUENCES IF IRBS ARE PERCEIVED OF AS UNFAIR

Most people do not act out when they receive an unwanted decision. Based on applying the results of studies in other organizational settings, it seems likely that most instances of negative IRB decisions elicit no outwardly problematic response from the recipients. Regarding researchers, a number of conditions mitigate against acting unethically, even when one feels upset about negative IRB feedback. These include the need to maintain one's position and place in the academic or institutional community, a desire to feel well regarded, and not wanting to do anything that would preclude favorable action by the IRB in the future. The strength of one's personal moral code, self-control, and the risk of being found out and punished also facilitate decisions to refrain from committing dishonest acts (Whitley & Keith-Spiegel, 2002). Some investigators smolder in silence, exhibit emotions in reasonably acceptable ways (e.g., express frustration to colleagues or send a letter to the IRB expressing disappointment), advocate reform in IRB management, or redirect interests away from conducting research. If the situation is intolerable, the individual may voluntarily terminate employment (Cortina & Magley, 2003).

Even investigators who do not act out overtly when feeling unfairly treated may disrespect the IRB and its processes, feel humiliated and marginalized, and develop an attitude that will affect future performance. Commitment to the institution may decline and, sadly, important research may never be conducted. As substantiated with other study populations, some investigators may become evasive and disregard the rules in the future, or believe themselves fully justified in committing dishonest or inappropriate responses, especially when an action seems arbitrary (Pastore, 1950) or if others appear to have had more fair treatment (Folger, 1984). The resulting loss of trust derived from perceived unfair treatment (Konovsky & Pugh, 1994) could further reduce the confidence investigators have in their IRBs.

Many angry investigators who confided their experiences to us expressed the belief that their deceitful actions were fully justified and necessary in the interest of continuing their contributions to science unfettered. Such actions included submitting incomplete protocols, submitting partially false protocols, conducting research prior to IRB approval, never submitting protocols to the IRB, and ignoring all or some IRB decisions and required changes.

It is probable that such behaviors may never actually result in measurable harm to a research participant. However, given that we all have blind spots, especially regarding our own interests and work, avoiding peer review most likely increases the risk of unforeseen harm befalling participants.

CONCLUSION

We acknowledge that IRBs that scrupulously impose procedural and interactional fairness standards will not likely halt the commission of scientific dishonesty among malintentioned investigators, and, unfortunately, people who exhibit negative affectivity (a predisposition to experience aversive emotional states) may not be positively influenced by being treated fairly (Irving, Coleman, & Bobocel, 2005). We do contend, however, that the wealth of research on other populations strongly supports our thesis that IRB policies and treatment of investigators can have a considerable impact on investigators' behavior and morale as well as on the quality of the institutional research climate.

Organizational justice theory predicts, and the research substantiates, that the best way to resolve dilemmas between individual goals and the organizational context involves exercising fairness (Folger & Cropanzano, 1998), thus enhancing the chances of being perceived of as fair. Perceptions of fairness have a causal impact on employees' decisions to behave as good organizational citizens and, as Moorman (1991) advises, managers should be aware of the benefits of behaving toward subordinates in a manner perceived of as fair. Applied to IRBs and research scientists, striving for fairness on the part of IRBs should enhance perceptions of fairness. Ideally, IRBs would The result may play a significant role in encouraging responsible behavior by researchers which, in turn, serves as a preventative protection of human research participants.

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Copies of the IRB Researcher Assessment Tool may be downloaded free of charge at www.ethicsresearch.com.

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