

## INSTITUTIONAL REVIEW BOARDS: IS THIS THE LEAST WORST WE CAN DO?

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### INTRODUCTION

Institutional Review Boards (“IRBs”) are polarizing institutions. IRB supporters view them as the best thing since sliced bread. Detractors believe IRBs impose costs and have no benefits. Supporters point to the good faith and hard work of those who volunteer to serve on an IRB. Detractors suggest that IRBs emphasize bureaucratic busy-work. Supporters ask for more money and more staff so they can do an even more thorough job reviewing research protocols. Detractors point out that the IRB framework of research oversight would never be approved by an IRB. Supporters counter that notorious examples of abuse show that IRBs are necessary. Detractors respond with anecdotes of IRB stupidity and incompetence. Supporters argue that conducting research is a privilege, not a right. Detractors complain about censorship, restrictions on academic freedom, and the chilling of constitutionally protected free speech. Both sides then return to their respective camps, secure in the knowledge that they are right and those on the other side are self-righteous zealots.

The controversy over IRBs arises from differing preferences, methodological commitments, and risk tolerances. Both sides believe fundamental principles (academic freedom—censorship versus the protection of vulnerable human subjects) are at stake, so the dispute is not readily subject to compromise.<sup>1</sup> Even King Solomon would find it difficult to solve the controversy in a way that makes everyone happy—and the original Solomonic strategy (cutting the director of each IRB in half) seems unlikely to do the job. This article offers some perspective on the dispute, and some modest strategies for improving on the status quo.

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<sup>1</sup> David A. Hyman, *Does Technology Spell Trouble With a Capital “T”? Human Dignity and Public Policy*, 27 *HARV. J.L. & PUB. POL’Y* 3, 17 (2003–2004) (“[O]nce both sides have claimed that human dignity is at stake, even a modest dispute on a minor issue is converted into a super-charged normative battle.”).

Part I provides an abbreviated background on the regulatory backdrop. Part II offers a simple theoretical framework for analyzing the issues raised by research oversight. Part III reviews what we know about IRB performance. Part IV assesses how we ended up in this situation. Part V considers whether judicial oversight of IRBs can improve matters. Part VI provides a comparative institutional perspective on the problem and suggests some modest reforms.

## I. IRB OVERVIEW

Federal regulations require all research funded by the federal government and involving human subjects to be overseen by an IRB.<sup>2</sup> These regulations are rooted in the work of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, which was created in response to several well-publicized biomedical research scandals.<sup>3</sup>

“Research” is defined by the regulations as “a systematic investigation . . . designed to develop or contribute to generalizable knowledge.”<sup>4</sup> A human subject in turn is “a living individual about whom an investigator (whether professional or student) conducting research obtains data through intervention or interaction with the individual or identifiable private information.”<sup>5</sup>

Each IRB must be composed of at least five members, including men and women, who should have diverse cultural and racial backgrounds.<sup>6</sup> At least one member of the IRB should have scientific expertise, while at least

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<sup>2</sup> 45 C.F.R. § 46.101 (2005). Strictly speaking, the regulations cover research that is “conducted, supported or otherwise subject to regulation by any federal department or agency which takes appropriate administrative action to make the policy applicable to such research.” *Id.* At present, fifteen federal departments/agencies/commissions have adopted the “Common Rule,” subjecting all research they conduct, support, or otherwise regulate to the IRB framework. A list of those agencies, and the enabling regulations, is found at HHS OFFICE FOR HUMAN RESEARCH PROTECTION, FEDERAL POLICY FOR THE PROTECTION OF HUMAN SUBJECTS, <http://www.hhs.gov/ohrp/policy/common.html> (last visited Nov. 8, 2006).

<sup>3</sup> Although there were classified regulations governing human experimentation issued by the Atomic Energy Commission and Department of Energy in the 1940s and 1950s, and the National Institutes of Health issued regulations on research involving human subjects in 1966, most scholars date the beginning of comprehensive federal regulation of human subjects research to 1974, when the regulation that ultimately gave rise to the Common Rule was issued. See Oral History of the Belmont Report and the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, Interview with Dr. Norman Fost, May 13, 2004, available at <http://www.hhs.gov/ohrp/docs/InterviewFost.doc>. See also NAT’L COMM’N FOR THE PROT. OF HUMAN SUBJECTS OF BIOMEDICAL AND BEHAVIORAL RESEARCH, THE BELMONT REPORT: ETHICAL PRINCIPLES AND GUIDELINES FOR THE PROTECTION OF HUMAN SUBJECTS OF RESEARCH (1979), available at <http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.htm>.

<sup>4</sup> 45 C.F.R. § 46.102(d) (2005).

<sup>5</sup> 45 C.F.R. § 46.102(f) (2005).

<sup>6</sup> 45 C.F.R. § 46.107 (2005).

one individual must be a nonscientist.<sup>7</sup> Each IRB must have at least one member who is not otherwise affiliated with the research facility and has no immediate family members who are so affiliated.<sup>8</sup>

IRBs have the authority to approve, require modification of, or disapprove research, both in its initial determination and as part of mandatory continuing (at least yearly) review.<sup>9</sup> In determining whether to approve a study, an IRB is required to evaluate whether the risks to subjects are minimized; whether those risks are reasonable in light of expected benefits; and whether subjects are selected in an equitable manner, with due concern for the particularized risks of conducting research in vulnerable populations.<sup>10</sup> For research that involves multiple institutions, an institution that obtains the appropriate approvals can “enter into a joint review arrangement, rely upon the review of another qualified IRB, or make similar arrangements for avoiding duplication of effort.”<sup>11</sup>

IRBs are also responsible for ensuring that informed consent is obtained from study participants.<sup>12</sup> The regulations specify a wide range of information that must be provided to study participants, including a statement that the study involves research, and a description of the procedures, expected duration, and reasonably foreseeable risks to the subject.<sup>13</sup> An IRB may approve an abbreviated consent procedure or waive consent entirely under limited circumstances.<sup>14</sup>

The IRB can conduct an expedited review in instances where there is minimal risk from the research. Minimal risk means that “the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.”<sup>15</sup> However, even expedited review can impose a delay of several weeks, and IRBs can always require full-blown IRB approval if they have any concerns about the research.

There are six categories of research exempt from IRB review, although many IRBs insist on reviewing exempt research protocols to confirm that they are exempt.<sup>16</sup> These exemptions are also quite limited, and several im-

<sup>7</sup> *Id.*

<sup>8</sup> *Id.*

<sup>9</sup> 45 C.F.R. § 46.109 (2005).

<sup>10</sup> 45 C.F.R. § 46.111 (2005).

<sup>11</sup> 45 C.F.R. § 46.114 (2005).

<sup>12</sup> 45 C.F.R. § 46.109 (2005).

<sup>13</sup> 45 C.F.R. § 46.116(a) (2005).

<sup>14</sup> 45 C.F.R. § 46.109 (2005).

<sup>15</sup> 45 C.F.R. § 46.102(i) (2005).

<sup>16</sup> 45 C.F.R. § 46.101(b) (2005); Mark A. Hall & Ronald F. Wright, Empirical Legal Studies Blog, FAQs re. Legal Scholarship and IRBs, [http://www.elsblog.org/the\\_empirical\\_legal\\_studi/irb.html](http://www.elsblog.org/the_empirical_legal_studi/irb.html) (last visited Nov. 10, 2006) (“University IRB committees normally have an expansive view of the activities that fall within their jurisdiction. Your institution probably expects you to apply for and receive verifi-

pose restrictive confidentiality requirements.<sup>17</sup> For example, one provision broadly exempts “survey procedures, interview procedures, or observation of public behavior,” unless

- (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects’ responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects’ financial standing, employability, or reputation.<sup>18</sup>

IRBs have interpreted this limitation quite expansively—meaning that the exemption has been quite narrow in practice.<sup>19</sup>

Finally, although the IRB regulations technically apply only to research funded by the federal government, institutions that receive such funds must provide assurance that they will protect the rights and welfare of human subjects in all its research, whatever the source of funding.<sup>20</sup> This mismatch is non-trivial; for example, nearly 80% of all research projects reviewed by the University of Chicago’s Social Science IRB are either personally funded, privately funded, or unfunded.<sup>21</sup> Many academic institutions have declined to commit themselves to using the Common Rule framework for reviewing non-federally funded research, but nonetheless seem to have adopted the IRB framework to review such research.<sup>22</sup>

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ation that an exemption applies, especially in debatable situations.”); posting of Mark A. Hall to Empirical Legal Studies Blog, Confessions of an Undocumented Human Subjects Researcher, [http://www.elsblog.org/the\\_empirical\\_legal\\_studi/2006/03/confessions\\_of\\_\\_1.html](http://www.elsblog.org/the_empirical_legal_studi/2006/03/confessions_of__1.html) (Mar. 27, 2006, 10:34) (“[T]here are several bases to claim that interaction with, or data about, living humans in the course of legal scholarship is not a covered activity (not identifiable, not systematic, not private, etc.). Naturally, those concepts have room for interpretation. The hitch is that institutions expect researchers to notify the IRB so it can have the final say on whether the exclusionary concepts apply. But, that quickly leads to innumerable absurdities.”).

The six specific categories are “survey procedures, interview procedures, or observation of public behavior” (as long as certain restrictions are satisfied); research in “established or commonly accepted educational settings, involving normal educational practices;” research on people who are “elected or appointed public officials or candidates for public office;” research on materials that are publicly available; and research designed to assess “public benefit or service programs.” The full text describing each of these exemptions may be found at 45 C.F.R. § 46.101(b) (2005).

<sup>17</sup> 45 C.F.R. § 46.101(b) (2005).

<sup>18</sup> 45 C.F.R. § 46.101(b)(2) (2005).

<sup>19</sup> Judith Jarvis Thomson et al., *Research on Human Subjects: Academic Freedom and the Institutional Review Board*, ACADEME, Sept.–Oct. 2006, at 95.

<sup>20</sup> *Id.*

<sup>21</sup> Richard A. Schweder, *Protecting Human Subjects and Preserving Academic Freedom: Prospects at the University of Chicago*, 33 AM. ETHNOLOGIST 507, 507 (2006).

<sup>22</sup> Thomson et al., *supra* note 19, at 99 (noting that 164 academic institutions have not agreed to subject non-federally funded research to the Common Rule, but “our impression at the moment, however, is that many of those institutions continue in practice to impose the same requirements on non-federally funded research as on federally funded research—perhaps out of lack as yet of an agreed alternative . . .”).

## II. RESEARCH OVERSIGHT: BALANCING FALSE POSITIVES AGAINST FALSE NEGATIVES

IRBs exist to perform research oversight. As Table 1 reflects, any system of research oversight will generate four kinds of results: true positives (Cell 1), false positives (Cell 2), false negatives (Cell 3), and true negatives (Cell 4).<sup>23</sup>

*Table 1: A Typology of Research Oversight Outcomes*

Should Research Be Approved?	Was Research Approved?	
	Yes	No
Yes	(Cell 1) True Positive	(Cell 3) False Negative
No	(Cell 2) False Positive	(Cell 4) True Negative

True positives and true negatives occur, respectively, when research that should have been approved is approved, and research that should not have been approved is not approved. False positives and false negatives occur, again respectively, when research that should not have been approved is approved, and when research that should have been approved is not approved. True positives and true negatives are correct results. False positives and false negatives are mistakes.<sup>24</sup>

The goal for any system of research oversight is to maximize the number of true positives and negatives (cases in Cells 1 and 4), and minimize the number of false positives and false negatives (cases in Cells 2 and 3), and the costs of research oversight. These costs include the transaction costs of operating the system (e.g., researcher time spent filling out forms and answering questions, the salaries for staff hired to deal with IRB compliance, the salaries of IRB personnel, the time that is volunteered to review protocols), and the costs of erroneous decisions and delay.

No system of research oversight will ever operate perfectly, but different strategies impose different costs. A commitment to screen every protocol exhaustively lowers the frequency of false positives, but increases the frequency of false negatives—and delays research across the board. Conversely, a commitment to expeditious approval lowers the frequency of

<sup>23</sup> A false positive (Cell 2) is also commonly known as a Type I error. A false negative (Cell 3) is also commonly known as a Type II error.

<sup>24</sup> For these purposes, I treat a protocol that was approved in a modified form as a false negative if the original protocol was properly approvable. Treating such cases as true positives is appropriate only if the original protocol was not properly approvable—which is precisely what many researchers say is in issue in many cases.

false negatives and minimizes delay, but increases the frequency of false positives.

In principle, there is no reason to prefer false negatives to false positives, or vice-versa, as long as the harms are symmetrical. From this perspective, the goal is to minimize the joint sum of administrative and error costs, irrespective of the source of those costs. In practice, however, false positives are viewed as a much more serious problem than false negatives. False positives that result in adverse outcomes are highly salient—and hindsight bias encourages everyone involved to view (ex ante) close cases as (ex post) clear mistakes. Because false positives can result in lawsuits, adverse publicity, government action, and disciplinary proceedings, they are self-revealing examples of institutional failure.

False negatives are not subject to the same dynamic. The victims of a false negative decision are the researcher and those who might have been helped by the research. Researchers have little incentive to pick a fight with their IRB or draw public attention to the dispute since there is a significant opportunity cost in doing so—particularly when they will have to get approval from the IRB for their next project. Those who might have been helped by the research are a diffuse group of invisible victims, who may not even know about the research. Even when there is a vocal group of identifiable victims, there is no mechanism for appealing an adverse IRB decision.<sup>25</sup>

This asymmetry means that institutions have a strong incentive to drive their false positive rate down, without weighing the cost of the increased false negative rate and the delays and transaction costs of review. This dynamic is compounded by the litigation and political scandal-mongering that dogs these controversies.<sup>26</sup> A high-profile false positive decision will cause university administrators to put pressure on their IRBs to avoid such problems—and IRBs will respond by becoming even more gun-shy than they are to begin with. These problems are compounded by the externalization of many of the costs of research review.<sup>27</sup> The result is that there is no feedback loop with regard to the rate of false negatives and the costs of compliance—so both tend to increase without effective constraint. Stated more concretely, there is a one-way ratchet in favor of fewer false positives and more false negatives.

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<sup>25</sup> Thomson et al., *supra* note 19, at 96.

<sup>26</sup> See generally Michelle M. Mello, David M. Studdert & Troyenn Brennan, *The Rise in Litigation in Human Subjects Research*, 139 ANNALS INTERNAL MED. 40 (2003) (tracking trends in litigation over research-related injuries, including diversification of the types of legal claims, expansion in the number and types of parties named as defendants and use of class-action techniques); Robert Steinbrook, *Improving Protection for Research Subjects*, 346 NEW ENGL. J. MED. 1425 (2002) (reviewing how past tragedies have given rise to increased political and regulatory attention to research and research oversight).

<sup>27</sup> See *infra* Part III.B.

The problem is made worse by mismatched incentives. A decision-maker is much more likely to be fired or held up to public scorn for a false positive decision than a false negative decision.<sup>28</sup> A former FDA official provides a chilling example of the resulting incentives:

In the early 1980s, when I headed the team at the FDA that was reviewing the NDA for recombinant human insulin, . . . we were ready to recommend approval a mere four months after the application was submitted (at a time when the average time for NDA review was more than two and a half years). With quintessential bureaucratic reasoning, my supervisor refused to sign off on the approval—even though he agreed that the data provided compelling evidence of the drug’s safety and effectiveness. “If anything goes wrong,” he argued, “think how bad it will look that we approved the drug so quickly.”<sup>29</sup>

Stated differently, a false positive is costly to the IRB, but a false negative is costly to the individual researchers and those who would have benefited from the research. An IRB will accordingly have an incentive to drive down its false positive rate, and be (relatively) indifferent to its false negative rate, while researchers will tend to have the opposite incentives.

If these problems sound familiar, it is because they are. Decision-makers always confront a trade-off between false positives and false negatives in deciding whether to approve a drug; determine the criteria for obesity, high blood pressure, or elevated cholesterol; use a per se test for assessing whether conduct violates antitrust laws; prohibit airplane passengers from bringing liquids aboard planes; declassify (or classify) government documents; decide whom to prosecute (and for what); set the speed limit or the level of blood alcohol that constitutes DWI; and so on.

Too often, policy debates over the “best” rule for handling such problems rely on platitudes and anecdotes. Such rhetoric provides no help in determining the optimal trade-off between false positives and false negatives for any given problem.<sup>30</sup> Careful assessment of the costs and benefits

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<sup>28</sup> HENRY I. MILLER, *TO AMERICA’S HEALTH: A PROPOSAL TO REFORM THE FOOD AND DRUG ADMINISTRATION* 42–43 (2000) (noting that a false positive “mistake is highly visible and has immediate consequences—the media pounces, the public denounces, and Congress pronounces. Both the developers of the product and the regulators who allowed it to be marketed are excoriated and punished in modern-day pillories: congressional hearings, television news magazines, and newspaper editorials. Because a regulatory official’s career might be damaged irreparably by his good faith but mistaken approval of a high-profile product, decisions are often made defensively—in other words, to avoid [false positive] errors at any cost.”); see also posting of Ron Wright, Empirical Legal Studies Blog, *IRBs and Regulatory Theory*, [http://www.elsblog.org/the\\_empirical\\_legal\\_studi/2006/03/irb\\_and\\_regulat.html](http://www.elsblog.org/the_empirical_legal_studi/2006/03/irb_and_regulat.html) (Mar. 27, 2006, 14:07).

<sup>29</sup> MILLER, *supra* note 28, at 41.

<sup>30</sup> Michael J. Saks, *Do We Really Know Anything about the Behavior of the Tort Litigation System—And Why Not?*, 140 U. PA. L. REV. 1147, 1161 (1992) (“It makes a difference if for every ten anecdotes in which an undeserving plaintiff bankrupts an innocent defendant, one, ten, one hundred, or one thousand equal and opposite injustices are done to innocent plaintiffs. The proportion of cases that results in one or the other error, and the ratio of one kind of error to the other, ought to be of greater inter-

of different decision rules is much more likely to result in good public policy than any of the alternatives. Accordingly, Part III turns to what we know about IRB performance.

### III. WHAT DO WE ACTUALLY KNOW ABOUT THE PERFORMANCE OF IRBS?

#### A. Benefits

There is no empirical evidence that IRBs have any benefit whatsoever.<sup>31</sup>

#### B. Costs

There is a modest literature on direct IRB costs. One of the most comprehensive studies on the subject looked at the costs incurred by sixty-three academic medical centers with IRBs.<sup>32</sup> It found that annual operating costs ranged from \$171,000 to \$4.7 million, with a median cost of \$742,000.<sup>33</sup> There were considerable economies of scale, with cost per reviewed protocol of \$431 at high-volume institutions, and \$644 at low-volume institutions.<sup>34</sup> Expedited reviews were as expensive as full protocol review—most likely because of the high opportunity cost of having senior IRB personnel perform the expedited review.<sup>35</sup> Earlier studies found comparable economies of scale,<sup>36</sup> but smaller costs per reviewed protocol—most likely be-

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est to serious policy-makers than a handful of anecdotes on either side of the issue. Reforms are intended to change that ratio and the tens of thousands of anecdotes the ratio summarizes.”).

<sup>31</sup> That’s right. None. Nada. Zip. This is based on my exhaustive search for such evidence, using LexisNexis and Westlaw, as well as my own inquiries to leading scholars. But why take my word for it? Go look for yourself. I’ll pay \$25 to the first person who finds anything in print (as of December 14, 2006) providing empirical evidence that IRBs have any benefit whatsoever.

One could reasonably draw an adverse inference from the absence of evidence indicating IRBs have any benefit. See GEORGE J. STIGLER, *THE THEORY OF PRICE* 24 (3d ed. 1987) (“How can we convince a skeptic that this ‘law of demand’ is really true of all consumers, all times, all commodities? . . . Perhaps as persuasive a proof as is readily summarized is this: if an economist were to demonstrate its failure in a particular market at a particular time, he would be assured of immortality, professionally speaking, and rapid promotion. Since most economists would not dislike either reward, we may assume that the total absence of exceptions is not from lack of trying to find them.”).

<sup>32</sup> Jeremy Sugarman et al., *The Cost of Institutional Review Boards in Academic Medical Centers*, 352 *NEW ENG. J. MED.* 1825 (2005).

<sup>33</sup> *Id.*

<sup>34</sup> *Id.*

<sup>35</sup> *Id.*

<sup>36</sup> Todd Wagner et al., *Economies of Scale in Institutional Review Boards*, 42 *MED. CARE* 817 (2004).

cause they did not include the opportunity cost of the time of those who volunteer to serve on an IRB in making their calculations.<sup>37</sup>

Two studies have examined the costs of obtaining IRB approval in multi-center studies.<sup>38</sup> One analysis involved an observational study of forty-three U.S. Department of Veterans Affairs primary care clinics.<sup>39</sup> Approximately 4700 hours of staff time over a nineteen-month period were devoted solely to the IRB process, with the time required to obtain approval varying from 52 to 798 days, with a median of 268 days.<sup>40</sup> The second study concluded that seventeen percent of the total research budget in a multi-center study was spent obtaining approval from seven additional IRBs after the “home” IRB had approved the protocol—a process that took nearly eighteen months to complete.<sup>41</sup>

### C. Output Variability and Inefficiency

Several studies have documented considerable variability, inefficiency, and uneven protection of study participants in multi-center studies, where the same protocol is reviewed by multiple IRBs.<sup>42</sup> In one such study, different IRBs used different standards to review the research protocol; although the study was designed to qualify for expedited review, one site exempted it from review, thirty-one required full review, and one rejected it outright.<sup>43</sup> Twelve sites requested (and two insisted) on provisions that increased the risks to study participants.<sup>44</sup> The IRBs were fixated on paperwork, and required researchers to submit multiple revisions of applications, consent documents, and ancillary forms—even though most revisions involved minor non-substantive editorial changes to the wording of the con-

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<sup>37</sup> See J.H.U. Brown, Lawrence S. Schoenfeld & Patricia W. Allan, *The Costs of an Institutional Review Board*, 54 J. MED. EDU. 294 (1979); Todd Wagner et al., *The Cost of Operating Institutional Review Boards (IRBs)*, 78 ACAD. MED. 638 (2003).

<sup>38</sup> See Lee A. Green et al., *Impact of Institutional Review Board Practice Variation on Observational Health Services Research*, 41 HEALTH SERVICES RES. 214 (2006); Keith Humphreys et al., *The Cost of Institutional Review Board Procedures in Multicenter Observational Research*, 139 ANNALS INTERNAL MED. 77 (2003).

<sup>39</sup> Green et al., *supra* note 38, at 219–20.

<sup>40</sup> *Id.*

<sup>41</sup> Humphreys et al., *supra* note 38, at 77; Michelle L. Brandt, *IRB Burden Studied in Cost Analysis*, STAN. REP., Aug. 6, 2003, <http://news-service.stanford.edu/news/2003/august6/humphreys.html>.

<sup>42</sup> See William Burman et al., *The Effects of Local Review on Informed Consent Documents from a Multicenter Clinical Trials Consortium*, 24 CONTROLLED CLINICAL TRIALS 245 (2003); Green et al., *supra* note 38, at 219–20; Jon Mark Hirshon et al., *Variability in Institutional Review Board Assessment of Minimal-Risk Research*, 9 ACAD. EMERG. MED. 1417 (2002); Rita McWilliams et al., *Problematic Variation in Local Institutional Review of a Multicenter Genetic Epidemiology Study*, 290 J. AM. MED. ASS'N 360 (2003); Thomas O. Stair et al., *Variation in Institutional Review Board Responses to a Standard Protocol for a Multicenter Clinical Trial*, 8 ACAD. EMERG. MED. 636 (2001).

<sup>43</sup> Green et al., *supra* note 38, at 214.

<sup>44</sup> *Id.* at 223.

sent document.<sup>45</sup> The authors dryly concluded that “several features of the IRB system as currently configured impose costly burdens of administrative activity and delay . . . and paradoxically decrease protection of human subjects.”<sup>46</sup>

In another study, the IRBs demanded many changes in the formatting and wording of the consent and survey forms, and each change demanded by one IRB had to be approved by all the others.<sup>47</sup> The researchers in this study asserted that by the end of the process, no substantial change had been made in the protocol, and the changes demanded had no discernible impact on the protection of human subjects.<sup>48</sup> Instead, there were “changes as trivial as saying ‘study description’ rather than ‘description of study,’ . . . [and they] ‘spent thousands of dollars doing things like changing the font from Helvetica to Times New Roman and making sure the border of the forms were the right color.’”<sup>49</sup> Other researchers have similarly noted that IRBs seem to spend most of their time tinkering with consent forms—generally making them longer, less readable, and introducing errors and delay.<sup>50</sup> Similar criticisms have been made by the Institute of Medicine and the National Bioethics Advisory Commission.<sup>51</sup>

These problems are not limited to multi-center studies. A survey of IRB chairpersons also found wide variation in the application of risk and benefit categories for pediatric research, with some of the determinations at odds with the IRB enabling regulations and with the available data on risks.<sup>52</sup> Finally, one study submitted three flawed biomedical research protocols to thirty-two IRBs at major universities.<sup>53</sup> Twenty-two IRBs participated in the study. The study found that IRBs gave inconsistent reasons to justify similar decisions, and there was substantial inconsistency “in the application of ethical, methodological, and informed-consent standards.”<sup>54</sup> The authors noted that “our evidence supports the conclusion that IRBs approve inappropriate investigations and inhibit appropriate investigations. Deficient protocols may be modified, but only the most glaring problems

<sup>45</sup> *Id.* at 221–22. The authors ascribed this dynamic to the “irresistibility of editing.” *Id.* at 225.

<sup>46</sup> *Id.* at 215.

<sup>47</sup> Humphreys et al., *supra* note 38, at 77.

<sup>48</sup> *Id.*

<sup>49</sup> Brandt, *supra* note 41.

<sup>50</sup> See Burman et al., *supra* note 42, at 248–49.

<sup>51</sup> REPORT AND RECOMMENDATION OF THE NATIONAL BIOETHICS ADVISORY COMM’N, ETHICAL AND POLICY ISSUES IN RESEARCH INVOLVING HUMAN SUBJECTS (2001); INSTITUTE OF MEDICINE, RESPONSIBLE RESEARCH: A SYSTEMS APPROACH TO PROTECTING RESEARCH PARTICIPANTS (2002).

<sup>52</sup> Seema Shah et al., *How Do Institutional Review Boards Apply the Federal Risk and Benefit Standards for Pediatric Research*, 291 J. AM. MED. ASS’N 476, 478 (2004).

<sup>53</sup> Jerry Goldman & Martin D. Katz, *Inconsistency and Institutional Review Boards*, 248 J. AM. MED. ASS’N 197 (1982). The study was criticized in Robert J. Levine, *Inconsistency and IRBs: Flaws in the Goldman-Katz Study*, 6 IRB 4 (1984).

<sup>54</sup> Goldman & Katz, *supra* note 53, at 197.

are identified.”<sup>55</sup> A separate description of the study by one of the authors was more cutting: “We submitted three flawed medical protocols with the expectations that the review boards would find the flaws evident in the proposals. But the boards, on the whole, did not find the flaws. Rather, they suggested changes that would, if approved, [have] made bad research projects worse.”<sup>56</sup>

To summarize, there is a fairly substantial body of research indicating that IRBs operate inconsistently and inefficiently and focus considerable attention on the submitted paperwork.

#### D. Complaints and Risks

There are a host of more generic complaints about IRBs, including delay, increased costs, and useless paperwork.<sup>57</sup> There have also been complaints about IRBs discouraging research in particular areas and harassing individual researchers.<sup>58</sup> Sometimes this process is triggered by pressure from third parties, while other times it is instigated by university administrators or IRB members.<sup>59</sup>

Scholars in the social sciences and humanities have been particularly vocal about their concern that the IRB model, which was designed to review biomedical research, does not “fit” their research methodologies.<sup>60</sup>

<sup>55</sup> *Id.* at 202.

<sup>56</sup> Jerry Goldman, Current Publications: Revisiting the Problem of Inconsistency and IRB Review, <http://www.oyez.org/goldman/currentpubs> (2004) (website no longer available and on file with author).

<sup>57</sup> See, e.g., Scott Burris & Kathryn Moss, *U.S. Health Researchers Review Their Ethics Review Boards: A Qualitative Study*, 1 J. EMPIRICAL RES. HUMAN RES. ETHICS 39 (2006). These problems are not unique to the United States. See William J. Burman et al., *Breaking the Camel's Back: Multicenter Clinical Trials and Local Institutional Review Boards*, 134 ANNALS INTERNAL MED. 152, 154 (2001) (“A questionnaire-based study of the effect of birth weight on child development required submission of 1095 copies of the protocol, 1116 forms, and additional supporting documents to 145 IRBs in the United Kingdom. Responses to this remarkably duplicative process varied greatly, including diametrically opposed mandates, and 22% of the IRBs had not responded within 3 months.”).

<sup>58</sup> See Jack Katz, *Ethical Escape Routes for Underground Ethnographers*, 33 AM. ETHNOLOGIST 499 (2006); Cary Nelson, *Can E.T. Phone Home? The Brave New World of University Surveillance*, ACADEME, Sept.–Oct. 2003, at 89, 90 (describing “insane review” by University of Illinois IRB of an essay in “creative nonfiction” and insistence of same IRB that undergraduates interviewing family members obtain signed consent forms); posting of Mark Hall to Empirical Legal Studies Blog, [http://www.elsblog.org/the\\_empirical\\_legal\\_studi/2006/03/coping\\_with\\_the.html](http://www.elsblog.org/the_empirical_legal_studi/2006/03/coping_with_the.html) (Mar. 31, 2006, 15:05); Christopher Shea, *Don't Talk to the Humans*, LINGUA FRANCA, Sept. 2000, at 27 (presenting litany of horror and woe); J. Michael Bailey, *Academic McCarthyism*, NW. CHRON., Oct. 9, 2005, available at <http://www.chron.org/tools/viewart.php?artid=1248>; Sharon Begley, *Review Boards Pose Threat To Social Scientists' Work*, WALL ST. J., Nov. 1, 2002, at B1; Carol Tavris, *The High Cost of Skepticism: Here's What Happened to Two Scientists who Believed that Tenure and the First Amendment Would Protect their Rights to Free Inquiry*, SKEPTICAL INQUIRER, Jul.–Aug. 2002, available at <http://www.csicop.org/si/2002-07/high-cost.html>.

<sup>59</sup> See *supra* note 58 and accompanying text.

<sup>60</sup> See Nelson, *supra* note 58 (“[T]he boards assembled to supervise biomedical research often haven't a clue about the culture of history or anthropology or literature departments.”); Jonathan T. Church et al., *Should All Disciplines Be Subject to the Common Rule: Human Subjects of Social Science Re-*

Law professors have started to pay attention to these issues as well.<sup>61</sup> There is no question that nonsensical results can follow from the unfortunate combination of good intentions, risk averse lawyers, and bungling bureaucrats. Consider a few of the more egregious examples from a recent AAUP report on the subject:

A linguist seeking to study language development in a pre-literate tribe was instructed by the IRB to have the subjects read and sign a consent form before the study could proceed.

A political scientist who had bought a list of appropriate names for a survey of voting behavior was required by the IRB to get written informed consent from the subjects before mailing them the survey.

A Caucasian Ph.D. student, seeking to study career expectations in relation to ethnicity, was told by the IRB that African-American Ph.D. students could not be interviewed because it might be traumatic for them to be interviewed by the student.

An experimental economist seeking to do a study of betting choices in college seniors was held up for many months while the IRB considered and reconsidered the risks inherent in the study.

An IRB attempted to block publication of an English professor's essay that drew on anecdotal information provided by students about their personal experiences with violence because the students, though not identified by name in the essay, might be distressed by reading the essay.

A campus IRB attempted to deny an M.A. student her diploma because she did not obtain IRB approval for calling newspaper executives to ask for copies of printed material generally available to the public.<sup>62</sup>

These incidents are ripe for caricature, but they help inform perceptions about the value (or lack thereof) added by IRBs. Academics who practice

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search, *ACADEME*, May–June 2002, at 62; J. Michael Oakes, *Risks and Wrongs in Social Science Research: An Evaluator's Guide to the IRB*, 26 *EVALUATION REV.* 443, 447–50 (2002); Posting of Jack Katz to Empirical Legal Studies Blog, [http://www.elsblog.org/the\\_empirical\\_legal\\_studi/2006/03/outside\\_of\\_biom.html](http://www.elsblog.org/the_empirical_legal_studi/2006/03/outside_of_biom.html) (Mar. 28, 2006, 19:25); Posting to Savage Minds, Notes and Queries in Anthropology, <http://savage minds.org/2006/02/08/ethnography-and-the-irb> (Feb. 8, 2006, 21:17).

<sup>61</sup> See Posting of Jason Czarnecki to Empirical Legal Studies Blog, [http://www.elsblog.org/the\\_empirical\\_legal\\_studi/2006/02/working\\_with\\_ir.html](http://www.elsblog.org/the_empirical_legal_studi/2006/02/working_with_ir.html) (Feb. 21, 2005, 10:23); posting of Dan Filler to Concurring Opinions, [http://www.concurringopinions.com/archives/2006/05/volokhs\\_law\\_rev.html](http://www.concurringopinions.com/archives/2006/05/volokhs_law_rev.html) (May 10, 2006); Hall & Wright, *supra* note 16; posting of Mike Madison to madisionian.net, <http://madisionian.net/archives/2006/03/23/irbs-ethnography-and-blogging> (Mar. 23, 2006, 13:12).

<sup>62</sup> Thomson et al., *supra* note 19, at 96. The first four of these examples are drawn from Joan E. Sieber, Stuart Plattner & Philip Rubin, *How (Not) to Regulate Social and Behavioral Research*, 15 *PROF. ETHICS REP.* 1 (2002).

oral history, ethnography, and journalism have been particularly vehement about the risks IRBs pose to their respective disciplines.<sup>63</sup>

### *E. Workload*

Concerns have been expressed about the adequacy of IRB funding and their heavy workload.<sup>64</sup> The largest IRBs review thousands of protocols per year, along with hundreds of reports of adverse events.<sup>65</sup> At Johns Hopkins University, until June of 2001, a single IRB, meeting once every two weeks, was responsible for the approval of 800 new protocols annually and the ongoing monitoring they generated.<sup>66</sup>

Some of these workload problems appear to be the result of “mission creep,” as IRBs assume (or are given) responsibility for more things.<sup>67</sup> Consider the fact that many IRBs review research that is exempt from IRB review to determine whether it is, in fact, exempt.<sup>68</sup> At many institutions, IRBs have also been given responsibility for assessing compliance with HIPAA.<sup>69</sup> As noted above, individualized review by the IRB at each site of

<sup>63</sup> See, e.g., Katz, *supra* note 58; Shea, *supra* note 58; Nelson, *supra* note 58; Begley, *supra* note 58; Church et al., *supra* note 60.

<sup>64</sup> Sharona Hoffman & Jessica Wilen Berg, *The Suitability of IRB Liability*, 67 U. PITT. L. REV. 365, 374–75 (2005). See also INSTITUTE OF MEDICINE, RESPONSIBLE RESEARCH: A SYSTEMS APPROACH TO PROTECTING RESEARCH PARTICIPANTS (2002); JUNE GIBBS BROWN, DEP’T. OF HEALTH AND HUMAN SERVICES, INSTITUTIONAL REVIEW BOARDS: A TIME FOR REFORM (1998) (DHHS publication no. OEI-01-97-00193); Donald F. Phillips, *Institutional Review Boards Under Stress: Will They Explode or Change?*, 276 J. AM. MED. ASS’N 1623, 1623 (1996) (noting that IRBs “find themselves under pressure from mounds of paperwork, regulatory fire from the federal bureaucracy, and economic constraints from the institutions they serve” and that “[n]ever before has such a pressure cooker atmosphere prevailed within the IRB system, leading government officials, university administrators, research sponsors, and IRB members to wonder whether the IRB system will crack or reform”).

<sup>65</sup> Hoffman & Berg, *supra* note 64, at 374.

<sup>66</sup> Robert Steinbrook, *Protecting Research Subject—The Crisis at Johns Hopkins*, 346 NEW ENG. J. MED. 716, 719 (2002).

<sup>67</sup> See CENTER FOR ADVANCED STUDY, IMPROVING THE SYSTEM FOR PROTECTING HUMAN SUBJECTS: COUNTERACTING IRB “MISSION CREEP” (2005) [hereinafter Illinois White Paper]; C.K. Gunsalus et al., *Mission Creep in the IRB World*, 312 SCIENCE 1441 (2006). One example of mission creep that has not attracted much attention is the penetration of IRBs into high schools, middle schools, elementary schools and kindergartens. Science fairs that are sanctioned by a national coordinating agency (Science Service) must set up a scientific review committee and an IRB to review all research protocols. Science Service, <http://www.sciserv.org/dcysc/Fairs/FAIRLIST.ASP> (last visited Nov. 29, 2006). This is not a law school hypothetical—one science fair for students in grades K–5 designated a university IRB that would handle their research oversight. Guidelines for the Clarksville–Montgomery County Schools Science Fair Grades K–5, <http://www.apsu.edu/robertsonr/sciencefair/2006%20COMPLETE%20SCIENCE%20FAIR%20MANUAL.doc> (last visited Nov. 29, 2006).

<sup>68</sup> See *supra* note 16 and accompanying text.

<sup>69</sup> See Burris & Moss, *supra* note 57 and accompanying text. HIPAA is the Health Insurance Portability and Accountability Act.

a multi-center study results in an obvious duplication of effort, and increase in the aggregate IRB workload.<sup>70</sup>

#### F. Summary

The available evidence indicates that there are substantial direct and indirect costs associated with IRB oversight of research. IRBs also operate inconsistently and inefficiently, and focus their attention on paperwork and bureaucratic compliance. Despite their prevalence, there is *no* empirical evidence IRB oversight has any benefit whatsoever—let alone benefit that exceeds the cost.

#### IV. WHY DOES RESEARCH OVERSIGHT LOOK THE WAY IT DOES?

How did we end up with thousands of IRBs, each busily reviewing protocols, and giving rise to considerable dissatisfaction among those they regulate? Understanding the development of the current state of affairs requires separate examination of the supply and demand sides of the dynamic.

On the supply side, the spread of IRBs is a typical example of how bureaucracies behave. The Common Rule represents the attempt of one bureaucracy (agencies within the federal government) to influence the behavior of another bureaucracy (academic medical centers and universities). The federal government leveraged the receipt of federal dollars into a requirement that these institutions create a new bureaucracy (IRBs) that would perform research oversight.

Once IRBs were created, they channeled and regularized the mandated demand for their services by requiring researchers to fill out forms that the IRBs could then review. The use of forms as the locus for decision-making resulted in a check-the-box mentality among IRB personnel, where the substantive content of the research was less important than the forms that had been submitted. The fixation on forms also encouraged IRB personnel to become obsessed with the language and formatting of consent forms.<sup>71</sup> These tendencies are worsened by the fact that evaluation of IRB performance is based on whether all forms and paperwork were filled out correctly, and whether IRB decisions were properly documented.<sup>72</sup>

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<sup>70</sup> In all fairness, such duplication is unnecessary to satisfy IRB regulations. *See supra* note 11 and accompanying text. It is a question for another day why institutions are willing to incur such duplicative expenditures, but the effect is the creation of institution-specific monopolies on research oversight. *See infra* notes 116–17 and accompanying text.

<sup>71</sup> *See* Burris & Moss, *supra* note 57, at 43–52; Gunsalus et al., *supra* note 67, at 1441.

<sup>72</sup> *See* Illinois White Paper, *supra* note 67, at 7 (“[T]he most frequently cited lapses in IRB audits by the two main federal oversight agencies, OHRP and FDA, are ‘poor or missing Standard Operating Procedures’ (28%) and ‘poor minute-keeping’ (21%), together accounting for about half the citations. Quorum failures account for an additional 13%. Thus, most citations have to do with internal IRB processes and are relatively trivial, not directly related to actual research protocols.”); Gunsalus, *supra* note 67, at 1441; Fost, *supra* note 3, at 15 (“OHRP, when it began shutting down places at Duke and subsequent medical centers some years ago, understandably, when they visited an institution, looked at everything.

Consider what happened after the death of a healthy young research subject at Johns Hopkins University. The review by the two federal agencies with responsibility for IRB oversight focused on the failure of the IRB to maintain adequate minutes, and the fact that Hopkins' reliance on executive subcommittees meant that "most protocols are neither individually presented nor discussed at a convened meeting of any IRB."<sup>73</sup> From a bureaucratic perspective, this approach makes perfect sense. Matters of form are readily verifiable and objective, while the actual substance of IRB review is not. The nexus of these matters with the actual issue at stake (the death of an otherwise healthy research subject) was quite another matter. No time was spent considering whether better minutes and less use of executive subcommittees would have made the slightest difference in the tragic outcome. However, this emphasis on things that could be readily measured (form completion, minutes, and use of subcommittees) instead of things that could not be readily measured (the ethical issues at stake in a research protocol) is typical of bureaucracies.<sup>74</sup>

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So they would find things like failure to document quorum requirements, and established a principle that goes beyond Robert's Rules. That is what all IRBs had been using, prior to that, was Robert's Rules, which was—you establish a quorum at the beginning of a meeting, and if it's not challenged, it's presumed to exist throughout the meeting. OHRP felt that was not sufficient; that a quorum needed to be proven for every one of a hundred action items. So IRBs now, as a result of that, have to record the actual vote and document the existence of a quorum. Well, that requires an enormous amount of paperwork. Our minutes are 150 single-spaced pages for a two-hour meeting, because of the need to document that and many things like that.”)

To be sure, the problem is not limited to the enforcement agencies; accrediting agencies have their own mishegoss:

When the accreditation agencies came along, one of them . . . looked at our minutes about documenting the quorum, and noted that it didn't say whether the non-scientific member of the IRB was in the room at the time, because it didn't have the names of the members. And since there's a requirement that IRBs have a non-scientific member, if he or she's not in the room, then you don't have a duly constituted IRB. The result of that—at Johns Hopkins, to take one place that I'm familiar with—was they began passing a clipboard around the room for each protocol, and got the signatures of all 24 people in the room, for a hundred action items. So, for one meeting, they had 2,400 signatures to document that the non-scientific member and the other appropriate members were in the room. Now, has there ever in the history of the world been a research protocol that was approved, that shouldn't have been approved, because the non-scientific member was out of the room at the time? I don't think so. Does this improve protection of human subjects? No. Does it require an enormous infrastructure, and storage, and so on? And that's just one of many examples. But that's an example of an accreditation agency going beyond where OHRP had gone and, in my view, OHRP had gone already too far in terms of cost-benefit ratio of these sorts of compliance things.

*Id.*

<sup>73</sup> Steinbrook, *supra* note 66, at 719.

<sup>74</sup> See Nelson Lund, *The Conservative Case Against Racial Profiling in the War on Terror*, 66 ALB. L. REV. 329, 337–38 (2002–03) (noting “natural tendencies of government bureaucracies to use easily administered rules, and to transform means into ends. . . . Government agencies are ordinarily very good at applying simple rules, but they are often very bad at using common sense, or taking appropriate risks, or adjusting their rules to take account of changing circumstances.”).

Bureaucracies also tend to expand to capture all available resources and regulatory space.<sup>75</sup> This tendency explains why IRBs ended up being the focal point for research oversight of non-federally funded research, and why many IRBs insist on reviewing exempt research to determine whether it is, in fact, exempt. Thus, the creation of a system for research oversight created a demand for more oversight—with associated mission creep.<sup>76</sup>

The scandal-based origins of the Common Rule also affected the nature and direction of the enabling regulations. The Common Rule focuses exclusively on the protection of human subjects and gives no weight whatsoever to the academic freedom of researchers or to the social costs from research that is delayed, constrained, or not performed at all.<sup>77</sup>

Because bureaucracies are risk averse, the threat that someone somewhere might sue for something encouraged IRBs to lawyerize the research oversight process.<sup>78</sup> This dynamic furthered the fixation of IRBs on increasingly detailed consent forms and the protection of study participants against increasingly remote and trivial risks—as well as consideration of the purported interests of third parties, and the adoption of politically correct attitudes towards proposed research.<sup>79</sup>

Finally, each institution's IRB has an effective monopoly on research oversight at that institution—meaning there is no competitive constraint on

<sup>75</sup> C. NORTHCOTE PARKINSON, *PARKINSON'S LAW, AND OTHER STUDIES IN ADMINISTRATION* 1 (1957).

<sup>76</sup> Health care compliance programs have been marked by a similar dynamic. See David A. Hyman, *Health Care Fraud and Abuse: Market Change, Social Norms, and "The Trust Reposed in the Workmen,"* 30 J. LEGAL STUD. 531, 559–60 (2001) ("The government encourages providers to invest in compliance programs directly (by effectively requiring providers to have such programs) and indirectly (by announcing high-profile antifraud initiatives). Once these programs are in place, compliance officers will predictably lobby for additional resources and remind supervisors of the threat of severe governmental sanctions to ensure that their wish list is taken seriously. External consultants offer increasingly elaborate educational programs, audits, and monitoring systems and emphasize the risks the institution is taking if it does not make these investments.").

<sup>77</sup> Thomson et al., *supra* note 19, at 99.

<sup>78</sup> See C.K. Gunsalus, *The Nanny State Meets the Inner Lawyer: Overregulating While Underprotecting Human Participants in Research*, 14 ETHICS & BEHAV. 369, 372 (2004) ("How many IRB meetings have gone from the imagined possibilities of what might go wrong to devising protections against those possibilities. . . . In how many of those meetings have members imagined that 'the lawyers' might require such protections or that people 'might get sued' if the protections were not in place."). Ironically, the existence of IRBs has given those inclined to sue an additional set of defendants and new causes of action. See Hoffman & Berg, *supra* note 64, at 381–95.

<sup>79</sup> Stephen J. Ceci, Douglas Peters & Jonathan Plotkin, *Human Subjects Review, Personal Values, and the Regulation of Social Science Research*, 40 AM. PSYCH. 994, 999 (1985) (noting political skew to IRB approval process, with hypothetical studies involving "sensitive" topics rejected as often as proposals with serious ethical problems for studying non-sensitive topics.). Indeed, "the primary reason for rejection of sensitive proposals was the potential political impact of the proposed findings." *Id.* at 994.

Those who have doubts as to whether involving lawyers in the process might have these effects should ponder how things played out with product warning labels. See JOEY GREEN, TONY DIERCKINS & TIM NYBERG, *THE WARNING LABEL BOOK* (1998).

inefficiency, incompetence, political correctness, and other forms of opportunistic IRB behavior.<sup>80</sup>

On the demand side, there were few natural constraints on IRB expansion, since researchers had little incentive to make a fuss—particularly when doing so marked one as a trouble-maker the next time through the process. Time spent disputing with the IRB was also time not spent on research.

These supply- and demand-side considerations reinforce one another, and result in the dysfunctional state of affairs that we find ourselves in today.

## V. JUDICIAL OVERSIGHT OF IRBS

As noted previously, multiple lawsuits have been filed in recent years against IRBs.<sup>81</sup> What happens when judges are invited to second-guess the research oversight process? Most of the lawsuits have not resulted in legal opinions, so it is hard to know how judicial oversight will ultimately play out—but, if one high-profile example of such litigation is any indication, judicial self-righteousness (if not out-and-out stupidity/incompetence) will create problems in handling such cases. In *Grimes v. Kennedy Krieger*, the highest state court in Maryland vented its collective spleen on a well-designed and sophisticated study intended to assess the comparative cost-efficacy of various strategies for remediation of lead paint.<sup>82</sup> The problem was an important one: 95% of the housing stock in the inner city neighborhood where the study was conducted had high levels of lead dust that had not been abated.<sup>83</sup> In many instances, the cost of full remediation exceeded the value of the housing, so any attempt to compel such remediation would result in the abandonment of the housing—making everyone worse off.<sup>84</sup>

Conversely, a cost-effective strategy for remediation had the potential to make everyone better off—a fact which helps explain why the study was funded by two federal agencies (the Department of Housing and Urban Development (“HUD”) and the Environmental Protection Agency (“EPA”)), and administered in cooperation with the Maryland State Department of Housing and Community Development. Indeed, the project has been replicated by HUD in 2600 houses in thirteen other cities.<sup>85</sup> The study was ap-

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<sup>80</sup> IRBs that obtain the necessary approvals can collectively agree to “share the load” in evaluating multi-site studies, but there is no comparable provision allowing an IRB to evaluate and approve a study that would be conducted at another institution.

<sup>81</sup> See Mello et al, *supra* note 26.

<sup>82</sup> See *Grimes v. Kennedy Krieger*, 782 A.2d 807 (Md. 2001).

<sup>83</sup> See Jack Schwartz, *The Kennedy Krieger Case: Judicial Anger and the Research Enterprise*, 6 J. HEALTH CARE L. & POL’Y 148, 149 (2002) (“Many of KKI’s patients came from low-income neighborhoods in Baltimore, where 95% of the housing stock had lead paint.”).

<sup>84</sup> See Joanne Pollak, *The Lead-Based Paint Abatement Repair & Maintenance Study in Baltimore: Historic Framework and Study Design*, 6 J. HEALTH CARE L. & POL’Y 89, 95–96 (2002).

<sup>85</sup> *Id.* at 96, 107.

proved by the EPA (after internal and external reviews), the Centers for Disease Control, and the Johns Hopkins IRB.<sup>86</sup> The IRBs for twenty-nine different entities in each of the thirteen other cities had also approved the protocol.<sup>87</sup>

Although the degree of remediation varied (which was, after all, the point of the study), all study participants lived in a remediated apartment.<sup>88</sup> Individuals could live in the remediated apartments without participating in the study, and they were solicited for participation in the study only after they were already living in a remediated apartment.<sup>89</sup> Even if an individual did not participate in the study, they got to live in a remediated apartment that had a better lead paint environment than the alternatives that were available to 95% of the affected population.<sup>90</sup>

The lawsuit was filed by several research subjects, alleging that they had been exposed to unsafe levels of lead because of their participation in the study. The trial court granted summary judgment to the defendants on the ground they did not have a generalized duty of care to study participants. The only issue before the court of appeals was whether or not there was a generalized duty of care. There was a sparse factual record, and the larger context of the dispute involved the balancing of complex issues of public policy. An amicus brief filed by a third party canvassed the history of research abuses, and argued that the court should find that there was a duty of care and send the case back for trial.<sup>91</sup>

Rather than address the narrow issue before it, the Court held that the research was per se inappropriate, unethical, and illegal. Relying on suspicion, innuendo, and a clear misunderstanding of the facts and the law, the Court smeared a well-respected researcher and the IRB with its flat assertion that the study “differs in large degree from but presents similar problems” as the Tuskegee Syphilis Study and the “research” performed in Nazi concentration camps.<sup>92</sup> The Court also felt compelled to remind the researchers that children were not “rats, hamsters, monkeys, and the like”—even though there was no evidence the researchers thought otherwise.<sup>93</sup>

The opinion also included language that would have closed down all non-therapeutic pediatric research in Maryland—notwithstanding a federal statutory commitment to the contrary, and the fact that such research ac-

<sup>86</sup> Motion of Appellee at 10–11, *Grimes v. Kennedy Krieger Institute*; *Higgins v. Kennedy Krieger Institute*, Sept. Term 2000-128, Sept. Term 2000-129 (Md. Sept. 17, 2001) [hereinafter Appellee’s Motion] (on file with author).

<sup>87</sup> Pollak, *supra* note 84, at 107 n. 140.

<sup>88</sup> *See id.* at 98.

<sup>89</sup> *Id.* at 98–104.

<sup>90</sup> *See* Appellee’s Motion, *supra* note 86.

<sup>91</sup> *See* Brief for Public Justice Center as Amicus Curiae Supporting Appellant, *Grimes v. Kennedy Krieger*, 782 A.2d 807 (Md. 2001).

<sup>92</sup> *Grimes*, 782 A.2d at 816.

<sup>93</sup> *Id.* at 852.

counted for millions of dollars of funding to Maryland institutions.<sup>94</sup> A motion for reconsideration pointed out these problems, using the understated opening line, “[o]n the day the mandate in this case issues, hundreds of fully accredited medical research projects now conducted in Maryland will terminate.”<sup>95</sup> A flurry of amicus briefs by prestigious organizations made the same point—including one from the third party that had started the whole process, but agreed the court had gone completely off the deep end.<sup>96</sup> In a press release, Johns Hopkins University noted the effect of the ruling would be “the loss of valued researchers and investigators, who will be forced to relocate elsewhere in order to conduct their research.”<sup>97</sup>

In response to this outpouring of criticism, the court denied the motion for reconsideration, but unpersuasively argued that critics had simply misunderstood the original opinion.<sup>98</sup> At no point did the court respond to the concurrence (issued with the original opinion), which made it crystal clear that the original opinion had said what it meant and meant what it said.<sup>99</sup> After the case was returned to the trial court, it was dismissed with prejudice—an unimpressive (if not ignominious) ending for a case where the state supreme court condemned the conduct of the defendants by analogizing it to Nazi research.<sup>100</sup>

The opinion is an intellectual embarrassment.<sup>101</sup> Anyone who thinks the quality of research oversight by IRBs will necessarily be improved by

<sup>94</sup> *Id.* at 858 (observing that a parent “cannot consent to the participation of a child or other person under legal disability in nontherapeutic research or studies in which there is any risk of injury or damage to the health of the subject”). The language was described in the opinion as a holding, but was actually dicta. Jack Schwartz, *The Kennedy Krieger Case: Judicial Anger and the Research Enterprise*, 6 J. HEALTH L. & POL’Y 148, 157 (2002).

<sup>95</sup> See Appellee’s Motion, *supra* note 86.

<sup>96</sup> See Karen Smith Thiel, *Parental Consent For Children’s Participation in Biomedical Research: The Ethical, Regulatory, and Judicial Framework of Grimes v. Kennedy Krieger Institute*, 6 J. HEALTH L. & POL’Y 169, 187–90 (2002); Schwartz, *supra* note 94, at 158–59; Memorandum of Law of Public Justice Center In Partial Support of Appellee’s Motion for Partial Reconsideration and Modification of Opinion, *Grimes v. Kennedy Krieger*, 782 A.2d 807 (Md. 2001) (on file with author).

<sup>97</sup> See Johns Hopkins University, Lead-Based Paint Study, available at <http://www.hopkinsmedicine.org/press/2001/SEPTEMBER/leadfactsheet.htm>.

<sup>98</sup> *Grimes*, 782 A.2d at 862 (asserting that by “any risk of injury or damage to the health of the subject” it had actually meant “any articulable risk beyond the minimal kind of risk that is inherent in any endeavor”).

<sup>99</sup> *Id.* at 861 (“I cannot join the majority in holding that, in Maryland, a parent or guardian cannot consent to the participation of a minor child in a nontherapeutic research study in which there is any risk of injury or damage to the health of the child without prior judicial approval and oversight.”).

<sup>100</sup> David R. Buchanan & Franklin G. Miller, *Justice and Fairness in the Kennedy Krieger Institute Lead Paint Study: The Ethics of Public Health Research on Less Expensive, Less Effective Interventions*, 96 AM. J. PUB. HEALTH 781, 782 (2006).

<sup>101</sup> See generally Schwartz, *supra* note 83, at 148 (“[T]he Court’s rhetoric was heated, its historical comparisons inflammatory and unjust, and aspects of its decision ill-considered.”). The same article later describes the court’s opinion as marked by “rhetorical excess and [a] condemnatory tone.” *Id.* at 164. Further, it noted that the opinion “suffers badly from imprecision and superficiality.” *Id.* at 166. When an assistant attorney general in the Maryland Attorney General’s Office describes the work of the

judicial oversight should read the opinion, and then apologize for their presumption. With judicial oversight of this caliber, we will not have to worry about the problem of human subjects research, since in short order there will be a lot less research.

#### VI. A COMPARATIVE INSTITUTIONAL PERSPECTIVE ON IMPROVING IRB PERFORMANCE

All human institutions operate imperfectly.<sup>102</sup> Expecting IRBs to prevent all bad outcomes or perform flawlessly is foolish. Indeed, a non-zero incidence of “bad outcomes” is fully consistent with an optimal level of research risk and of research oversight.<sup>103</sup> “The alternative . . . ‘is not to do any clinical investigation . . . and still have children on ventilators after polio.’”<sup>104</sup>

The question we should be asking is whether IRBs constitute the “least worst” institutional response to the problem of balancing the marginal cost and marginal benefit of research and research oversight. As the foregoing suggests, in several important respects the answer to that question is almost certainly “no.”

This assessment should not lead to regulatory nihilism. Even if the Common Rule had never been enacted, there are good reasons to think most research institutions would have developed mechanisms for reviewing the work done by their personnel. However, it is unlikely that each institution would have arrived at the solutions dictated by the Common Rule—let alone the Common Rule’s obsession with the race, gender, cultural background, and affiliation of those serving on the IRB.<sup>105</sup> Instead, it seems probable that a diverse array of research oversight methods would have emerged, and that they would have:

- varied significantly across institutions, depending on local culture and the degree of risk-aversion;
- varied significantly across disciplines and research modes;

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highest state court in Maryland using such words, the words “intellectual embarrassment” may be too kind.

<sup>102</sup> NEIL K. KOMESAR, *IMPERFECT ALTERNATIVES: CHOOSING INSTITUTIONS IN LAW, ECONOMICS AND PUBLIC POLICY* (1997).

<sup>103</sup> See ROBERT CORAM, *BOYD: THE FIGHTER PILOT WHO CHANGED THE ART OF WAR* 211 (2002) (“‘General, if you’re not having accidents, your training program is not what it should be,’ Boyd said. He told the general about Nellis and how realistic the training was—and how it resulted in a ten-to-one exchange ratio in Korea. ‘Goddamnit, General, you need more accidents,’ he said. ‘You need to kill some pilots.’”). See also Steinbrook, *supra* note 66, at 716 (“‘At a certain point, some patient is going to die in clinical trials,’ Miller said. ‘There is no question about it.’ The challenge is to do everything possible to ensure the safety of research subjects and to make the risk as small as possible.”) (quoting Dr. Edward D. Miller, dean of the Johns Hopkins University School of Medicine).

<sup>104</sup> See Steinbrook, *supra* note 66, at 716 (quoting Dr. Edward D. Miller, Dean of the Johns Hopkins University School of Medicine).

<sup>105</sup> See *supra* notes 6–8 and accompanying text.

- treated different researchers differently, based on the relative risk of the underlying research and the reputation and experience of the individual researcher; and
- varied in the relative amount of ex ante review and ex post enforcement.

As this short list suggests, there is no compelling reason why universities and academic medical centers should be shackled to the Common Rule in evaluating non-federally funded research—particularly given the potential gains from greater diversity in the forms and modes of research oversight. The balance of this section accordingly offers some suggestions for improving the performance of research oversight.

#### *A. Make the Invisible Visible*

We have some empirical evidence on the costs of operating an IRB, modest empirical evidence on the cost of obtaining IRB approval, and no empirical evidence whatsoever on the social cost of false negatives and the social benefits of IRB oversight.<sup>106</sup> Any attempt to assess the value of IRB oversight requires quantification of these costs and benefits. It is long past time for IRBs to be an object of study, instead of simply the toll gate through which all studies must pass.

#### *B. Make the Cheap Expensive*

Most of the cost of research oversight is externalized. The federal government requires the use of IRBs for federally funded research, but it does not pay its fair share of those costs.<sup>107</sup> The federal government also strongly encourages the use of IRBs for non-federally funded research, but it pays nothing toward those costs either. If the federal government wants IRB review, it should pay for it.

At the level of individual institutions, the reliance on volunteers means that even the direct costs of IRB review are not fully captured in the institution's budgeting process. Similarly, an institution's budgetary expenses for IRBs do not reflect the social costs of delay and false negative decisions. If individual institutions want to rely on IRB review, they should face up to its full cost. Stated differently, only by making the cheap expensive (i.e., by making off-budget expenses on-budget) will we be able to assess the true cost of the IRB review process.

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<sup>106</sup> See *supra* Part IV.

<sup>107</sup> Howard B. Dickler & David Korn, *The Costs of Institutional Review Boards*, 353 NEW ENGL. J. MED. 315, 316 (2005).

*C. Make the Expensive Cheap*

Although certain research methodologies are exempt from IRB review, there are significant constraints on the scope of those exemptions—and many IRBs require submission of exempt research protocols in order to determine whether they in fact are exempt.<sup>108</sup> Instead of this approach, as a recent AAUP report suggested, “research on autonomous adults whose methodology consists entirely in collecting data by surveys, conducting interviews, or observing behavior in public places should be exempt from the requirement of IRB review—straightforwardly exempt, with no provisos, and no requirement of IRB approval of the exemption.”<sup>109</sup> This approach will save researchers a great deal of time and effort. It will also eliminate a considerable amount of unnecessary work currently done by IRBs—freeing them to focus on projects that impose greater risks.<sup>110</sup>

The existing framework for exemptions purports to ensure more confidentiality than would otherwise be the case—but even that “benefit” is likely illusory. IRB oversight will only add value to existing departmental and disciplinary practices for ensuring confidentiality if IRB members are better equipped to assess practices for collecting and storing data than members of the discipline—a proposition which is dubious on its face.<sup>111</sup> Worse still, IRBs have expansively interpreted the requirement that exemption is not available if “any disclosure of the human subjects’ responses outside the research could . . . be damaging to the subjects’ financial standing, employability, or reputation.”<sup>112</sup> As the AAUP report noted, it is hard to see a clear line between cases in which a breach of confidentiality might be damaging to the subjects’ financial standing, employability, or reputation, and cases in which it would not be.<sup>113</sup> It is also hard to see why full-blown IRB review is necessary for surveys and interviews when autonomous individuals can decide whether or not to participate—and there is no obvious justification for full-blown IRB review of cases involving observation of public behavior.<sup>114</sup>

Similar logic applies to the willingness of some IRBs to consider third-party interests in weighing whether or not to approve a research protocol. The point of the IRB framework was to protect research subjects—not to engage in censorship at the behest of vocal interest groups or the ideologi-

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<sup>108</sup> Thomson et al., *supra* note 19, at 97–98.

<sup>109</sup> *Id.*

<sup>110</sup> See *Time to Cut Regulations That Protect Only Regulators*, 414 NATURE 379 (2001) (“The time spent by committees reviewing such routine protocols to the full extent required by law is time that could be better spent on the more controversial applications.”).

<sup>111</sup> Thomson et al., *supra* note 19, at 97.

<sup>112</sup> 45 C.F.R. § 46.101(b)(2) (2005).

<sup>113</sup> Thomson et al., *supra* note 19, at 97.

<sup>114</sup> *Id.*

cal preferences of IRB members or campus administrators.<sup>115</sup> If an institution does not want its personnel to perform certain research because it is unprepared for the political heat, it should forthrightly announce that it does not want to be associated with such projects, instead of hiding behind the IRB and the purported desire to protect human subjects.

#### *D. Destroy Local Monopolies*

The current regulatory framework effectively creates institution-specific monopolies for each IRB. Such monopolies are inherently undesirable. A robust market in IRB review would create better incentives than the current system, and would keep the review process and reviewers in line. It would also provide a market test of the claim routinely heard from IRB members and their supporters that IRB oversight improves the quality of the research that is conducted.<sup>116</sup> Any IRB meeting the requirements of the Common Rule should be authorized to perform reviews of research protocols, irrespective of where the research will be performed. The Common Rule authorizes a version of this proposal for multi-center studies, so this proposal simply extends this model to single-center studies. As in the current system, institutions would be free to scrutinize the IRB decision and turn down the proposed research—but they could not do so on the grounds it was not approved by their IRB.<sup>117</sup>

#### *E. Just Say No to Bioethics*

IRBs are one of the few success stories of bioethics—an institutionalized arrangement for the evaluation of the ethical implications of all research conducted by every entity that receives federal funding. There may be a bioethics cop on the beat, but as noted previously, it has proven itself prone to lawyerization, and a host of other predictable pathologies.<sup>118</sup> IRBs also provide a rhetorical hook for criticism and an institutional focus for liability; instead of criticizing an individual research project, the fact of IRB approval means that the institution as a whole is on the line for any shortcomings. IRB approval provides no protection against criticism by novice

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<sup>115</sup> Indeed, the IRB regulations flatly prohibit such stratagems. See 45 C.F.R. § 46.111(a)(2) (2005) (“The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.”). This clear prohibition has not stopped IRBs from doing precisely the opposite. See *supra* note 58 and accompanying text; see also Ceci, Peters & Plotkin, *supra* note 79, at 1000 (noting an IRB rejected a study of reverse discrimination on the grounds that “the findings could set affirmative action back 20 years if it came out that women with weaker vitae were asked to interview more often for managerial positions than men with stronger vitae”).

<sup>116</sup> Stop laughing. This is serious.

<sup>117</sup> 45 C.F.R. § 46.112 (2005).

<sup>118</sup> Predictable, that is, to anyone with the slightest knowledge of regulatory theory or bureaucracy—subjects that are apparently not part of the bioethics canon. On the lawyerization of bioethics, see David A. Hyman, *How Law Killed Ethics*, 34 PERSP. BIOLOGY & MED. 134 (1990).

bioethicists looking to “make their bones” on the latest controversy, or established bioethicists who want to see their names in print.<sup>119</sup> Wholly apart from these problems, it is hard to make the case that IRBs, with their obsession with paperwork and the tweaking of consent forms, actually promote the protection of human subjects. I have previously expressed my skepticism about various aspects of the bioethics enterprise, but with a success like this, who needs failure?<sup>120</sup> The next time a bioethicist comes calling with their latest bright idea, just say no.

#### CONCLUSION

As noted previously, the right question to ask about IRBs is not whether they are perfect, but whether they are the “least worst” institutional response to the problem of balancing the marginal cost and marginal benefit of research and research oversight. Even judged by this modest standard, IRBs fall well short. Minimal improvements have the potential to move us closer to a “least worst” world, and constrain the excesses that currently prevail in research oversight.

What role is there for lawyers, law professors, and judges in jump-starting this process? Until recently, law professors did research by leaning back in their chair and staring at the ceiling. Not surprisingly, the result was that most law professors knew little and cared less about IRBs. When I organized a program at the 2004 Association of American Law Schools (“AALS”) Annual Meeting on “Institutional Review Boards and You” (subtitled “What Every Law Professor Should Know About IRBs,”) it was a challenge coming up with enough legal academics to make up a panel. I ended up inviting two non-legal academics to participate. At the actual program, the five members of the panel were outnumbered—but barely

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<sup>119</sup> For example, the Kennedy Krieger study was criticized by several bioethicists on the grounds the researchers should not have accepted the proposition that resource constraints made full abatement unlikely. Buchanan & Miller, *supra* note 100, at 783–84 (cataloging and criticizing such complaints). From this exalted perspective, trying to find more cost-effective abatement strategies meant that the researchers were, in fact, capitulating or colluding with “status quo conditions of gross social injustice.” *Id.* at 783.

How could anyone believe that “sticking it to the man” was a better strategy than actually doing something to help the children of Baltimore? As George Orwell has noted, “[O]ne has to belong to the intelligentsia to believe things like that: no ordinary man could be such a fool.” GEORGE ORWELL, *Notes on Nationalism*, in ENGLAND YOUR ENGLAND 41, 65 (1945).

Similar complaints will predictably be raised anytime anyone acknowledges the reality of resource constraints instead of wishing them away. See David A. Hyman, *Professional Responsibility, Legal Malpractice, and the Eternal Triangle: Will Lawyers or Insurers Call the Shots?* 4 CONN. INS. L.J. 353, 391–94 (1997–1998) (analyzing similar episode involving placebo controlled trials of short-course AZT in Africa). As I noted in that article, “Some commentators are unable to understand that scarcity is not an artificial construct or a conspiracy against the less fortunate.” *Id.* at 394 n.178.

<sup>120</sup> See, e.g., David A. Hyman, *Commentary*, in ETHICAL CHALLENGES IN MANAGED CARE: A CASEBOOK 176 (1999); David A. Hyman, *Case Discussion*, MID-ATLANTIC ETHICS COMM. NEWSL., Fall 1995, at 8; Hyman, *supra* note 118.

so—by the audience. The 2006 AALS Annual Meeting, which was devoted to the theme “Empirical Scholarship,” did not have a single program on IRBs.

The times are (slowly) changing if the Symposium of which this article is a part is any indication. Yet, it would be unfortunate if this increased interest in IRBs results in further lawyerization of the research oversight process. Lawyers, law professors, and judges are prone to believe that “things go better with due process,” and the keys to the courthouse are the keys to the kingdom. Those inclined to such views should be required to read the *Grimes* decision,<sup>121</sup> and then write 100 times on their respective blackboards Professor Grant Gilmore’s warning against such tendencies: “[i]n Heaven there will be no law, and the lion will lie down with the lamb. . . . In Hell there will be nothing but law, and due process will be meticulously observed.”<sup>122</sup>

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<sup>121</sup> See *supra* note 78.

<sup>122</sup> GRANT GILMORE, *THE AGES OF AMERICAN LAW* 111 (1977).

