

## IGNORANCE IS NEITHER BLISS NOR ETHICAL

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*The whole aim of practical politics is to keep the populace alarmed (and hence clamorous to be led to safety) by menacing it with an endless series of hobgoblins, most of them imaginary.*

—*H. L. Mencken*<sup>†</sup>

### CONTEXT

It is a common ritual among today's academics to submit research proposals to a group of "colleagues," the Institutional Review Board (IRB; REB in Canada). When IRBs were first created in 1974,<sup>1</sup> they were directed to assess whether a researcher's proposed project would expose the public to greater than everyday risk. Over the last thirty years, IRBs have evolved to review research proposals against criteria well beyond the scope of their original mandate or their ostensible purpose.<sup>2</sup> For example, instead of assessing whether proposed research would expose the public to greater than everyday risk, IRBs now ask whether proposed research would expose members of the public to even "minimal risk." In practice minimal risk is a euphemism for "zero risk," which is an impossible objective to achieve.<sup>3</sup> Likewise, IRBs have expanded the review process beyond the issue of pub-

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<sup>†</sup> H. L. MENCKEN, IN DEFENSE OF WOMEN 29 (Dover Publications 2004) (1922).

<sup>1</sup> See National Research Act of 1974, Pub. L. No. 93-348, § 474, 88 Stat. 342, 352-53 (1974).

<sup>2</sup> I will not review the thirty-year history here, originating from the National Research Act of 1974, see *id.*, and as many others have done so elsewhere during this symposium. See, e.g., MARK ISRAEL & IAIN HAY, RESEARCH ETHICS FOR SOCIAL SCIENTISTS (2006).

<sup>3</sup> Of course, if the goal were explicitly specified as zero risk, then most people would realize that IRBs engage in an impossible exercise. However, not all understand the limits to risk determination, as in this excerpt from the IRB instructions at one large western Canadian university: "[B]oth identifiable and *unforeseen* risks must be considered." UNIVERSITY OF CALGARY, UNIVERSITY POLICY AND PROCEDURES, ETHICS IN HUMAN RESEARCH—ETHICS REVIEW OF RESEARCH INVOLVING HUMAN SUBJECTS 8 (1999), <http://www.ucalgary.ca/uofc/research/documents/ethics.pdf>. Few, except perhaps Nostradamus, would reasonably accept that challenge.

lic safety to pursue more nebulous agendas, including whether the proposed research is worthwhile. They now weigh expected social benefits, legal liability, and similar issues, presuming to judge at the outset that which can only be determined by examining the results.

The broadening scope of IRB inquiry can charitably be described as “mission creep,”<sup>4</sup> and because this expansion has happened in small steps over thirty years, the successive impositions were seldom challenged. However, the cumulative effect is striking,<sup>5</sup> and there is no sign this mission creep has been stalled. Such subterfuge is typical of the way the research ethics enterprise has expanded over the years, always with the result that control of inquiry is increased with no documented evidence of enhanced subject safety. Today, particularly in the field of non-medical research, the institutional review process is more accurately described as censorship than safety screening.<sup>6</sup>

My intent here is to (1) describe how various distortions are used to defend and justify the ethics reviews, and (2) highlight some costs of the ethics enterprise that are routinely ignored. I will focus on social science and humanities research, in part because of my interests, but also because these disciplines seem most vulnerable to unwarranted censorship. When all of the results, intended and otherwise, are considered, it is clear that the constraints imposed on academic inquiry have not been accompanied by an increase in public benefits.

## I. BENEFITS

The benefits of IRBs can be divided into two sets. The first set includes benefits IRB supporters claim accrue to the public despite the lack of reliable evidence that such benefits have materialized. My attention to these will be mainly to critique the shortcomings of the claim that procedure X improves public safety. The second set will concern benefits that accrue exclusively to regulators. These benefits are far more obvious, though they remain unacknowledged by IRB supporters.

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<sup>4</sup> C.K. Gunsalus et al., *The Illinois White Paper—Improving the System for Protecting Human Subjects: Counteracting IRB “Mission Creep”* 3 (The Center for Advanced Study, U. Ill. L. & Econ. Research Paper No. LE06-016, 2005), <http://www.law.uiuc.edu/conferences/whitepaper/papers/SSRN-id902995.pdf>; see also Gunsalus et al., Editorial, *Mission Creep in the IRB World*, 312 SCIENCE 1441 (2006); Kevin D. Haggerty, *Ethics Creep: Governing Social Science Research in the Name of Ethics*, 27 QUALITATIVE SOC. 391 (2004).

<sup>5</sup> See John Mueller, *Best Practices: What Perspective, What Evidence?* 15 J. SOC. DISTRESS & HOMELESS 13, 14, 18 (2006).

<sup>6</sup> See Philip Hamburger, *The New Censorship: Institutional Review Boards*, 2005 SUP. CT. REV. 271.

*A. What is the Evidence, and How Do We Evaluate It*

Before I analyze the claimed benefits and the actual benefits to regulators, it is important to establish a clear understanding of what constitutes reliable evidence that can support a claim that IRBs produce certain benefits. By definition, identifying something as a “benefit” requires some variation of a pre-post assessment. That is, one needs the identification of a null or undesirable state to begin with, a manipulation, and then a secondary assessment that documents improvement. The former shows evidence of a need, and the latter shows evidence of the effectiveness of the manipulation, in this case the ethics review.

The general claimed benefit is “improved public safety,” and I think the burden of proof for that is on the claimant. What is the evidence and what is its validity? Answering this requires some critical perspective from which to assess the claimant’s allegation of benefit. One perspective that comes to mind, given that these committees are examining scientific research proposals, is to adopt the role of the journal editor in deciding whether an author’s submission warrants the claims. Editors routinely advise authors that the plural of anecdote is not data, for example, and the same must be said of opinions, feelings, intuitions, hunches, convictions, and so forth, no matter how firmly expressed. Another perspective is that of the courtroom, where an ample history of rules of evidence exists, excluding things such as hearsay and facts not in evidence, for example, as the readers of law reviews are well aware. To be sure that we attain a benefit that might warrant some censorship, we must have clear and consensual evidence of the benefit, and so it seems reasonable to ask the following questions: Would this claimed benefit be acceptable in a peer-review journal, or would this claimed benefit be admissible in a court of law? By using neutral and conventional benchmarks such as these, we avoid committing the mistake summarized so well by Bertrand Russell when he said “assumptions have all the advantages of theft over honest toil.”<sup>7</sup>

*B. Problems with Claimed Benefits*

The ethics review committees claim to prevent the abuse of subjects. Toward the end of establishing need, certain historical incidents are routinely cited in an effort to establish the need for this enterprise. Not only do these historical abuses not establish a need, they also fall short of showing the IRB process to be effective, especially in non-medical research.

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<sup>7</sup> BERTRAND RUSSELL, INTRODUCTION TO MATHEMATICAL PHILOSOPHY 71 (1919). This sentiment is captured in social cognition research as “wishful thinking,” “self-serving bias,” “confirmatory bias,” and similar self-explanatory conceptions. *Id.*

1. *Genuine Evil.*—A commonly used National Institute of Health training film<sup>8</sup> identifies as abuse such historical incidents as the Nazi experiments in World War II, the Tuskegee syphilis project in which penicillin was withheld even after it became available, CIA experiments administering the psychoactive agent LSD to soldiers and others, military projects exposing soldiers to nerve gas and radiation, and so forth. A careful reader<sup>9</sup> will note that these are almost all government research projects, and the specific cases implicate medical research rather than social-behavioral topics.

Indeed, there have been some sorry historical incidents, but they do not connect with contemporary procedures on campus. Much as lawmakers might like to think otherwise, history clearly shows that those who are going to do something illegal or unethical are not very likely to petition for permission to do so. Therefore, no matter how heinous, these very real incidents do not constitute evidence to justify the present campus IRB process. That is, the present IRB process would not have prevented such abuses, so those events are logically irrelevant. These headline-grabbing incidents are irrelevant to a need-effectiveness demonstration—what we are doing in IRBs now would not have prevented them, so it is inappropriate to bring them up to justify present practices.<sup>10</sup>

These incidents seem to serve as scare tactics, inciting a moral panic to do something,<sup>11</sup> but closer inspection shows they do not demonstrate the need for nor the value of current procedures. It may be understandable that at first one might overlook this point, but to continue to insinuate that these historical atrocities justify the ongoing censorship by campus IRBs is poor scholarship, and seems unethical in itself.

2. *Speculative Evil.*—Other incidents cited as justification are likewise questionable. For example, Alston Chase<sup>12</sup> notes that the Unabomber,

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<sup>8</sup> Videotape: *Evolving Concern: Protection for Human Subjects* (National Institute of Health and the Food and Drug Administration 1986) (on file with Office for Human Research Protections, Department of Health and Human Services) [hereinafter *Videotape: Evolving Concern*], available at <http://videocast.nih.gov/ram/evolving.ram>.

<sup>9</sup> Richard M. O'Brien, *The Institutional Review Board Problem: Where It Came From and What to Do About It*, 15 J. SOC. DISTRESS & HOMELESS 23, 33–35 (2006).

<sup>10</sup> Likewise, the various forms of faking research and data fraud will not be stopped by the IRB reviews, nor will plagiarism, nor will malfeasance, nor can IRB reviews prevent simple human error. As undesirable as such misbehavior may be, campus IRB procedures cannot prevent them, so the incidents are also logically irrelevant to establishing a need. Misconduct by government agencies likewise does not vindicate the campus censorship by academic IRBs in the social and behavioral sciences; misconduct by government agencies, including the military, merely illustrates the old maxim about doing as I say and not as I do. It may be possible to conclude from these historical cases that government research should not be allowed, but that is another matter altogether.

<sup>11</sup> See, e.g., JOHN FEKETE, *MORAL PANIC: BIOPOLITICS RISING* (1994).

<sup>12</sup> Alston Chase, *Harvard and the Making of the Unabomber*, THE ATLANTIC MONTHLY, June 2000, at 41, 53–58 [hereinafter Chase, *Making of the Unabomber*]; see also ALSTON CHASE, *HARVARD AND*

Ted Kaczynski, was a subject in psychology experiments conducted at Harvard by Henry Murray, and conjectures that this may have been the cause of his anti-social behavior many years later. Chase is careful to say we cannot be sure Murray's experiment caused it, but he repeatedly returns to this inference, so the innuendo is clear.<sup>13</sup>

This alleged connection avoids many compelling questions. What else at Harvard, or in Kaczynski's life, might have more directly triggered his troubles? How typical was this of the reaction of other subjects? How many other terrorists have managed to develop without participating in Murray's experiments? Did any of Murray's subjects do something magnificent? What should the comparison(s) be here before we begin using this speculation as a reason for IRBs to expand or justify their efforts? The causal connection with Murray is just gratuitous. Given what we know about Kaczynski otherwise, a very plausible counter-argument can be made that he would have become the Unabomber even if an IRB had refused the project or he had missed Murray's experiment for other reasons.<sup>14</sup> It is intriguing speculation, even entertaining in a sense, but an editor or judge would not consider this gratuitous connection sufficient to justify initiating or expanding IRBs.<sup>15</sup>

3. *Overgeneralize.*—Finally, with regard to Murray's experiment, Chase also offers this: "what we now view as the abuse of human subjects was common. Researchers around the country performed experiments on undergraduates that put them in psychological peril."<sup>16</sup> Chase is not alone in this characterization, as this overstatement has become an urban legend in the service of justifying current IRB censorship. Unfortunately it is a not just a misrepresentation; it is false.

The psychological research of the Murray era was not rife with misbehavior. Some of us know this from having lived through that era, others can document it by examining the research literature. Furthermore, it was clear in the early days of the IRB literature that the miniscule incidence of

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THE UNABOMBER: THE EDUCATION OF AN AMERICAN TERRORIST (2003) [hereinafter CHASE, EDUCATION OF AN AMERICAN TERRORIST].

<sup>13</sup> Other innuendos in the article have to do with alleged military involvement in Murray's research, and his alleged use of psilocybin via an association with Timothy Leary and LSD. See Chase, *Making of the Unabomber*, *supra* note 12, at 58. If memory serves me, there was a fair amount of drug use on campus, not just in military labs, without coercion by mad scientists!

<sup>14</sup> Of course, by Chase's argument, anyone who participated in pre-IRB psychology experiments and later committed a crime now has this alibi. Perhaps this is good news, maybe we can expect crime rates to drop dramatically as IRB influence spreads. Was Timothy McVeigh also in Murray's or a similar experiment?

<sup>15</sup> Ironically, Chase seems upset that Harvard would not violate the original assurance of subject anonymity and confidentiality in Murray's research to prove his thesis that "purposely brutalizing psychological experiments" turned Kaczynski into the Unabomber; that is, he seems to favor suspending the research ethics rules when it suits *his* cause. See Chase, *Making of the Unabomber*, *supra* note 12, at 41.

<sup>16</sup> See Chase, *Making of the Unabomber*, *supra* note 12, at 62.

negative outcomes was well known.<sup>17</sup> Arguably, awareness that social and behavioral research incidents were an essentially non-existent problem may explain why there was no assessment plan to measure increases in public safety at the outset; that is, the IRB regulators knew how difficult it is to improve on an incident rate near zero. But then if the federal regulators were aware that there were essentially no problems, and that little improvement was possible, why have IRBs relentlessly expanded coverage in subsequent years?

Elsewhere Alston Chase claims that in 1952, 96% of federally-funded research in the social sciences was for the US military.<sup>18</sup> Chase's implication appears to be that virtually all social science research was for the military, and that it was all as nefarious and unethical as he perceived Murray's research to be. Although this remark is true as far as it goes, it adds to the claim about common abuse of human subjects to create a very distorted picture of the past in social science research. Consider the rest of the context: In 1952, the vast majority of social science research was unfunded, and thus not connected with the military. Suppose then that 10% of all social science research was funded in 1952,<sup>19</sup> then one sees that "96% of 10%" is a very different matter. Furthermore, not even all military research was evil, a great deal of it had to do with human factors and related benign topics (e.g., monitoring radar screens). Chase also uses the oft-quoted claim that the CIA was the biggest employer of college professors, which is impossible to prove, but something that becomes highly implausible if we think back and realize how little research was funded at all. These misrepresentations of the history of social science research seem ideologically motivated, and serve only to create a fictional need for IRB controls.

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<sup>17</sup> See E.L. Pattullo, *Modesty Is the Best Policy: The Federal Role in Social Research*, in ETHICAL ISSUES IN SOCIAL SCIENCE RESEARCH 373, 373 (Tom L. Beauchamp et al. eds., 1982); Edward L. Pattullo, *Institutional Review Boards and Social Research: A Disruptive, Subjective Perspective, Retrospective and Prospective*, in NIH READINGS ON THE PROTECTION OF HUMAN SUBJECTS IN BEHAVIORAL AND SOCIAL SCIENCE RESEARCH 10, 13–14 (Joan E. Sieber ed., 1984) [hereinafter *Social Research*]; see also Edward L. Pattullo, *Governmental Regulation of the Investigation of Human Subjects in Social Research*, 23 MINERVA 521 (1985). The rate of adverse incidents was very low, and the severity of the few that were even claimed was very minor. See Hamburger, *supra* note 6, at 333–41. Further, in the 1980s, federal authorities estimated that 80% of social and behavioral research would fall into the exempt category. See Charles R. McCarthy, *The IRB and Social and Behavioral Research*, in NIH READINGS ON THE PROTECTION OF HUMAN SUBJECTS IN BEHAVIORAL AND SOCIAL SCIENCE RESEARCH 8, 8–9 (Joan E. Sieber ed., 1984). It seems unlikely that would have been their judgment had there been any evidence of widespread abuse.

<sup>18</sup> See CHASE, EDUCATION OF AN AMERICAN TERRORIST, *supra* note 12, at 262.

<sup>19</sup> In fact, the 10% figure may be high for 1952; personally I know all too well that federally funded social science research even twenty years later was a novelty and a luxury. Interestingly, a recent article reports that even now nearly 80 percent of all research projects reviewed by the University of Chicago's Social Science IRB are personally funded, privately funded, or unfunded. See *Research on Human Subjects: Academic Freedom and the Institutional Review Board*, ACADEME, Sept.–Oct. 2006, at 95, 98 (2006) (citing Richard Schweder, *Protecting Human Beings and Preserving Academic Freedom: Prospects at the University of Chicago*, 33 AM. ETHNOLOGIST 507 (2006)).

Two other classic psychology studies seem to be regularly and selectively misrepresented toward the objective of establishing widespread abuse in behavioral research. Both actually demonstrate interesting psychological principles, but the negative aspects of each seem to grow with every retelling of their tales. For example, conventional wisdom is that Milgram's subjects<sup>20</sup> were upset, but we have no systematic evidence on the extent, breadth and duration of this distress, much less its severity relative to everyday experience, which was the mandated criterion. An anecdote about one or two subjects does not constitute systematic data. An IRB review would have been hard-pressed to identify harm a priori because there actually was no shock. Conventional wisdom would have been that normal people just would not do it. The outcome may be offensive to modern self-images, each generation tends to feel morally superior to the preceding one, but a priori the procedure itself would not have seemed that troublesome.

Similarly, conventional wisdom is that Zimbardo's prison guards<sup>21</sup> treated the prisoners harshly, but hardly anyone seems to admit that the procedure went through ethics review, which saw no problems. Furthermore, the experiment in progress was observed by parents, colleagues, a priest, and others (50 visitors in all). Also ignored is that the prisoners were volunteers who could quit at any time. As with Milgram, we have only anecdotal data about distressed prisoners, nothing systematic on how long-lasting the distress was, how it compared to daily stressors, or how widespread it really was.

Ironically, we seem oblivious to how many everyday situations have the essential features of Zimbardo's prison without raising a concern. For example, regulatory agencies, including IRB committees, employ many of the mechanics used by Zimbardo's guards, such as enforcing minor indiscretions vigorously to establish authority. In both Milgram's and Zimbardo's projects, the outcome was surprising and offensive to some today. That is censorship, not public safety. In 2002, the BBC did a reality-television program using the prison experiment format,<sup>22</sup> and the mechanics

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<sup>20</sup> See Stanley Milgram, *Behavioral Study of Obedience*, 67 *J. ABNORMAL & SOC. PSYCHOL.* 371–78 (1963); STANLEY MILGRAM, *OBEDIENCE TO AUTHORITY: AN EXPERIMENTAL VIEW* (1974). In these experiments, subjects were led to believe that they were administering electric shocks to a person in another room. They were induced to progressively increase the shock levels, and did so. This deference to arbitrary authority surprised and disappointed many.

<sup>21</sup> See Philip G. Zimbardo, *The Stanford Prison Experiment: A Simulation Study of the Psychology of Imprisonment Conducted at Stanford University* (2006), <http://www.prisonexp.org/>; see also C. Haney, W.C. Banks, & P.G. Zimbardo, *Interpersonal Dynamics in a Simulated Prison*, 1 *INT'L J. CRIMINOLOGY & PENOLOGY*, 69, 72–88 (1973). In this experiment, college students were designated as prisoners or guards, and the prisoners were put in cells and had to role play by obeying the guards. The situation became confrontational and even mildly abusive, even though the prisoners voluntarily showed up for several days running.

<sup>22</sup> This touches on a recurrent question: Why do journalists have a freer hand in public research than well-trained academics? See, e.g., Christopher Shea, *Don't Talk to the Humans: The Crackdown on Social Science Research*, *LINGUA FRANCA*, Sept. 2000, at 26, 34.

of the prison simulation are common to military boot camp and other non-academic settings where they go unchallenged. Are drill instructors in boot camp more ethical than trained scientists? The reaction to these studies may be part of the contemporary tendency to pathologize common negative life events<sup>23</sup> and to turn everyone into a “victim,” but such over-reactions should not be confused with higher ethical standards or a safer public.<sup>24</sup>

It is inappropriate to put Milgram’s and Zimbardo’s studies in the same category of public safety as the rest of the NIH film incidents (e.g., Mengele, Tuskegee, LSD, radiation, etc.). Just ask yourself: Would you rather have been a subject in Milgram’s (Zimbardo’s) experiment or a prisoner in the Auschwitz concentration camp (or an untreated syphilis patient)? It is rewriting history to see the Milgram and Zimbardo experiments as indicative of rampant abuse of human subjects in psychological research before modern IRBs, if they were abuses at all.

4. *Protecting the Establishment.*—Another interesting study from this era was Rosenhan’s<sup>25</sup> infiltration of mental hospitals with sane investigators pretending to be mental patients—pseudopatients. In this case, no one in the public was even affected, much less harmed, just some vested interests in the psychotherapy industry. Once again, investigative journalists, such as John Stossel,<sup>26</sup> could do this at any time (e.g., shopping a healthy car around to garages for repair estimates). Stopping such research by trained academics is censorship in the service of the establishment. It protects the gatekeepers,<sup>27</sup> but it has nothing to do with public safety or higher ethics.<sup>28</sup> One can see that the regulators might like to construe this as misbehavior to justify the need for a priori review, and presumably stop the project, but it is not evidence of need or benefit to public safety.

5. *Accusation is Enough.*—These apparent misrepresentations that are alleged to justify IRB censorship suggest problems that go well beyond

<sup>23</sup> See FRANK FUREDI, *THE CULTURE OF FEAR: RISK-TAKING AND THE MORALITY OF LOW EXPECTATION* (2002); CHRISTINA HOFF SOMMERS & SALLY SATEL, *ONE NATION UNDER THERAPY: HOW THE HELPING CULTURE IS ERODING SELF-RELIANCE* (2005); ROGERS H. WRIGHT & NICOLAS A. CUMMINS, *DESTRUCTIVE TRENDS IN MENTAL HEALTH: THE WELL-INTENTIONED PATH TO HARM* (2005).

<sup>24</sup> The BBC replication was not mentioned, but the question of “reality TV” in general and IRB approval has been discussed, unofficially and largely facetiously, without answering the real question of why academics are forbidden to do what other citizens can freely do. See Barbara A. Spellman, *Could Reality Shows Become Reality Experiments?*, *APS OBSERVER*, Mar. 2005, at 34, 35. Any number of classic television shows, such as “Candid Camera,” would be disallowed on campus, even though they clearly were harmless (albeit not always tasteful perhaps).

<sup>25</sup> See D.L. Rosenhan, *On Being Sane in Insane Places*, 179 *SCI.* 250 (1973).

<sup>26</sup> See JOHN STOSSEL, *GIVE ME A BREAK: HOW I EXPOSED HUCKSTERS, CHEATS, AND SCAM ARTISTS AND BECAME THE SCOURGE OF THE LIBERAL MEDIA* (2004).

<sup>27</sup> Editorial, *Time to Cut Regulations that Protect Only Regulators*, 414 *NATURE* 379 (2001).

<sup>28</sup> Actually, the strategy of sending sane people to an insane asylum is well understood by the citizenry in many countries, so in a sense it seems unethical to remain uninformed on the matter.

the behavior of researchers. Whether the misrepresentation is deliberate or merely confusion, it continues to this day. For example, a document maintained by one campus IRB office alleges to demonstrate problems in social science research.<sup>29</sup> It describes the case of Loftus and Guyer<sup>30</sup> as follows: “the PI (principal investigator) violated numerous privacy rights of subjects as well as numerous research integrity practices.”<sup>31</sup> Actually, the privacy issue was created by the subject’s self-identification, and the PIs were cleared of research integrity issues.<sup>32</sup> Furthermore, at the outset, the PIs had made an IRB inquiry, which indicated the project fell into the exempt category. This decision, of course, allows a critic or journalist to proclaim, “It didn’t receive ethics review!”—which is literally true, but only because it did not have to, not because of researcher misconduct. The resolution of this case is diametrically opposed to the accusations,<sup>33</sup> and creates an impression of misbehavior where none existed.

6. *Redundancy.*—IRBs are just one part of the overall process of evaluating research. For example, peer-review is another part, both before funding and again before publication, and it existed long before IRBs. Before IRBs, this step identified bad research. Today the IRBs get the first chance, but even if an IRB finds a problem, that does not mean that it would have actually been overlooked without IRBs, in the past or now. The appropriate question is just what is the *added* value of the IRB review above and beyond the value of other forms of review in the research process? We have no data on added value that accrues specifically to the IRB machinations. The IRB industry seems unconcerned that they may well be claiming credit for what other parties historically achieved, which at the least seems irresponsible.

In a similar vein, IRBs might hypothetically provide an annual report to the campus Research Officer to the effect that, “We had no complaints from research subjects this year, thanks to the diligent efforts of our ethics reviewers.” Does such a claim reflect ignorance about basic issues in causal attribution, such as “correlation is not causation”? Is it just wishful thinking? Given the inherent low risk of social science research, even before IRBs, the absence of incidents may just indicate the baseline, not the benefits of the review committee. Allowing someone to take credit for pre-

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<sup>29</sup> See RUTGERS UNIVERSITY, HISTORICAL EXAMPLES OF SOCIAL-BEHAVIORAL RESEARCH RESULTING IN HARM TO HUMAN SUBJECTS OR PERCEPTION OF CONTROVERSY (2006), <http://orsp.rutgers.edu/Humans/SBHarms.pdf>.

<sup>30</sup> See *infra* notes 64–69 and accompanying text (discussing Loftus and Guyer).

<sup>31</sup> See RUTGERS UNIVERSITY, *supra* note 29. For this description to be a fair representation of what occurred, it would have to be rewritten as follows: “the PI was *accused of* violating numerous privacy rights of *one subject* as well as numerous research integrity practices.”

<sup>32</sup> Carol Tavis, *The High Cost of Skepticism*, 26 SKEPTICAL INQUIRER, July/Aug. 2002, at 41, 43.

<sup>33</sup> I have tried to correct this by writing to the apparent maintainer of the document, but with no change to date. One can reasonably wonder how widespread such claims of misbehavior actually are when, in fact, they are only accusations.

venting an unlikely event does not constitute the quality of evidence that our editor or judge should require.

7. *Revisions.*—IRBs may occasionally reveal some result such that “80% of all proposals submitted require revision,” for example. The implication is that this shows a high incidence of hazardous research avoided. However, if the grounds for requesting a revision are revealed, these are mostly a problem of filling out the form that is required, or similar paperwork issues. In other words, it is not a matter of public safety nor a problem avoided by the IRB industry, but instead it is a problem created by the review enterprise, and it hardly indicates unethical researchers, much less improved public safety. If you have enough regulations you can entrap a lot of people and call them offenders. Likewise, if IRB reviewers are given the charge to “find a problem,”<sup>34</sup> this becomes a very different cognitive challenge than “is there unusual risk?” The former is an open invitation to creative obstructionism, not a safety review. Hours spent contriving and debating hypothetical moral dilemmas may be stimulating (to some), but that is a far cry from enhancing public safety. Mixing these minor and hypothetical problems with actual public safety merely deflects attention from how little substance there is for these IRB committees in social science research.

8. *Indoctrination.*—Undaunted by the minimal evidence of value, the contemporary strategy seems to be to try to remedy complaints about IRBs by offering “Best Practices” workshops. This inappropriately shifts the blame to the experimenters, but more importantly, it ignores the implications of the lack of evidence of their effectiveness (much less the lack of evidence of need). Review criteria have changed many times over the past 30 years,<sup>35</sup> but just as there was no documented need to begin with, neither has any systematic evidence been gathered as to just which changed practice improved public safety and by how much. If one has no evidence-based idea about just which review criteria work, how can one seriously pretend to know best practices? One cannot, without being unethical, and the editor and judge would certainly disallow this claim.

9. *Hypothetical Benefits.*—Another ploy in lieu of evidence is to speculate about the cost of doing nothing. This alarmist concern seems intended to stifle criticism. Given that we cannot know the future, researchers are simply supposed to acquiesce to whatever IRB demands are being made. However, insurance risk analysis, for example, adopts a more practical strategy, knowing that the cost of doing nothing can be estimated from past experience, such as with actuarial tables. The cost of doing nothing us-

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<sup>34</sup> See John Mueller, John Furedy, & Clive Seligman, ‘Overkill’ by IRBs, 16 APS OBSERVER, Aug. 2003, at 10.

<sup>35</sup> See Mueller, *supra* note 5, at 17.

ing such a lens of past experience reveals that such cost may well be functionally nil in non-medical research, given the difficulty of finding bona fide concrete problems in the past.<sup>36</sup> Hypotheticals are not admitted in court or in peer-review journals, and seem to have mainly obstructionist value for IRBs.

The real test of this benefit would be to have some proposals reviewed by IRBs and others not, then to compare the incidents that occur in each condition. This idea is invariably rejected, but sometimes we get an unintended glimpse into the alleged risk of doing nothing.<sup>37</sup> Twenty-five randomly selected experiments at the Harvard Medical School were audited by federal health officials (Office of Human Research Protections, OHRP). Eight out of the 25 research projects were judged to have involved “errors” in research ethics reviews, but no patients were harmed in these eight experiments. An obvious interpretation is that the lapses in the reviews were of no consequence, irrelevant, and unnecessary. It also indicates that the researchers were quite capable, in contrast to their common characterization as incompetents or deviants in need of constant supervision by ethicists.

However, if you are an evangelical research ethicist, this happy outcome means the researchers were just “lucky.” That attribution would not suffice for a peer-review journal or courtroom, and it is gratuitous here as well. Probabilistically, eight out of eight is impressive for randomly selected cases. Interestingly, we do not know about the 17 experiments that were deemed appropriately reviewed. That is, did they also produce no harm? One hopes so. Of course, perhaps not, and if reviewed experiments involved harmful incidents whereas unreviewed projects did not, that makes it even harder to justify the review process at all, much less divert additional resources from other institutional activities.

This inadvertent “experiment” seems to demonstrate that public safety can be achieved without the heavy hand of the ethicists and regulators, even in medical research.<sup>38</sup> In the category of naturalistic experiments, one might also note that ethics-review procedures differ from one country to another, with no obvious differences in public safety. These unintended comparisons may lack laboratory rigor, but they provide no evidence that social science reviews yield a benefit to public safety.<sup>39</sup>

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<sup>36</sup> See, e.g., *Social Research*, *supra* note 17 (showing that even federal authorities accepted a very low rate of adverse incidents in social science research, and those were minor in adversity); McCarthy, *supra* note 17 (same).

<sup>37</sup> See Raja Mishra, *Lapses Cited in Harvard Clinical Trials*, BOSTON GLOBE, May 13, 2004, at A1.

<sup>38</sup> The federal regulators also deemed the Harvard research ethics committee to be too dominated by white males, without explaining how *any* demographic subset could have improved on “no problems.” Given the absence of harm, this racist and sexist preoccupation reinforces the suspicion that some agenda other than public safety is involved. Harvard seems destined to needlessly spend a lot of money trying to improve on having achieved the medical holy grail of “no harm.”

<sup>39</sup> “Track records” are an accepted strategy for projection in the private sector, a variant of an old adage in psychological testing: “Past performance is the best predictor of future performance.”

10. *Public Relations.*—Occasionally one hears the argument that even if we do not know much about which review procedures do and do not work in research ethics reviews, we should continue with the IRB exercise to give the public confidence in the research enterprise. This is just unacceptable to me for several reasons. Given the many recent public scandals in medical research, like that surrounding the arthritis drug VIOXX, the public should rightly be very skeptical of the medical research enterprise, including its “protective” component, the IRB, in part because the IRB pretends to control things beyond its reach (e.g., simple error, as well as misconduct and fraud in the pursuit of profit). The public likely makes little distinction between medical and non-medical research. Do we really want to put forward a system for social and behavioral research that we do not know works or, worse, that we know does not work? Is that ethical? The last thing we should propose in this context is style over substance in the name of scientific research, even less in the name of public safety. We are short on good evidence, seemingly unwilling to address the shortfall, but willing to mislead the public. The research ethics industry seems especially blind to its own faults, and continues to blame the researchers.

11. *More Porridge, Sir.*—Confronted with criticisms, IRB advocates often indicate that they could do a better job if they just had more resources.<sup>40</sup> Where do those come from? They have to be reallocated from some other campus enterprise, so that, for example, the English department would lose faculty positions, psychology classes would get even larger, and so forth—all to get more money to keep doing something that we have no evidence is needed or effective? Why?<sup>41</sup> An answer follows in the next section, and it has nothing to do with public safety.

### C. Hidden “Benefits”

In contrast to the alleged benefits, there actually are some concrete achievements associated with the research ethics regulations: jobs, jobs, jobs. An industry has developed, and it is now big business. Some people have spent their full 30-year careers in academia attending to regulations that may well be a waste of time. Just how much this adds to the economy is not clear, but one wonders if there may not be nearly as many ethics reviewers, regulators, and staff as there are researchers—certainly the growth

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<sup>40</sup> For example, in response to alleged problems at Virginia Commonwealth University, the result was a 450% increase in IRB administrative personnel (2 to 9), a 250% increase in IRB membership (20 to 50), and a 1875% increase in the budget (from \$40,000 to \$750,000). See John Mueller, John Furedy, & Clive Seligman, *Re: ABCs of IRBs*, APS OBSERVER, Oct. 2002, at 7.

<sup>41</sup> As an old maxim advises: “The definition of insanity is doing the same thing over and over and expecting different results.” There may be, somewhere at some time, a bureaucracy whose performance was improved by increased resources, but history suggests that such an entity is even less common than a participant being injured in the course of psychological research. In the absence of evidence, we do not even know what to spend more money on.

rate for the former seems to exceed that of the latter. After 30-plus years of this enterprise, many people have spent their entire “research” careers apparently needlessly thwarting the efforts of others—and they are happily guiding others into what would otherwise be called a pyramid scheme. Given the impossibility of achieving a zero-risk world, likewise a litigation-proof world, the employment horizon seems limitless.

Gatekeepers have proliferated at every level. For example, we have one report from Australia in which a research proposal went through 60 reviews!<sup>42</sup> Those researchers argue for a national review committee, which might be meaningful if it actually meant the abolition of local committees. However, existing bureaucracies are loath to eliminate their jobs and empires. In that respect the research ethics reviewers seem not unlike Zimbardo’s prison experiment, in which the prisoners volunteered, the guards imposed menial demands to establish arbitrary authority, and so forth. If one recalls that Zimbardo’s guards did not want to quit,<sup>43</sup> then it is not surprising that those in the jobs created by the research ethics enterprise want to persist and expand their reach. There are more jobs coming, with the appearance of an accreditation scheme, again with no evidence of need or any plan to document the effectiveness of accreditation reviews, and without any firm evidence of *what* to accredit given the lack of valid information on best practices discussed above.<sup>44</sup>

The ethics industry is unlikely to publicly proclaim these developments as “benefits.” However, these empires are much more obvious than the nebulous benefits in the category of public safety. In terms of a balance sheet, one cannot help but ask: Does it really take so much to achieve such minimal true benefits? Most outsiders, researchers and tax-paying citizens, would rightly deem these to be costs rather than benefits. However, as the next section will demonstrate, there are other costs as well.

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<sup>42</sup> See David C. Whiteman et al., *National Ethics Committee Urgently Needed*, 178 MED. J. AUSTRALIA 187, 187 (2003).

<sup>43</sup> See Zimbardo, *supra* note 21. “Even the ‘good’ guards felt helpless to intervene, and none of the guards quit while the study was in progress. Indeed, it should be noted that no guard ever came late for his shift, called in sick, left early, or demanded extra pay for overtime work.” *Id.* After 6 days, Zimbardo decided to end the anticipated two-week experiment. “In the encounter sessions, all the prisoners were happy the experiment was over, but most of the guards were upset that the study was terminated prematurely.” *Id.*

<sup>44</sup> Bureaucracies expand, often by trivializing the focus of their original mandate. For example, consider the expansion of the concept of “disability,” in the Americans with Disabilities Act, that arguably mirrors the distortion of the notion of everyday risk in IRB settings. See STOSSEL, *supra* note 26, at 202–03.

## II. COSTS

A. *Hard Costs*

1. *Dollar Value.*—Costs offset benefits, and the IRB industry has two types of cost associated with it. First are the hard costs that the federal agencies offload to campuses: the salaries of the committee members and staff (the jobs above), the space, the office equipment, and so forth. It is very difficult to get a precise figure for such costs, because many are hidden, such as the unpaid time volunteer reviewers put in. One simple way to put this cost in perspective is to identify how many departments on campus have fewer faculty than there are people on the IRB, how many departments make do with fewer office staff, and so forth. Many social sciences and humanities departments are smaller than the IRB committee (even on campuses where the medical school IRB is a separate entity). As the IRB enterprise grows to satisfy the accreditation demand, the IRB will continue to grow, whereas many academic departments seem to be basically stagnant or reduced in size over these 30 years (especially in areas where the prospects for external funding are limited, primarily non-medical research).<sup>45</sup>

2. *Time Flies.*—Then there are the costs associated with inordinate delays, resubmissions to create the paper trail, and so forth. The data collection phase of a social science project seldom takes as long as the review process. In my experience, universities tend not to value time as much as it is valued in off-campus endeavors. On campus, if there is an accusation of wasting time, we form another committee to meet once a week to study it. Time taken from other truly productive activities is a hidden cost, unappreciated on campus perhaps, but a cost nonetheless. It would be bad enough if these committees were just wasting their own time, but the IRB process taxes all of us. Time spent learning to fill in the forms is time not available to learn further intricacies in one's discipline, a cost that is invariably ignored, but a loss that is especially acute for young academics.

3. *Collegiality and Scholarship Lost.*—Other costs have nothing to do with money or time; they have to do with the change in campus climate that has occurred in the name of fostering an ethical research climate. Although posturing themselves as creating respect for ethical research, IRBs have in reality created an adversarial relationship between researchers and IRB reviewers. Instead of increasing attention to ethical principles among researchers, the IRB's obsession with forms and process has produced a pragmatic minimalist response: Researchers learn to play the game, and in the process they self-censor their research proposals. Given that research is

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<sup>45</sup> See *Research on Human Subjects*, *supra* note 19, at 98.

a graduation or job requirement, not a “privilege” as some try to frame it,<sup>46</sup> researchers and students will predictably do just what is required, and little more.<sup>47</sup> The committees exhibit no trust of researchers, and researchers chafe at the actions of the committees; there is no feeling of being peers engaged in a common mission.

4. *Bad Data, Bad Policy Advice.*—Although IRBs sometimes pride themselves in terms of ultimately approving most research, nonetheless, the approved project has still been censored.<sup>48</sup> The total cost of unnecessary interference is substantially increased by considering the pre-review hidden self-censorship, combined with the fact that the only means of appeal is back to the censorship board itself—to the guards.<sup>49</sup> These compromised research designs may well yield misleading results, and there is a cost associated with that, especially when these outcomes are cited as the basis for governmental policies, whether the compromise was imposed by the IRB or by self-censorship. As IRBs increasingly intrude on methodological issues, and purport to know “worthwhile” research before the data are in, these compromised designs seem likely to proliferate.

The IRB industry has produced a preoccupation on campus with non-controversial research projects (focusing on areas funded by the federal grant agencies, yet another form of censorship). For example, a recent study of Master’s theses in Anthropology departments in Canada<sup>50</sup> showed

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<sup>46</sup> See Tom Puglisi, *IRB Review: It Helps to Know the Regulatory Framework*, APS OBSERVER, May–June 2001, at 1, 34–35. The commentary in the 1986 NIH training film by Edmund Pellegrino, a medical ethicist who at that time was Director of the Kennedy Institute of Ethics at Georgetown University, is also illustrative. See Videotape: *Evolving Concern*, *supra* note 8. Such a pious characterization seems to have little purpose other than stifling dissent. The same is true of the more recent fashion to argue that subject safety trumps everything else, when in fact we have not a shred of evidence to indicate that subject safety is affected at all.

<sup>47</sup> This should not be a surprise, in that in most other situations where “standards” are imposed they do not become the minimum that they are promoted to be, but rather a soft maximum, given that there is no added profit or incentive for exceeding the required level.

<sup>48</sup> Most proposals may be approved eventually, but the revision sends the message about who is in control. Outright rejection is not required; more subtle on-going “velvet totalitarianism” and self-censorship provide effective censorship without leaving burned books as evidence. See John J. Furedy, *Velvet Totalitarianism on Canadian Campuses: Subverting Effects on the Teaching of, and Research in the Discipline of Psychology*, 38 CAN. PSYCHOL. 204 (1997). Likewise, you need not be beaten in jail to be coerced; for example, when a junior scholar’s research proposal on odor and memory is described as “silly,” the message is quite clear.

<sup>49</sup> This is colloquially known as a “kangaroo court,” and given the secrecy of IRB deliberations it also qualifies as a “star chamber.” However, at least one institution has been successful in getting IRB decisions included in the campus’ collective bargaining agreement, so an appeal could be a grievance, and the IRB would not be the judge, jury and executioner. This was possible on the grounds that research is a job requirement, a part of the campus holy trinity, “teaching, research, and service.” See O’Brien, *supra* note 9, at 38–40.

<sup>50</sup> See Will C. van den Hoonaard & Anita Connolly, *Anthropological Research in Light of Research-Ethics Review: Canadian Master’s Theses, 1995–2004*, 1 J. EMPIRICAL RES. ON HUM. RES. ETHICS 59 (2006). Similar research is in progress on theses in other disciplines.

that the research methodology has become simplified over the past 10 years, given the trouble with getting approval for more complete procedures. There is little reason to believe that faculty research has not been similarly affected. If we are basing public policy decisions on such compromised research designs, there is a clear societal cost due to the way that the adversarial climate and the invisible self-censorship have affected scholarship.

Similarly, an IRB rejected the proposal of a journalism student at the University of Missouri, Michael Carney, and directed him to cease his research.<sup>51</sup> Carney asserted that this violated his First Amendment rights, but ultimately did not file a legal claim. However, the journalism department changed its Master's program requirements by eliminating the scientific research project. This is quite disturbing because it involves journalists who usually vigorously defend the freedom of the press, so it speaks to the perceived power of IRBs and the extent of self-censorship. Along with IRBs reviewing classroom research projects,<sup>52</sup> this shows how far the research ethics industry has intruded into the academic mission on campus, without credible evidence of any societal benefit.

5. *Deference rewarded.*—Another component of this campus climate is the selection process that this system of constraints has worked on the campus over the past 30 years. I have watched, as have others, when undergraduates decide not to go on to graduate research careers, and graduate students leave vowing never to do research again after their PhD. Senior faculty are replaced by junior faculty, who must be deferential, and perhaps more importantly who have no historical perspective on freedom of inquiry. Furthermore, there has been a growth of non-tenured appointments on campus—part-time and contract faculty, for example—and these individuals must also be deferential. Combined with the pursuit of non-controversial projects, this selection of the deferential and compliant seems a poor recipe for innovation in the long term.<sup>53</sup>

6. *Authority or Ethics.*—Another manifestation of the adversarial campus may arise when, facing criticism, research ethics representatives

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<sup>51</sup> See Student Press Law Center, *Graduate Student Contests Review Board's Authority to Approve Journalism Research*, SPLC REPORT, Fall 2001, at 23; Student Press Law Center, *Supreme Court Refuses to Hear Paper's Appeal*, SPLC REPORT, Spring 2001, at 17.

<sup>52</sup> As described by a colleague: "When the head of it [the IRB] told me a student would need the approval of her office to interview the local member of parliament, or even the student's own mother, if the interview results were to be included in an essay submitted for credit in a course, I concluded that she and I are living in very different worlds." E-mail from Kenneth Westhaus, Professor, Univ. of Waterloo, to John Mueller, Professor, University of Calgary (June 12, 2002, 7:20 PM EST) (on file with author). The time required to route classroom research through the IRB makes it increasingly difficult to incorporate a research experience into a single semester course.

<sup>53</sup> This campus coalition of the meek may seem desirable to university administrators, but a wise man once advised: "Be careful what you wish for."

may eventually offer a defense such as “it’s the law” as a dismissive pronouncement intended to deflect any further criticism or prospect of reform. However, it would be more accurate to state this as “it’s *just* the law,” given that the law is an arbitrary human construct that changes regularly.<sup>54</sup>

7. *Overkill.*—To this point there are many clear costs that are associated with the IRB process, and at best only meager, ill-defined, and undocumented benefits. To some extent these costs are incurred because local IRBs go beyond the federal regulations. For example, IRBs ignore the categories of proportionate, expedited, and exempt (PEE) reviews,<sup>55</sup> add legal liability, translate everyday risk into zero risk, turn every normal adult into a member of a vulnerable population, and so forth. The government agencies may not explicitly require some of the practices that now create the local problems and abuses, but they disingenuously encourage them—for example, by insisting that “expedited review does not mean review lite,” and threateningly advising local IRBs, “don’t miss anything,” and “better to aim high,” with a take-home message that clearly encourages overkill.<sup>56</sup> Their failure to acknowledge, much less take action to correct, local abuses can be reasonably construed as acceptance of the culture of deference that these abuses produce. The local committees violate the regulatory mandate, without penalty from the federal agencies, and typically with the encouragement of the university, which even adds concerns of liability, for example. Although the federal authorities may excuse themselves as not being explicitly responsible for such local abuses, the added costs are nonetheless real and much more visible than any enhanced public safety.

We need research on the research ethics industry indeed, but not the parametric sort that merely involves how better to comply. If all of this, or any of it, is unnecessary (ineffective), then it is also a waste to fine-tune it. Is it necessary? Is it working? That is the needed research. Even to this point, it does not seem that the censorship imposed by IRBs meets the possible requirement that the constraints on faculty activities at least provide commensurate social benefits. However, there are yet more costs—genuine harms to researchers.

### B. Harms and Abuse

In addition to the adversarial campus climate, where researchers are demonized and infantilized, the emergence of the research ethics industry

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<sup>54</sup> Further, to honor the IRB industry’s preoccupation with the Nuremberg trials, we should all recall another development in those trials, namely that “just following orders” was not deemed a satisfactory defense.

<sup>55</sup> In the 1980s, federal authorities estimated that 80% of social and behavioral research would fall into the exempt category. See McCarthy, *supra* note 17, at 9.

<sup>56</sup> See Mueller, Furedy, & Seligman, *supra* note 34, at 10.

has created a new basis for litigation and harassment of faculty,<sup>57</sup> often by off-campus interests and sometimes even within the university. Such abuses do not always emerge publicly, and thus this disgraceful treatment is likely more common than we know on the public record. Cases like these contribute further to the negative campus climate noted above, whereby the researcher has become an unprotected second-class citizen, under the subterfuge of creating an ethical climate on campus. Careers, even lives, are being ruined by the research ethics industry, with no documented evidence of greater public safety, and worst of all, with no evidence of remorse. I will relate what we know of six such incidents.

1. *Justine Sergent*.—Sergent was a successful young neuroscientist at McGill University, and her ordeal was described in various articles in the *Montreal Gazette* from 1994 to 1997.<sup>58</sup> Having obtained ethics approval for her brain imaging research, she decided to expand the design in a minor way, involving no harm, without formally getting committee approval.<sup>59</sup> In July of 1992, an anonymous complaint surfaced, and this led to an official reprimand in January of 1993. Sergent noted that the ethics committee violated its own rules by not having a mandatory content expert review her proposal, someone experienced with PET scans.<sup>60</sup> She appealed, and the matter went to arbitration. During arbitration, an anonymous letter was sent more publicly to the university, the press, grant agencies, and major journals, alleging various fraudulent activities in her research. A news story on April 9, 1994, indicated that she was continuing her work, had been reprimanded, and that arbitration was still ongoing. Four days later, 20 months after the reprimand began, the news reported that she and her husband had committed suicide. She was 42.

Sergent believed that she was the subject of a personal vendetta. Montreal had just experienced a case where a medical researcher had truly falsified patient records, and the anonymous letter and press coverage exploited the inference that hers was a similar case—guilt by association. The university honored her request for a scientific audit, and the audit was pursued posthumously, but it was suspended January 15, 1997. There still was no evidence of fraud in any official communication. As far as one can tell,

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<sup>57</sup> See John H. Mueller, *Research Ethics: A New Tool for Harassment in the Academic Workplace*, in *WORKPLACE MOBING IN ACADEME: REPORTS FROM TWENTY UNIVERSITIES* 290, 291 (Kenneth Westhues ed., 2004).

<sup>58</sup> From 1994 to 1997, John Kalbfleisch, among others, wrote many articles in the *Montreal Gazette* regarding Justine Sergent's suicide. See Document Collection, <http://mueller.educ.ucalgary.ca/sergent.txt>.

<sup>59</sup> Having received approval to use faces as the cognitive stimuli in a brain scanning study, she decided to add another condition, listening to music. Twenty years ago, such a minor variation would have been commonplace without a full reapplication, and it certainly appears to be harmless.

<sup>60</sup> As these six cases reveal, it is hardly uncommon for an IRB to employ this double standard, that is, failing to follow its own rules, especially timelines, and yet criticizing the researcher for the least incident.

there were no consequences other than her death; that is, no one else was even reprimanded, apparently. The research ethics committee did not perform the ultimate act, but the research ethics industry made the harassment possible.

2. *Louis Pagliaro.*—In March of 2000, Louis Pagliaro, an educational psychologist at the University of Alberta, was advised to stop talking to the media about drug use in Edmonton schools.<sup>61</sup> He had gathered his information by talking with children, teachers, police, and drug counselors.<sup>62</sup> The police and school boards complained, so the university told him he was under investigation for performing these interviews without approval by the research ethics committee. Pagliaro ignored the gag order. An independent investigator recommended that the university drop the case, but the university continued trying to find a breach of some technical detail that would permit discipline or dismissal. After a full year of fruitless investigation and harassment, Pagliaro received a two-line letter from the university dismissing the complaint, sans even an apology.<sup>63</sup>

3. *Elizabeth Loftus and Melvin Guyer.*—As described in a report by Carol Tavis,<sup>64</sup> and from communications with Loftus and Guyer, Loftus and Guyer decided to reexamine the evidence in a published study of an adult's alleged recovered memory of childhood sexual abuse. Because the material was in the public domain, no ethics review should have been necessary. Guyer, at the University of Michigan, was so advised at first, but a month later this decision was reversed, the project disapproved, and he was recommended to the Office of Vice President for Research ("VPR") for a reprimand.<sup>65</sup> The VPR rejected the recommendation for a reprimand, and a year later, a new IRB chair advised Guyer that there was to be no reprimand and that the project was indeed exempt.<sup>66</sup>

Elsewhere in this saga, the University of Washington received an e-mail from Jane Doe, asserting that her privacy had been violated. The au-

<sup>61</sup> See Charlie Gillis, *Professor Again in Hot Water Over Findings*, NAT'L POST, Nov. 18, 2000, at A03.

<sup>62</sup> Again, a journalist could have conducted such interviews and written about the drug problem without a priori permission, but a trained academic could not. The journalist would, of course, face the eventual editorial decision as would the researcher, but not the a priori review.

<sup>63</sup> E-mail from Louis Pagliaro, Professor, Univ. of Alberta, to John Mueller, Professor, Univ. of Calgary (Sept. 13, 2003, 3:38 PM EST) (on file with author).

<sup>64</sup> See Tavis, *supra* note 32, at 42–43.

<sup>65</sup> The full recommendation letter itself was not sent to Guyer, and it made use of an additional letter that alleged unethical behavior, also not provided to Guyer. Guyer only learned of these when they surfaced at the U. Washington, having been sent there to aid in the prosecution of co-investigator Loftus. To this day the University of Michigan has not released these communications directly to Guyer. This seems both an ethical and a legal aberration.

<sup>66</sup> One doubts this inconsistency will inspire public confidence, yet the lack of repeat reliability is typical of IRB decisions, and committee disagreements are even celebrated as displaying the many "voices" of ethicists.

thor of the original report, her therapist, had been showing a video of her in public presentations, but Loftus and Guyer had never used her actual name.<sup>67</sup> This began a 21-month ordeal for Loftus. It started with the invasion of her office and seizure of her computer on just minutes' notice, but it was five weeks before Loftus even learned the charges against her—"possible violations of human subjects research." Lawyers tried to subpoena her personnel file, something the university should have rejected but which she had to accomplish with her own lawyer. As Tavriss notes: "This was the modus operandi at both universities: keep the charges secret, keep changing the charges, keep the meetings secret, keep the accused in the dark."<sup>68</sup> Furthermore, as in other cases, the University of Washington violated its own rules, which, for example, required a committee to be formed within 30 days and a conclusion reached within 90 days, not 21 months.

The university committee eventually concluded that Loftus was not guilty of scholarly misconduct, but astonishingly recommended that she be banned from publishing, and required her to take remedial education in ethics. Some weeks later, the Dean's letter exonerated her of all charges and dismissed the remediation requirement, but the Dean still advised her not to contact Jane Doe's mother, nor interview anyone else about the case. Universities may think they have given up their *in loco parentis* role for students,<sup>69</sup> but now they and their IRBs treat eminent scholars as children.

Some research just should not be done, and some findings just cannot be tolerated. Credible evidence is not required to start an inquiry, just an accusation. The accused must then prove innocence and personally bear the legal costs, and there is no compensation for winning against an unsubstantiated charge. There are ethical problems here, but to me they seem to involve lawyers, administrators, and journalists—not researchers.

4. *Russel Ogden, Ted Palys, Russell Lowman.*—At Simon Fraser University in Vancouver, Palys and Lowman<sup>70</sup> reported problems with the university's attempt to abridge the obligatory confidentiality agreement

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<sup>67</sup> This tactic of self-identifying and then claiming a privacy violation seems to have become standard operating procedure. See J. Michael Bailey, *Academic McCarthyism*, NORTHWESTERN CHRON., Oct. 7, 2005, at 1.

<sup>68</sup> Immigrants from certain regions of the world will readily recognize this strategy, but it is frightening to find it in supposed bastions of free inquiry in North America.

<sup>69</sup> Of course, critics of speech codes might well argue otherwise. See, e.g., DIANE RAVITCH, *THE LANGUAGE POLICE* (2003); ALAN CHARLES KORS & HARVEY A. SILVERGLATE, *THE SHADOW UNIVERSITY* (1998).

<sup>70</sup> Ted Palys & John Lowman, *Ethical and Legal Strategies for Protecting Confidential Research Information*, 15 CAN. J.L. & SOC'Y 39, 39–40 (2000); see also John Lowman & Ted Palys, *The Research Confidentiality Controversy at Simon Fraser University*, <http://www.sfu.ca/~palys/Controversy.htm>; *Russel Ogden v. SFU*, <http://www.sfu.ca/~palys/OgdenPge.htm>. In a later case, on October 27, 2005, Simon Fraser University awarded Criminology M.A. student Tamara O'Doherty a two-semester waiver of tuition fees in recognition of delays to her research program caused by the actions of the Research Ethics Board.

with subjects. A Master's student, Russel Ogden, was studying those who assist in the suicides of people with AIDS when the Vancouver Coroner's office subpoenaed him to give evidence at an inquest. Ogden refused to provide the identities of those assisting. The university administration decided they could not mount a legal defense for him in spite of having required Ogden to assure the subjects of absolute confidentiality. Ogden was eventually reimbursed by the university for his legal fees and lost wages, and he received an apology and a guarantee that the university would stand behind future researchers provided they comply with institutional policies.

In a fascinating instance of *déjà vu*, Ogden next experienced the same problem working on his Ph.D. at Exeter University in England.<sup>71</sup> Exeter likewise failed to abide by an assurance that it would protect the identities of his subjects who were assisting in suicides. In the Exeter case, Ogden was awarded \$140,000 in damages. In both cases involving Ogden, the institutions failed to honor their commitments until forced to do so by external adjudication, as has been the case with many campus speech codes.<sup>72</sup>

5. *Michael Bailey*.—Michael Bailey, a psychologist at Northwestern University, wrote a book<sup>73</sup> after counseling several transsexual surgery candidates. Therapists have often done this in the past, and without prior ethics review, because the content only becomes generalizable knowledge after a series of clients begin to fall into an identifiable taxonomy.<sup>74</sup> Because it was not planned as research, there was no proposal, and because the clients were not conceived as subjects, there was no consent form. The subjects were not identified by name in the book. However, anonymity was later breached when a subject self-identified to a third-party individual, who then publicized it and sought out others to identify themselves. This harassment used the mechanisms provided by the research ethics industry on campus, and it seems likely that a private therapist would not have been such an easy target, nor would have a journalist.

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<sup>71</sup> D. Todd, *Academic Wins Ruling on Assisted Suicide Research*, VANCOUVER SUN, Nov. 1, 2003, at B3; see also Exeter Pays Canadian Prof \$140K Damages, [http://www.caut.ca/en/bulletin/issues/2003\\_nov/news/exeter.asp](http://www.caut.ca/en/bulletin/issues/2003_nov/news/exeter.asp). From Ogden's two experiences, it appears that the foibles of the research ethics industry and university administration are more replicable than the benefits.

<sup>72</sup> See RAVITCH, *supra* note 69; KORS & SILVERGLATE, *supra* note 69.

<sup>73</sup> See J. MICHAEL BAILEY, *THE MAN WHO WOULD BE QUEEN* (2003).

<sup>74</sup> Many other research areas are similar in starting without formal hypotheses—for example, ethnography. See Catherine Scott, *Ethics and Knowledge in the Contemporary University*, 6 CRITICAL REV. INT'L SOC. & POL. PHIL. 93 (2003); Jack Katz, *Ethical Escape Routes for Underground Ethnographers*, 33 AM. ETHNOLOGIST 499 (2006). This misunderstanding seems to be a by-product of using medical research as a model. The term "protocol" (i.e., recipe, or algorithm) seems to derive from medical research, specifically the profitable clinical trials where the procedures are highly standardized, being more like *Consumer Reports* product testing than research in general. Medical protocols have developed in large part as a way to deflect liability, and likewise "good clinical practices," but exporting these concepts to review social-behavioral projects yields many distortions. Social science subjects are seldom "patients," and the research method of choice is not always based on precedent; in fact, a contrarian approach is often most productive.

Bailey eventually revealed some of the machinations involved in the controversy that followed his book's publication.<sup>75</sup> Like Loftus and Guyer, he anticipated that some might disagree with his conclusions, but the degree of hostility and distortion was not expected. There seems little doubt that the controversy derived from the ideas proposed, having nothing to do with public safety. Research ethics provided the opportunity to threaten a lawsuit against the university, and the media were used again to publicize just one side of the matter in sound bites focused on accusations rather than conclusions. And, as with Loftus and Guyer, Bailey's case continues to be described solely in terms of the accusations, with no concern about the outcome.<sup>76</sup> There seems to me to be an ethical problem in equating an accusation with a fact by IRB advocates, but it is not the ethics of social science researchers.

6. *Gretchen LeFever*.—Lenzer reports the case of Gretchen LeFever, a clinical psychologist and associate professor in the department of pediatrics at the East Virginia Medical School.<sup>77</sup> Dr. LeFever had reported that students in southeastern Virginia were being prescribed drugs for ADHD at a rate two to three times the national average. The medical school's own review had indicated the research was exempt from ethics review, but an anonymous letter alleged scientific misconduct. LeFever's computer was seized, she was charged with scientific misconduct, and she was placed on "administrative leave with intent to terminate her employment."

The use of drugs such as Ritalin is a contentious issue, with strong sentiments and interests on every side.<sup>78</sup> The message that children are increasingly being drugged is unwelcome in some quarters, though the pattern of increased diagnoses apparently is real. It is small wonder that the messenger would be eliminated when possible, again using the research ethics industry, perhaps because of the generous contributions and support that drug companies give to medical schools.<sup>79</sup> In this case, LeFever was also even-

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<sup>75</sup> See Bailey, *supra* note 67, at 2–3.

<sup>76</sup> See RUTGERS UNIVERSITY, *supra* note 29.

<sup>77</sup> See Jeanne Lenzer, *Researcher to be Sacked After Reporting High Rates of ADHD*, 330 BRIT. MED. J. 691 (2005).

<sup>78</sup> The drug pacifies rambunctious children, typically boys, and thus makes classroom management easier for the schools and teachers. Many parents worry about the side-effects; others favor it because the children are also easier to handle at home. And, of course, the drug provides larger profits to the manufacturer as more children take it. Whether the drug is over-prescribed is difficult to say because the condition is so loosely defined, but it is generally accepted that the number of diagnoses and thus the number of prescriptions have increased over the years.

<sup>79</sup> A good example of this was the Nancy Olivieri case at the University of Toronto, where she went public about the apparently harmful effects of a drug after her supervisors did nothing. Over a 16-month period, Olivieri was harassed by her University because "she complained about the conduct of the hospital's medical advisory committee, noting it: heard witnesses in secret, failed to allow Dr. Olivieri's counsel to cross-examine witnesses, [and] failed to disclose documents or respond to her lawyer's requests for information." Marina Jimenez, *Olivieri Case Referred to Regulatory Body*, NAT'L POST, Apr.

tually cleared,<sup>80</sup> reinforcing the pattern that the mere existence of the research ethics industry provides a ready mechanism for personal and professional vendettas. As in the other cases, apparently there were no penalties associated with gratuitous harassment for the anonymous accuser. Again the institution initially sets the stage by declaring no problem, but then readily joins in to pursue the groundless charges, failing to honor its own decisions. If we can't trust the judgment of the campus IRB, why bother? It is easy to identify a lot of agendas here, but public safety is not one of them.

In sum, these six cases can only be described as abuse, prototypic workplace harassment. Being the target of such an inquisition is a horrible experience, personally and professionally, and even witnessing it as a bystander sends a chilling message encouraging self-censoring. Charitably this abuse can be considered as yet another unintended result of the research ethics industry, with good intentions. That may be an accurate description, but surely lack of intention is not an excuse to accept the existence and continuation of such abuse. Whatever the intentions, such abuse is nonetheless shameful, all the more so because it occurred in the name of ethics. Small wonder that researchers and students might feel victimized by the research ethics industry, all in the name of undocumented benefits to the public and under the subterfuge of creating a more ethical campus. When these cases wind down, the needless abuse is clear, far clearer than any alleged benefits from the research ethics industry. Perhaps the concept of collateral damage in the cause of victory is justifiable, but when it occurs in the absence of any documented benefits, it is just very hard to accept.

We do not know precisely how extensive this problem is, but there is a clear pattern just from the six cases noted above and other examples of ideological intrusions in social science research.<sup>81</sup> There are surely other cases involving junior faculty and students who simply could not resist enough to generate publicity. Further, because research ethics reviews and complaints are generally declared "confidential," there is more reason to credit the judgment that this abuse is more widespread than we know. And, given the lack of consequences for abusing the ethics process in these six examples, one can reasonably expect more such abuse in the future, with the campus ethics industry becoming a tool of choice for off-campus

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28, 2000, at A08. Eventually Olivieri won, for doing the right thing. See A.M. Viens & J. Savulescu, *Introduction to The Olivieri Symposium*, 30 J. MED. ETHICS 1, 2–5 (2004).

<sup>80</sup> See Jeanne Lenzer, *Researcher Cleared of Misconduct Charges*, 331 BRIT. MED. J. 865, 865 (2005).

<sup>81</sup> There are some others not included here involving even senior faculty who elected not to be identified, because continuing to relive the ordeal was too stressful, even after having been found innocent. Hunkering down in the trenches and carrying on has been a strategy for coping with IRB hassles for scholars over the years. This strategy may provide some psychological relief to individuals, but it serves to hide the extent of the IRB problems and speaks volumes about the failure of the censors to create an ethical research environment on campus.

causes.<sup>82</sup> Where is the “best practices” workshop to deal with preventing these abuses of researchers? How will accreditation prevent such abuse? What, if anything, can be done to establish a truly ethical environment in the present system, or at least some independent justice for researchers who are harassed for doing as required?

### CONCLUSIONS

It would be nice to conclude with recommendations that would quickly and easily solve these problems. That is well beyond the scope of the present essay, which has the objective of trying to call attention to the obvious negative by-products relative to the very minor, if any, benefits of censoring a generation of social science researchers. I am reluctant to go too far in the direction of solutions, in part because I do not like to take too much ownership of problems created by others. Perhaps more to the point, I have considerable pessimism that there is a will to change things, without which identifying some means of change is pointless. This is partly because it seems the nature of all bureaucracies to preserve themselves and expand,<sup>83</sup> more like an amoeba than anything to be reasoned with, but there is more. In short, Zimbardo knew enough to stop his prison experiment, but I see no sign that the research ethics industry has similar insight or integrity. A review of why I feel that way may help somewhat.

As the discussion above shows, I think, the problem is with the ethics industry, not the researchers. What seems required is a thorough rethinking of the ethics industry and how it has wittingly and otherwise transformed itself over the years. The need for IRBs equivalent to medical review

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<sup>82</sup> It seems that these abuse cases may be more common in non-medical research, where censorship is more likely to be ideologically-motivated. There are other recent developments that involve political intrusions in social science research and journals. See, e.g., Judith H. Langlois and Lynn S. Liben, *Child Care Research: An Editorial Perspective*, 74 *CHILD DEVELOPMENT* 969 (2003); Scott O. Lilienfeld, *When Worlds Collide: Social Science, Politics, and the Rid et al. (1998) Child Sexual Abuse Meta-Analysis*, 57 *AM. PSYCHOLOGIST* 176 (2002). Indeed, *Science* magazine pulled an article on the different ways men and women think: “The journal considered the article for seven months and, after making a number of changes, gave Mr. Lawrence a publication date, proofs and a chance to order reprints. But at the last minute he received an e-mail from Donald Kennedy, the editor-in-chief, in which he said that the journal was not going to publish the article.” See Roger Highfield, *Scientists Are Split on the Different Ways Men and Women Think*, TELEGRAPH ONLINE, July 2, 2006, <http://www.telegraph.co.uk/connected/main.jhtml?xml=/connected/2006/02/07/ecnthink07.xml&%5C1sSheet=/connected/2006/02/07/ixconn.html>. The article was then published on-line by the Public Library of Science (Biology). See PETER A. LAWRENCE, *Men, Women, and Ghosts in Science*, 4 *PLOS BIOLOGY* 19, available at <http://biology.plosjournals.org/perlserv?request=get-document&doi=10.1371/journal.pbio.0040019>. At one time, IRBs were explicitly directed away from using social criteria, but no longer. See, e.g., S. J. Ceci, D. Peters & J. Plotkin, *Human Subjects Review, Personal Values, and the Regulation of Social Science Research*, 40 *AM. PSYCHOLOGIST* 994, 995, 1000–01 (1985). There are likely many more of these than have become public as well.

<sup>83</sup> See Letter from Thomas Jefferson to Carrington (May 27, 1788), in *THE COLLECTED WORKS OF THOMAS JEFFERSON*, at 412 (Paul L. Ford ed., 1904) (“The natural progress of things is for liberty to yield and government to gain ground.”).

committees was never established for social and behavioral research, and the effectiveness of the continuous mission creep remains similarly undocumented. There is little evidence that IRBs have protected the public in psychological research, and ready evidence that demonizing researchers as the problem has been an expensive 30-year failure. I see no evidence that federal regulators and campus zealots are willing to see themselves as even part of the problem; therefore, they will continue to blame researchers, and this is at the root of my harsh attitude about the research ethics industry. For example, a few days spent listening to the discussion on an e-mail list of IRB administrators will convince one that the enterprise, at that level at least, is not ready to rethink matters and accept any meaningful amount of blame. The research ethics industry has many forums for compliance workshops, but nothing for serious discussion of problems. As a result of this control of the lines of communication, it is very difficult to devote serious attention to problems other than compliance.

When you continue to put the blame in the wrong place—on researchers—it seems unlikely that any suggestion will be effective. Having routinely denied deception in psychological research, the ethics industry has spent over 30 years deceiving us, in ways noted above, about the costs and benefits of the enterprise. The problem is not a shortfall of resources, nor is it an evil researcher behind every proposal, nor will it be solved at all by accreditation. Considering the abuses noted above, the assurance that IRBs protect researchers as well as subjects is revealed to be merely patronizing rhetoric.<sup>84</sup> Perhaps researchers can at least stop blaming themselves. By analogy, few would expect tax reform to originate with the IRS, nor your local H&R Block franchise, so likewise the local IRBs and the federal agencies are unlikely to take the lead on ethics reform.

Universities have revealed themselves to be, at the best, quite useless in the cases of abuse, not willing or able to defend the institution and the researcher at the same time. Too often university administrations serve as accomplices in the abuse, ignoring their own decisions and policies. In fact, the universities have also ignored federal regulations, by, for example, adding legal liability to the review. Universities seem willing to put up with these problems to retain access to the federal grant teat,<sup>85</sup> because the entire

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<sup>84</sup> See, e.g., Marjorie A. Speers, *Accreditation Helps Researcher and Subject Alike*, APS OBSERVER, May 2003, at 9–10.

<sup>85</sup> This situation can hardly be dismissed as another unintended consequence because it has long been acknowledged that federal funds can corrupt scholarship: “The prospect of domination of the nation’s scholars by Federal employment, project allocations, and the power of money is ever present—and is gravely to be regarded.” Dwight Eisenhower, Presidential Farewell Address (Jan. 17, 1961), available at <http://www.eisenhower.archives.gov/farewell.htm>. One is tempted to paraphrase Benjamin Franklin’s observation to the effect that “[t]hose who would give up essential Liberty, to purchase a little temporary Safety, deserve neither Liberty nor Safety,” see 6 THE PAPERS OF BENJAMIN FRANKLIN 242 (Leonard W. Labaree ed., 1963), along modern lines as “he who would sacrifice liberty for grant funding deserves neither?” Or to paraphrase yet other ancient advice, “he who pays the piper calls the tune”—so at least be sure that you get a really good price?

institution's research can be shut down by vindictive false accusations.<sup>86</sup> As long as universities honor anonymous accusations, deny researchers the opportunity to confront their accusers, and ignore institutional policies and decisions, researchers can justifiably view the proceedings as one-sided star chambers. This is hardly the best format for either justice or truth to emerge, and seems lacking in ethics however the term is defined. "Best practices" workshops seem more in need for university administrators and IRB committees than for researchers.

Universities seem unlikely to confront the federal agencies, thus we can expect more of the same. For many years, universities eagerly combined unfunded and federally funded projects under the IRB review, even though the federal regulations actually only covered funded projects. The recent development whereby many institutions opt their unfunded research out of the Federalwide Assurance Agreement might seem promising.<sup>87</sup> However, it remains to be seen how unfunded proposals are handled. Universities intruded with legal liability themselves, and deceptively combined funded and unfunded research. Given that campus zealots are responsible for many of the distortions of the review of everyday risk, will universities now rein them in? I would like to be wrong, but I doubt the changes here will be as great as might be hoped. I realize that many campus officials work hard to cope with this over-regulated enterprise, but ever greater resources will not achieve the fundamental redirection that is really needed here.

Professional organizations are similarly unlikely to take much initiative here. Organizations such as the American Psychological Association and the American Sociological Association, and for that matter umbrella organizations like the American Association of University Professors, all strive to maintain cordial relationships with federal agencies, perhaps fearing that their constituent members might suffer by having federal funding redirected to other disciplines if they become too assertive. In fact, some of them had their own codes of ethical conduct long before the IRB industry began to spread, and in that respect had already had a positive effect on research and professional conduct before the ethics industry began to intrude on campus. At this point professional organizations mostly acquiesce, hosting best practices workshops for federal regulators and promoting symposia directed at tweaking the compliance process even if it is not known to be effective. This is hardly the sort of critical judgment they expect their journal editors and reviewers to display. One would think that they would have a vested interest in challenging the misrepresentation (a la Chase) of the ethi-

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<sup>86</sup> Consider an analogy: One child may misbehave (or make a mistake) in the classroom, so the teacher comes in and spanks everyone? Whether legal or not, this sounds like a better plan for intimidation than correction.

<sup>87</sup> See *Research on Human Subjects*, *supra* note 19, at 98 (citation omitted).

cal behavior of their past members, but maybe even that seems to be perceived as too confrontational.

Given that most of the disreputable research historically was done by government agencies,<sup>88</sup> why expect them to be experts on research ethics? The manner of the government's collection of census data suggests the double standard for government research still continues. For example, census surveys are not anonymous, lack informed consent, are coercive (for the vulnerable and the capable alike), have data that are deceptively linked to other unspecified databases, and so forth—not exactly the standards they expect of us. Further, the census bureau recently reported the loss of hundreds of laptop computers containing data;<sup>89</sup> we are assured that no harm will ensue, not quite the response a campus sociologist might expect for leaving a file cabinet unlocked. Given that the regulations come from federal agencies, they will have to be involved in any change, but at the moment they seem entirely concerned with adding regulations and exacting compliance. It is hard to be optimistic here, because federal agencies took a system that was working acceptably 30 years ago in the social-behavioral sciences and broke it, or allowed it to be broken, for no documented benefit. Admitting to a long-standing waste of time and money is no doubt hard even in federal politics.

One of the more recent and more interesting analyses of how the ethics industry has hampered inquiry on campus has been provided by Philip Hamburger.<sup>90</sup> If the IRB process could be found to be an unconstitutional constraint on freedom of speech and association, for example, that should provide the authority to compel meaningful revision of the present wasteful enterprise. I find his analysis convincing, in fact obvious in many ways, but I am not a constitutional expert nor a lawyer, and I have long been convinced that IRB activities involve agendas well beyond public safety. To the extent that such freedoms *may* be constrained if the constraints are shown to be sufficiently in the public interest, it seems clear to me that there never has been and still is not sufficient evidence of benefit offsetting the 30-year sacrifice, certainly not in the social sciences. I thoroughly enjoyed the discussion of this prospect at our Symposium, and I look forward to watching a court action succeed because, as noted above, I do not see the other agents being willing or able to confront the regulators sufficiently.

In sum, the costs of the research ethics industry are far more obvious than the claimed benefits to public safety, at least in the social and behavioral research sector. The censorship cannot be denied at this point in time, nor can it be justified by any tradeoff involving public safety. Researchers are far more the victims of meaningless regulations than the cause of dan-

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<sup>88</sup> See O'Brien, *supra* note 9, at 24–26.

<sup>89</sup> See, e.g., Douglass K. Daniel, *Census Bureau Loses Hundreds of Laptops*, AP NEWS MYWAY, Sept. 22, 2006, <http://apnews.myway.com/article/20060922/D8K9RCB80.html>.

<sup>90</sup> See Hamburger, *supra* note 6, at 306 n.92.

gerous research. If we, as researchers, can accept that reorientation, we may have taken a small but very necessary first step toward other reforms.