

## INSTITUTIONAL REVIEW BOARDS, REGULATORY INCENTIVES, AND SOME MODEST PROPOSALS FOR REFORM

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### INTRODUCTION

It is time to rethink the role of Institutional Review Boards (IRBs) in approving social science research. Whatever the merits of Philip Hamburger's creative and provocative constitutional arguments, legal scholars owe him a great deal for bringing fresh attention to the IRB phenomenon.<sup>1</sup> While most law professors conduct their research in an almost unregulated environment—pouring through cases, statutes, and each other's articles, all without the kind of human interaction subject to IRB regulation—their colleagues elsewhere in the university have been coping for decades with an increasingly intrusive bureaucracy that sometimes undermines basic academic values. IRBs started out in part as a way to stop the next Joseph Mengele from physically torturing humans under the guise of medical research,<sup>2</sup> but have ended up chilling valuable social science that might, for example, explain how someone gets to be a Joseph Mengele.<sup>3</sup>

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<sup>1</sup> Philip Hamburger, *The New Censorship: Institutional Review Boards*, 2004 SUP. CT. REV. 271 (arguing that IRBs constitute a form of prior restraint that violates the First Amendment). Criticism of IRBs in legal periodicals goes back at least 25 years. For examples of early criticism of IRBs in legal scholarship, see David Favre & Matthew McKinnon, *The New Prometheus: Will Scientific Inquiry Be Bound by the Chains of Government Regulation?*, 19 DUQ. L. REV. 651 (1981); Richard Delgado et al., *Can Science Be Inopportune? Constitutional Validity of Governmental Restrictions on Race-IQ Research*, 31 UCLA L. REV. 128 (1983).

<sup>2</sup> The three cardinal ethical principles guiding human-subject research—respect for persons, beneficence, and justice—are themselves outgrowths of the World War II war-crimes trials, which uncovered shocking Nazi mistreatment of human subjects in “medical” experimentation. Richard S. Saver, *Medical Research and Intangible Harm*, 74 U. CIN. L. REV. 941, 951–52 (2006). The guiding ethical principles are laid out in the *Belmont Report*. Report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 44 Fed. Reg. 23,192 (Apr. 18, 1979) (notice of report). However, perceived lapses of ethical judgment in some social science experiments involving human subjects in the United States also motivated the creation of the IRB system. For examples of ethically questionable biomedical and social science research prior to the IRB system, see CARL H. COLEMAN, JERRY A. MENIKOFF, JESSE A. GOLDNER & NANCY NEVELOFF DUBLER, *THE ETHICS AND REGULATION*

Three things seem very clear. First, there are a lot of IRBs—at least 4,000—and their numbers are growing.<sup>4</sup> Second, they have recently “increased their scrutiny of social science protocols, and all indications suggest even more scrutiny is imminent.”<sup>5</sup> Third, social scientists are “increasingly frustrated, annoyed, and upset by IRB decisions, inconsistencies, delays, and misunderstandings.”<sup>6</sup> There is much less consensus on what, if anything, should be done about these developments. Some experts favor even more IRB oversight, expanded IRB jurisdiction, and larger budgets and staffs for IRBs. The cure for the ills of IRBs, on this view, is more IRBs.

In this article, I suggest a different and more liberalized path. In Part I, I describe the regulatory metastasis of IRBs and some problems it is causing for social science research.<sup>7</sup> In Part II, I offer some thoughts on the ways in which these problems might arise from the pro-regulatory incentives to which IRBs are exposed.

Finally, in Part III, I outline some modest liberalizing reforms to counter the effects of these pro-regulatory incentives. The reforms I propose broadly fall into three categories: IRB membership and structure, substantive IRB jurisdiction, and institutional liability. In the first category, IRB membership and structure, I propose that we should require basic First Amendment training for IRB members and include a First Amendment expert as a member of the IRB; that we should require that more than one, perhaps even a majority, of the members of the IRB have the expertise and competence to evaluate the risks and benefits of the particular research being reviewed; and that every research institution using IRBs should establish separate boards for biomedical and social science research. In the second category, substantive IRB jurisdiction, I propose that oral history and other interview-based research should be exempt from IRB approval; that IRBs should be permitted to prohibit or alter research in the social sci-

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OF RESEARCH WITH HUMAN SUBJECTS 3–50 (2005); J. Michael Oakes, *Risks and Wrongs in Social Science Research: An Evaluator's Guide to the IRB*, 26 EVALUATION REV. 443, 444 (2002).

<sup>3</sup> Stanley Milgram, *Behavioral Study of Obedience*, 67 J. ABNORMAL PSYCHOL. 371 (1963) (demonstrating that, out of a desire to obey authority figures, otherwise normal people could be motivated to impose extreme pain on other humans). While no subjects were physically harmed during the Milgram experiment, a few of the subjects were very upset at the realization that they were capable of imposing such perceived harm on other people. The study was almost immediately criticized as ethically questionable. Diana Baumrind, *Some Thoughts on the Ethics of Research: After Reading Milgram's "Behavioral Study of Obedience,"* 19 AM. PSYCHOLOGIST 421 (1964).

<sup>4</sup> Oakes, *supra* note 2, at 444.

<sup>5</sup> *Id.*

<sup>6</sup> *Id.* at 445.

<sup>7</sup> By “social science research,” I mean the study of human society and of the relationship of individuals in and to society. It encompasses fields like sociology, psychology, anthropology, economics, political science, journalism, and history. By “biomedical research,” I mean research related to matters of human health and disease. It encompasses fields like medicine, chemistry, and bio-engineering. While it does not usually involve invasive procedures, social science research sometimes uses methods common to biomedical research, like testing physiological reactions to social interactions.

ences only where the risks of the research *substantially* outweigh the anticipated benefits; that rather than have IRBs screen social science research before it is performed, they should review it (and enforce internal discipline on researchers, if necessary) only after ethical breaches cause some harm; and that social science researchers themselves, rather than IRBs, should determine at the threshold whether their research is exempt from prior IRB approval. In the third category, institutional liability, I propose that evidentiary rules in civil trials should exclude evidence of a university's failure to adopt the Common Rule for non-federally funded research. Many details of these proposals will need to be worked out, but I offer them here as a starting point for reform efforts.

I will assume the reader has a basic familiarity with the nature and structure of IRBs as they exist throughout the United States and at all levels of education. For those who are not familiar with IRBs, Professor Hamburger's trailblazing article, *The New Censorship: Institutional Review Boards*, provides excellent background.<sup>8</sup>

### I. IRBS AND REGULATORY METASTASIS

Because there has been no systematic empirical study of the effects of IRB regulation on social science research, we are left to traverse a growing mountain of anecdotes and testimony from researchers themselves about the harm done to potentially valuable work.<sup>9</sup> Many problems have arisen from overzealous IRBs that exceeded their statutory or institutional authority. For example, where the same IRB reviews both biomedical and social science research, the IRB will often simply apply ethical standards for biomedical research to social-science research,<sup>10</sup> despite the fact that the risks to human subjects and the requisites for practical research are very different.<sup>11</sup> In the words of a report from the American Association of University Professors, "IRBs . . . too often mistakenly apply standards of clinical and

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<sup>8</sup> Hamburger, *supra* note 1. Northwestern University also has a useful FAQs section on its website explaining the functions, procedures, and requirements of IRBs. Office for the Protection of Research Subjects, Institutional Review Board, Northwestern University, FAQs (2005), <http://www.research.northwestern.edu/research/oprs/irb/faqs>.

<sup>9</sup> Charles L. Bosk & Raymond G. De Vries, *Bureaucracies of Mass Deception: Institutional Review Boards and the Ethics of Ethnographic Research*, 595 ANNALS AM. ACAD. POL. & SOC. SCI. 249, 256–57 (2004) (reports on IRBs are rarely supported by data and are based on anecdote, unscientific surveys, and testimony given to government committees).

<sup>10</sup> "[T]he fact is that the regulations on which IRBs rely were written for and by biomedical researchers trying to protect subjects from physical risks of surgical and pharmacological experiments." Oakes, *supra* note 2, at 447.

<sup>11</sup> *For the Record: Should All Disciplines Be Subject to the Common Rule? Human Subjects of Social Science Research*, ACADEME, May–June 2002, at 62, 68 (remarks of Margaret A. Blanchard). Blanchard is a journalism professor at the University of North Carolina at Chapel Hill. Social scientists frequently complain that IRB review "is modeled on the standard clinical trial." Bosk & De Vries, *supra* note 9, at 252.

biomedical research to social science research, to the detriment of the latter

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The so-called Common Rule—the set of federal regulations governing federally funded research involving human subjects—establishes the basic structure under which IRBs operate.<sup>13</sup> A proper interpretation of either the Common Rule or particular institutional guidelines might prevent some abuses. But the main problem, as I argue in Section II, is that overzealous enforcement is inevitable given the pro-regulatory incentives IRBs face. In this Section, I argue that IRB power to review and approve research before it is conducted, including the power to forbid or alter proposed research, has chilled social science work that could prove beneficial.

### A. Forbidding Research

IRBs have the power to forbid proposed research that is federally funded or otherwise subject to an institution's own guidelines. For example, an IRB may forbid such research on the grounds that the risks it poses to human subjects outweigh the anticipated benefits from the experiment.<sup>14</sup> This is the most blatant way in which an IRB might prevent useful research. It also appears, however, to be the least likely. Outright rejection of a proposed project appears to be rare.<sup>15</sup> It does happen, but given the self-censorship in which researchers now engage, truly cutting-edge and controversial research of the kind that runs a genuine risk of rejection, especially on sensitive topics, probably gets proposed less often than it would in the absence of IRB review.<sup>16</sup>

For example, it seems beyond question that the famous and influential study by Stanley Milgram of the effects of authority on the willingness of subjects to inflict pain on others<sup>17</sup> could not be conducted today, even though nobody was physically harmed in the study. The IRB instructional course required of all human-subject researchers at the University of Minnesota, goes as far as to name the Milgram experiment as a prototypical example of abuse of human subjects since it deceived the subjects about the purpose of the study and “[s]ome of the subjects, after being ‘debriefed’ from the study experienced severe emotional crises.”<sup>18</sup> While some decep-

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<sup>12</sup> *Protecting Human Beings: Institutional Review Boards and Social Science Research*, ACADEME, May–June 2001, at 55, 55–56.

<sup>13</sup> Several federal agencies have adopted regulations set out for the Department of Health and Human Services in 45 C.F.R. pt. 46, often referred to as the Common Rule.

<sup>14</sup> 45 C.F.R. §§ 46.111–46.112 (2005).

<sup>15</sup> *Protecting Human Beings*, *supra* note 12, at 56.

<sup>16</sup> *See infra* Part I.C.

<sup>17</sup> Milgram, *supra* note 3.

<sup>18</sup> University of Minnesota, CITI Course in the Protection of Human Research Subjects, available at <https://www.citiprogram.org/members/courseandexam/moduletext.asp?strKeyID=2848BDF6-C88D-4F38-B0FD-5F9B6067D161-1057435> (last visited Sept. 1, 2006) (password required).

tion of subjects is still permissible under limited circumstances, a modern IRB would probably reject the Milgram study if it were proposed.

### *B. Altering and Limiting Approved Research*

Short of forbidding proposed research, IRBs may limit or alter proposals. According to one study, fewer than 20% of research proposals are approved as submitted.<sup>19</sup> One journalism professor who chairs an IRB believed that no proposal from her department was accepted as written in the previous year, even though applicants had taken great care to meet the presumed requirements.<sup>20</sup> She reports that the journalism department at her university battled the campus IRB on things like:

an attempt to deny a master's 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; a demand that a student prove that a source was not her father; and a requirement that the students or faculty members conducting a mail survey instruct recipients that the mail survey could be mailed back unanswered, thus increasing the cost of the survey and decreasing the likelihood of obtaining sufficient responses.<sup>21</sup>

Similarly, researchers on college campuses report trouble getting IRB approval of studies on sensitive but important subjects like date rape, binge drinking, and academic cheating.<sup>22</sup>

IRBs reviewing proposed oral history research have sometimes required pre-approval of questions the researcher expected to use in interviews.<sup>23</sup> Giving a detailed roadmap of questions before an interview is impractical in oral history work because questions depend on the flow of the interview and the responses—including nonverbal cues—of the interviewee. IRBs have also demanded that researchers preserve the anonymity of interviewees to save them from subsequent embarrassment or retaliation. Yet anonymous sources have less credibility in historical scholarship.<sup>24</sup> IRBs have admonished historians not to ask their interviewees about illegal activities or other embarrassing matters. But learning such information is often the very point of historical research. “If I am studying racism, am I to protect people from their racism?” asked one researcher.<sup>25</sup>

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<sup>19</sup> *Protecting Human Beings*, *supra* note 12, at 56.

<sup>20</sup> *For the Record*, *supra* note 11, at 67 (remarks of Margaret A. Blanchard).

<sup>21</sup> *Id.*

<sup>22</sup> *Id.*

<sup>23</sup> *Id.* at 64 (remarks of Linda Shopes). Shopes is a historian at the Pennsylvania Historical and Museum Commission.

<sup>24</sup> *Id.* at 65.

<sup>25</sup> *Id.*

### C. *Chilling Research*

Forbidding and limiting research are just the tip of the regulatory iceberg. The bigger effect of intrusive regulation may be its chilling effect on researchers. A real-world example exemplifies this effect: A student interested in gender studies was thinking about doing research on the lives of exotic dancers—strippers—and specifically on whether they experience stripping as a form of exploitation or objectification. A friend of the student's, who had just started stripping, had told her that dancing empowered her, turning the tables on the men who ogled the dancers. The friend promised to introduce the student researcher to exotic dancers, who would be interviewed about their experiences. The study would involve interaction with people—interviews of the strippers—and therefore was subject to approval by the university's IRB. The research would require IRB approval even if the student's research were not funded by the federal or state government, since, out of fear of displeasing federal and other funding authorities, the institution applies IRB rules to all research involving human subjects.<sup>26</sup>

Her project advisor, however, warned that such a study probably would not receive IRB approval. In an informal discussion involving the student researcher, the project advisor, and an IRB member, that warning proved accurate:

The project raised all sorts of red flags for the IRB member: How would the student protect the anonymity of dancers who might become embarrassed if a wider community found out about their alleged "profession"? What liability would the student face if she found out that illegal activities (perhaps sexual, perhaps drug related) occurred at the club? What specific interview questions did she plan to ask, and how would the interview format protect the identity of the dancers interviewed? What would happen if one night her interview notes were stolen?<sup>27</sup>

The student researcher feared that even if the university IRB eventually approved her project, the approval process would take so long that she would not be able to complete her research in time to graduate. So she abandoned the project and opted for something less controversial.

Another student researcher abandoned an ethnographic study of AIDS activists in Philadelphia, fearing that her senior year would be wasted dealing with the IRB.<sup>28</sup> She opted for "a statistically significant, but dull, survey of the relationship between healthy eating habits and the extracurricular activities of college students."<sup>29</sup>

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<sup>26</sup> *Id.* at 62–63.

<sup>27</sup> *Id.* at 62.

<sup>28</sup> *Id.* at 63.

<sup>29</sup> *Id.*

A few years ago, a colleague of mine, criminal law scholar Barry Feld, proposed to research the taped interrogations of minors accused of crime.<sup>30</sup> His research involved no actual contact with the minors, either by interview or survey. He reviewed only the audiotapes of their interrogations by police, the associated police reports, and juvenile court filings. The identities of the delinquents were disclosed to him pursuant to a previously obtained court order and under stringent confidentiality constraints. Nevertheless, he was obliged to seek approval for his research from the university IRB through the expedited review process (available to certain specific categories of research that involve no more than minimal risk to human subjects).<sup>31</sup> Feld informed the IRB that he would also like to interview the police officers who had interrogated the minors. This raised immediate concerns from the IRB, which required detailed interview protocols out of a concern that Feld might somehow intimidate the police officers during his interviews.

Unable to respond to the IRB's demands for a more detailed recruitment strategy and interview protocol prior to conducting the research, Feld dropped the idea of interviewing the police and confined his research to reviewing the audiotapes of the interrogation sessions.<sup>32</sup> As a result, part of a potentially groundbreaking project was lost without an IRB formally rejecting or even limiting the research. And while Feld's truncated study was ultimately approved, the entire "expedited" process took months to complete.

These examples illustrate the most pernicious effect of regulatory metastasis: the chilling effect. Note what did *not* happen in these cases: An IRB did not disapprove the research proposal; nor did an IRB limit or alter a proposed method, set of interview questions, or anything else. Instead, potentially valuable studies never happened because the researchers never even proposed them. The very existence of the IRBs, knowledge gained from stories like those above of IRBs' presumed regulatory inclinations, and fear of time-consuming encounters with a bureaucracy, chilled the researchers' proposals.

IRB control over research has another especially insidious effect: it helps to insulate IRBs from criticism by deterring researchers from airing their grievances. Some researchers hesitate to challenge IRBs "because they are concerned about drawing attention to themselves and their work. They fear such attention will lead to further supervision by the IRB and more restrictions on their work."<sup>33</sup> The *in terrorem* effect of IRB review chills serious critical analysis by the very people—researchers—most familiar with how IRBs operate.

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<sup>30</sup> Interview with Barry Feld, Centennial Professor of Law, University of Minnesota Law School (Sept. 5, 2006).

<sup>31</sup> See 45 C.F.R. § 46.110 (2005).

<sup>32</sup> Interview with Barry Feld, *supra* note 30.

<sup>33</sup> *For the Record*, *supra* note 11, at 68 (remarks of Margaret A. Blanchard).

The very discretionary and value-laden nature of the IRB review—requiring an assessment of potential risks in research in relation to its importance—can itself have a chilling effect on innovative research, especially research on sensitive topics like family life and human sexuality:

From the perspective of the scholar with so much at stake in obtaining IRB approval, the uncertainty about whether any particular research will be considered important in relation to its risks, and the vagueness of such an inquiry, may dampen enthusiasm for challenging traditional habits of thinking, testing new theories, or criticizing social and political institutions. Why chance an IRB's displeasure when a more cautious approach is likely, so the scholar might plausibly reason, to secure uncontroversial approval?<sup>34</sup>

Nor is the chilling effect limited to individual researchers; whole institutions can be cowed by the threat of lost funding:

The desire to protect a university's federal funding is understandable. Duke University had its federal funding frozen briefly because it had not instituted proper protections for participants in biomedical research. That action was enough to send shivers down the spines of administrators in Chapel Hill.<sup>35</sup>

In any rigorous study of the effects IRBs have on social science research, these chilling effects would be hard to register. (Of course, a systematic study of the effects that IRBs are having on research and researchers would likely involve surveys or interviews (or both) of researchers, administrators, and IRB members, and would thus be subject to rejection or alteration *by an IRB*.) Examples like those provided above would not appear in a list of studies formally rejected or limited by IRBs. We will never know about much of the research not proposed, proposed in dramatically limited form against the better judgment of the researcher, or conducted using more conventional techniques than the researcher would like, in an effort to avoid IRBs or to assuage their presumed concerns.

## II. IRBS AND REGULATORY INCENTIVES

The problem is not that IRB members are overbearing, Stalinist busybodies with nothing better to do than squelch all creative and interesting human inquiry. Most IRB members are probably “principled, ethical, [and] deeply concerned about protecting human subjects.”<sup>36</sup> Many are “equally concerned that sound research go forward and that unsound research be re-designed so it could go forward.”<sup>37</sup> The problem is not that IRB members are bad people; the problem is that they are exposed to institutional and other incentives that incline them toward increasing regulation of research.

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<sup>34</sup> *Protecting Human Beings*, *supra* note 12, at 62.

<sup>35</sup> *For the Record*, *supra* note 11, at 67 (remarks of Margaret A. Blanchard).

<sup>36</sup> *Id.* at 63 (remarks of Jonathan T. Church).

<sup>37</sup> *Id.*

“Better safe than sorry” describes the ethos that develops. This section lays out the regulatory pressures on IRBs and on the larger institutions of which they are a part.

#### *A. Regulatory Pressures on IRBs*

Consider some incentives on IRBs themselves. The pro-regulatory bias starts at the threshold question of whether proposed research should even be reviewed. Some research involving human subjects is wholly exempt from IRB review, though the determination about what is exempt is made by the IRB itself.<sup>38</sup> IRB members “who have doubts about whether a research project should be exempt favor classifying the research as not exempt in order to avoid appearing cavalier about risks to human subjects.”<sup>39</sup> As the AAUP reports, “[n]o one is likely to get into trouble for insisting that a research proposal is not exempt.”<sup>40</sup>

The same phenomenon is present when IRBs face difficult decisions about whether to disapprove research, or whether and how to limit or alter proposed research. From the IRB’s perspective, more regulation means less potential for embarrassment from harm to human subjects. The resulting diminution in the vitality and ingenuity of research is not something that the IRB fully considers as a cost of its decision-making. The IRB lacks a process by which this loss to research would be internalized by the IRB. IRBs thus engage in a form of single entry bookkeeping. Every research proposal they approve involves some immediate, focused, and tangible risk to human subjects that might end up reflecting poorly on them and on their institutions. But the potential knowledge to be gained from such research is often distant, diffuse, and intangible. To the rational IRB member, therefore, research is all (potential) pain for speculative gain.

IRB members must review proposed research with the knowledge that they must please several regulatory-minded constituencies. First, they must worry about the views and reactions of government funding authorities. The federal Office of Human Research Protections (OHRP) has threatened to suspend an entire institution’s federally funded research in the event of an ethical lapse.<sup>41</sup> Federal government reports have proposed fines of up to \$1 million for ethical breaches.<sup>42</sup> Second, they must consider the cautious and nervous university administrators to whom they are beholden. Third, they must take into account the institution’s private donors, who may be displeased if a project the IRB approved goes awry in a way that draws negative publicity. Fourth, they must worry about the possibility of legal

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<sup>38</sup> 45 C.F.R. § 46.101(b) (2005) (listing exempt categories of research).

<sup>39</sup> *Protecting Human Beings*, *supra* note 12, at 60.

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

<sup>41</sup> Oakes, *supra* note 2, at 450.

<sup>42</sup> *Id.*

action by human subjects.<sup>43</sup> Fifth, especially if they work at public universities dependent on state legislatures for general funding, they must account for the possible financial consequences of constituents pressuring legislators to limit funding or to regulate research more directly. Loss of public trust and confidence could deal a major blow to a research institution.

Another pro-regulatory pressure arises from IRBs' ignorance of the types of nonphysical risks that are presented by social science research. IRBs understand well the physical risks to subjects that come from biomedical research. They are much less adept at identifying substantial *non-physical* risks or the research methods in social science that can create them. Thus, in an abundance of caution, they "make decisions on the basis of worst-case scenarios."<sup>44</sup> Fear of these worst-case scenarios leads them to overregulate.

There are factors mitigating these strong pro-regulatory pressures. There is no doubt most IRB members also value academic freedom and good research. Many IRB members themselves engage in research involving human subjects, and are sympathetic to the regulatory and other hardships faced by their colleagues in conducting such research. University administrators certainly have some interest in promoting good research in order to attract funding and prestige to their institutions. In the abstract, these might be good enough reasons for IRBs to give the benefit of ethical doubt to research.

But placed in the formalized setting of research review, subject to the regulations and pressures listed above, the danger is that their commitment to academic freedom and advancing human knowledge will be subsumed. The phenomenon of otherwise neutral authorities subjected to pro-regulatory institutional incentives is common in First Amendment experience. Consider, for example, the institutional pressure on a police officer who must maintain public order when a speaker is exciting the hostility of a crowd in a public place. While the police officer may have no personal bias against the views of the speaker, he will be strongly inclined to err on the side of caution and stop the speech well before the crowd becomes violent.<sup>45</sup> His institutional role requires him to keep the peace, not to ensure that unpopular views are heard. Similar concerns about bias have led the Supreme Court to reject licensing requirements for public parades and protests that

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<sup>43</sup> *Id.* at 452.

<sup>44</sup> *Id.* at 449.

<sup>45</sup> The Supreme Court has moved from a deferential posture toward law-enforcement judgments about the need to control hostile audiences by arresting speakers toward a more skeptical review of such judgments in the civil rights era. Compare *Feiner v. New York*, 340 U.S. 315 (1951), with *Cox v. Louisiana*, 379 U.S. 536 (1965). This shift can be understood, in part, as a recognition of the pro-regulatory pressures on police officers.

give licensors unbridled discretion in deciding which parades and protests to approve.<sup>46</sup>

I am not suggesting that pro-regulatory pressures on IRBs are unusual or even inappropriate taken in isolation; recipients of funds must always worry about pleasing donors, and donors are right to expect that funding recipients will consider their concerns. I am only pointing out that the constituencies IRBs must be concerned about are primarily pro-regulatory. Of course, these pressures would be present to some extent on social science researchers themselves even if IRBs did not exist. Social science researchers too, must worry about how their research reflects on their home institutions, as well as the reactions of administrators, peer-review bodies, other researchers in their field, funding agents, state legislatures, and the public. But at least researchers would fully consider the other side of the ledger—the need to advance knowledge, sometimes in unconventional ways, and to do so even about controversial matters. The very existence of a body charged with overseeing social science research means that pro-regulatory incentives have a weight and formal authority they would not be given in the absence of IRBs.

What we have, then, is a spectrum of incentives regimes: one end of the spectrum leans toward extensive pre-research oversight (IRBs) and the other end of the spectrum leans toward minimal pre-research oversight (no IRBs). The IRB-dominated regime is structured so that errors will be made in favor of more bureaucracy and regulation. That was indeed the very point of establishing IRBs, since many ethicists worried that pre-IRB research erred too often in ways that were genuinely harmful to human subjects. I am prepared to say that, for biomedical research, erring on the side of caution may be appropriate. But in social science research, where the risks to human subjects are typically less drastic, less obvious, and less frequent, a move along the spectrum toward somewhat less pre-research review is needed.

### *B. Regulatory Pressures on Academic Institutions*

Pro-regulatory incentives also affect the larger research institutions of which IRBs are a part. As a condition of receiving federal research money, universities must give assurance to the federal government that they have adopted principles to protect human subjects in research *regardless of whether the research is supported by federal funds*.<sup>47</sup> While federal law does not specify the content of these principles for non-federally funded re-

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<sup>46</sup> See, e.g., *Shuttlesworth v. City of Birmingham*, 394 U.S. 147 (1969) (striking down a parade permit scheme whose administration effectively vested unfettered discretion in licensing officials); *Hague v. CIO*, 307 U.S. 496, 500 (1939) (striking down ordinances that, inter alia, imposed a flat ban on public distribution of printed materials, and required a permit, issued at the uncontrolled discretion of the public safety director, for all public meetings and demonstrations).

<sup>47</sup> 45 C.F.R. § 46.103(b)(1) (2005).

search, “a university is plainly under considerable pressure from the government to apply its procedures to all human-subject research.”<sup>48</sup>

Possible litigation arising from claimed harm to human subjects in research is another source of pro-regulatory pressure on universities to expand the jurisdiction of IRBs beyond federally funded research. Litigants can be expected to claim that the Common Rule sets the standard of care in negligence actions and that a university’s failure to adopt it for non-federally funded research is unreasonable. Similarly, universities can be expected to defend against tort claims by pointing to their rigorous adherence to the Common Rule.<sup>49</sup>

### C. *Incentives and First Amendment Theory*

The ultimate effect of these incentives on IRBs and universities is a tendency to overregulate: that is, to regulate more than is optimal as measured against the amount and quality of regulation we would expect if the incentives were more balanced between the needs of research and the need to protect human subjects from unethical and harmful research. Overregulation leads to two effects that are troubling under First Amendment theory.<sup>50</sup> First, overregulation will produce regulatory partisanship.<sup>51</sup> It will systematically disadvantage research advancing unpopular causes and ideas, discourage the use of novel methodologies, and deter research on sensitive topics. Second, overregulation will exacerbate the problem of regulatory incompetence.<sup>52</sup> More regulation will increase the opportunities for regulatory authorities to get it wrong, that is, to make decisions that are erroneous even given the goals of the regulatory system. For example, lack of knowledge of the subject matter of proposed research or of the methodologies appropriate to a given field will cause IRBs to place restrictions on it in serious and unnecessary ways they cannot fully appreciate. Regulatory incompetence theory suggests that these errors will not necessarily even advance the goal of protecting human subjects.

The “mission creep”<sup>53</sup> that results from pro-regulatory incentives both enlarges the jurisdiction of IRBs (e.g., beyond federally funded research)

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<sup>48</sup> *Protecting Human Beings*, *supra* note 12, at 60.

<sup>49</sup> *Id.*

<sup>50</sup> I am not arguing, here, that existing IRB regulation necessarily violates the First Amendment. Instead, I am arguing that regardless of whether the First Amendment has been violated, existing IRB regulation raises concerns that should be familiar to First Amendment theorists.

<sup>51</sup> On the problem of partisanship under the First Amendment, see Dale Carpenter, *The Antipaternalism Principle in the First Amendment*, 37 CREIGHTON L. REV. 579, 649 (2004) (free speech operates as a safeguard against ideological favoritism by government).

<sup>52</sup> On the problem of incompetent regulation under the First Amendment, see *id.* at 632 (free speech operates as a safeguard against regulatory incompetence by government).

<sup>53</sup> See Richard A. Shweder, *Protecting Human Subjects and Preserving Academic Freedom: Prospects at the University of Chicago* 2–3 (unpublished essay), <http://humdev.uchicago.edu/shwederProtectingSubjects.doc> (last visited Mar. 17, 2007).

and causes them to act unnecessarily restrictively within that enlarged jurisdiction (e.g., by erring in favor of finding research nonexempt). The prospect of overregulation contributes to even more self-censorship by researchers.

### III. SOME MODEST REFORMS

With these incentives tugging IRBs and their universities toward ever-greater regulation of social science research, we should consider reform that will pull them in the other direction. Some of the proposals below could be adopted at the individual institutional level, without the need for any change in federal or state regulation. Some would require adjustments in the Common Rule. All of them are relatively modest. No single one of them by itself will make a real difference. Several of them together might.

A more radical series of proposals—like ending IRB supervision of social science research not involving physical risk to human subjects or even eliminating IRBs altogether—might be sound in principle, but they seem unlikely to be adopted given the bureaucratic momentum behind the regulation of research.<sup>54</sup> Many reform proposals have been offered by others, some quite good and others probably not very helpful. A common proposal—to give researchers a right to appeal unfavorable IRB decisions to an “appellate” IRB—sounds good in theory but is likely to be unattractive to either universities or researchers in practice since it would add another layer of bureaucracy.<sup>55</sup> I have tried not to repeat most of the prominent reform proposals here.

The modest reforms I propose below broadly fall into three categories: IRB membership and structure, substantive IRB jurisdiction, and institutional liability.

#### A. *IRB Membership and Structure*

##### 1. *Require basic First Amendment training for IRB Members and include a First Amendment expert as a member of the IRB.*—

University IRBs require social-science researchers “to take the same training as is required of medical researchers.”<sup>56</sup> My own home institution,

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<sup>54</sup> For some reform proposals, see Bosk and De Vries, *supra* note 9 (proposing more and better studies of how IRBs work, increasing social scientist participation on IRBs, increasing social scientists’ knowledge of IRB rules, educating IRB members about various methods of research, creating a speedy appeals process, and learning from other countries’ review of social science research); *Protecting Human Beings*, *supra* note 12, at 67 (proposing an increase in the number of social scientists serving on IRBs, a right to appeal, more education at universities about how IRBs work, compiling synopses of research proposals submitted to IRBs along with a description of their decisions on the proposal, and exemption of certain types of research from IRB review).

<sup>55</sup> See *Protecting Human Beings*, *supra* note 12, at 66–67.

<sup>56</sup> Jack Katz, To the Participants in the UCLA, May 2002, Fieldwork Conference (May 8, 2002) (unpublished memorandum on file with author).

the University of Minnesota, has adopted the collaborative training program known as CITI, which is shared by numerous other IRBs across the country.<sup>57</sup> Under the CITI program, training begins by recalling the horrors of Nazi experimentation on humans, as if social science researchers in the modern United States are even remotely analogous. Little attention is given to the enormous importance of social science research in advancing human knowledge and informing public policy makers.

Notably absent from “IRB culture” is “any recognition of First Amendment issues” and values.<sup>58</sup> For IRB members (and researchers), the backdrop for considering restrictions on social science research ought to be these values of free speech, association, and academic freedom, not gruesome experiments on human bodies. The relevant political context is “the American Revolution and the Bill of Rights, not fascist regimes and twentieth century war crimes trials.”<sup>59</sup> IRB members need to be nudged out of the regulatory mindset that academic research “is a privilege, not a right.” I am not arguing here that research *is* a “right” enforceable in courts, though there are plausible First Amendment interests at stake. Instead, I am suggesting that IRB members should be sufficiently informed about these interests so that they internalize a norm of respect for the value of research and a concern about the dangers of regulation.

First Amendment training might include, among other things, familiarizing IRB members with basic free-speech theories about the need for a robust marketplace of ideas; the need to avoid chilling valuable speech and research; the history of government incompetence and ideological partisanship in suppressing speech and academic freedom and in censoring ideas and books; the critical role of universities in fostering self-government and in incubating once unpopular ideas that are now widely accepted, and so on. IRB members who are made familiar with this history and these principles might be more sensitive to the risks inherent in their own review of research. They might come to see themselves less as potential human guardians and more as potential human censors.

A related reform would be to require that at least one member of the IRB have some expertise in the area of free-speech theory and doctrine. While not every such expert is likely to be as libertarian as free-speech advocates might like, at least the presence of such a person will make it more likely that free speech and academic freedom concerns will be heard when an IRB considers restrictions on research. The First Amendment expert could, for example, be a civil liberties or law professor from within the university or a lawyer from outside the university who specializes in First Amendment law.

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<sup>57</sup> University of Minnesota, *supra* note 18.

<sup>58</sup> Katz, *supra* note 56.

<sup>59</sup> *Id.*

2. *Establish separate IRBs for biomedical and social science research at all universities.*<sup>60</sup>—IRBs developed primarily as a response to abuses in biomedical research, like the infamous Tuskegee study, in which the United States Public Health Service denied information and medical treatment to hundreds of black men infected with syphilis over a period of decades in order to track the natural progression of the disease in the human body.<sup>61</sup> Most of the proposed research that comes before IRBs is biomedical. Those in the clinical and biomedical fields, accordingly, dominate IRB membership.<sup>62</sup>

IRBs often simply transfer principles designed for the biomedical setting to the social science setting. For example, a cardinal rule of human research covered by Common Rule principles is that the researcher should ordinarily obtain informed consent before conducting the research.<sup>63</sup> This makes some sense in a laboratory setting, where an invasive procedure may take place. But the requirement of informed consent as a pre-condition for conducting, say, an oral interview for historical research, can often effectively thwart it because such consent is an ongoing process between the researcher and the person or community being studied. “Often, the demand for signed consent appears as rude, potentially threatening, and a breach of the trust previously established” between the researcher and the subject, says one researcher.<sup>64</sup>

While many large research institutions like the University of Minnesota already maintain specialty IRBs to cover biomedical, social science, and other matters,<sup>65</sup> this practice is not universal. It should be.

3. *In lieu of separate boards, require that more than one, perhaps even a majority, of the members of the IRB reviewing proposed research have the expertise to evaluate the risks and benefits of the particular research.*—As noted above, a persistent problem with IRB review of social science research is that biomedical researchers who have comparatively little familiarity with the risks, methodologies, and needs of social science research dominate IRB boards. This causes IRBs to impose restrictions that unduly hobble social science research: not because IRBs are mendacious but because they are too oblivious to the needs of research in specialized fields. While the Common Rule does mandate that an

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<sup>60</sup> Bosk and De Vries, *supra* note 9, at 257 (proposing a “specialized IRB for vetting social science research”).

<sup>61</sup> For a history of the study and its effects, see JAMES H. JONES, *BAD BLOOD: THE TUSKEGEE SYPHILIS EXPERIMENT* (2d ed. 1993).

<sup>62</sup> *For the Record*, *supra* note 11, at 63 (remarks of Jonathan T. Church).

<sup>63</sup> For a review of the informed consent requirement, see COLEMAN ET AL., *supra* note 2, at 297–369.

<sup>64</sup> *For the Record*, *supra* note 11, at 63 (remarks of Jonathan T. Church).

<sup>65</sup> *Protecting Human Beings*, *supra* note 12, at 65.

IRB have some relevant expertise for proper review, it does not go far enough.

### B. Substantive IRB Jurisdiction

1. *Exempt oral history and other interview-based research from IRB approval.*—In contrast to biomedical research, oral history and other interview-based research present no physical risk to humans. In contrast to some behavioral research, oral history and other interview-based research also present very minimal legitimate<sup>66</sup> nonphysical risk. Oral history and other interview-based research also require maximum flexibility in preparing and conducting interviews. These factors counsel strongly against pre-research IRB oversight.

If abuses occur in purely interview-based research, the institution or the law can deal with them in the way we deal with most wrongdoing in our society—*after it occurs*, through tort and other liability rules, as well as through internal institutional discipline for harmful ethical breaches. While oral-history research now qualifies for expedited review, all such wholly interview-based research should be exempt.

2. *Allow IRBs to prohibit or alter research in the social sciences only where the risks of the research substantially outweigh the anticipated benefits.*—Currently research can be prohibited or altered when, in the judgment of the regulatory-minded IRB, the risks outweigh the anticipated benefits. Given the tendency of IRBs to overestimate the risks of research when weighed against the benefits, a higher threshold might help minimize pro-regulatory errors by shifting the burden to those supporting a prohibition or alteration of proposed research.

3. *Allow social science researchers themselves, rather than IRBs, to determine whether their research is exempt from IRB approval.*—

This will save the researchers the time necessary to get validation of their exempt status. It is true that researchers will tend to conclude that their work is exempt more often than IRBs would. Researchers may be thought to have a conflict of interest in making this judgment about the exempt status of their own work.<sup>67</sup> But that is not terribly problematic if (a) we expect that IRBs will tend to *underestimate* the amount of research that is properly exempt and (b) researchers are still subject to post-research discipline when actual harm is caused.

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<sup>66</sup> I do not count as “legitimate,” for example, the embarrassment that a racist might experience in revealing that he opposed desegregation or that a police officer might have in admitting that he fabricated evidence.

<sup>67</sup> One IRB member told me that allowing researchers to determine their own exempt status would be like foxes guarding chicken coops. The analogy itself says a lot about how IRB members come to see researchers as adversarial predators who simply cannot be trusted to act ethically toward other humans.

Under this proposal, one might ask, what incentive would a researcher have to choose IRB review rather than to decide his or her research was exempt? Two incentives might be made available. First, the institution itself could enforce internal discipline against researchers who make clear errors in determining whether they are exempt. This would be something like the clearly erroneous decision standard common in law. Second, we could make pre-research IRB review a limited “safe harbor” from individual liability for researchers whose work is both approved by the IRB and conducted fully in conformity with the approved procedures.

For this proposal to work, researchers would need some basic education about the Common Rule and their home institution’s own additional rules for exemption, if any. The categories for exempt research are not terribly complicated and could probably be distributed to researchers in a very brief memo, perhaps with periodic reminders about what kinds of research qualify for exempt status.

4. *Rather than have IRBs screen social science research before it is performed—that is, engage in the sort of prior restraint the First Amendment disfavors<sup>68</sup>—have them conduct a review (and enforce internal discipline on researchers, if necessary) only after problems actually arise.*—Finally, here is my most aggressive proposal for substantive change. The general preference of the First Amendment, and of law generally, is that we punish only after harm is caused, not in anticipation that it might occur. Wrongdoers are deterred by the knowledge that they might face liability after their actions cause harm; this is usually considered sufficient to maintain a decent and humane free society. Only where the harm is unusually serious or likely should we abandon the ordinary presumption of *post hoc* punishment.

Yet IRBs turn the presumption on its head for all covered human subject research, even where the risks are usually nonphysical, minimal, and unlikely to obtain. They do not function as standard peer-review bodies—like editors of research journals or tenure committees—that examine research after it is completed. They “review” and censor research at the threshold, before it even gets off the ground.

A justification for prior restraint in the IRB context is that, in the absence of prior restraint, researchers will tend to focus too much on their own interests and goals in conducting their research, to the exclusion of ethical concerns, and thus lack the kind of objectivity we should want them to have. But this justification for IRB prior restraint applies with mirrored force to IRBs themselves. They will inordinately emphasize their own institutional interests favoring regulation to the derogation of other important interests, like academic freedom, and thus lack the kind of objectivity we

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<sup>68</sup> See generally *Near v. Minnesota*, 283 U.S. 697 (1931) (striking down a state statute placing a prior restraint on the publishing decisions of newspapers on first amendment grounds).

should expect of them. Under a post-research review system, an enforcement body akin to an IRB can appropriately rein in researchers for *actual* and harmful ethical breaches, not anticipated ones. Under a prior restraint system, there is very little to rein in pro-regulatory breaches by IRBs.

### C. Institutional Liability

1. *Adopt evidentiary rules in civil trials that exclude evidence of a university's failure to adopt the Common Rule for non-federally funded research.*—Researchers and research institutions face increasing risks of tort litigation for harm allegedly done in human-subjects research. Three developments in particular have increased the pressure on them: a diversification of legal claims, an increase in the number and types of defendants named in the lawsuits, and the use of class-actions to bring into court huge numbers of claimants and larger damage claims.<sup>69</sup> In response to this liability risk, universities have adopted federal guidelines provided in the Common Rule even for non-federally funded research as a way to satisfy federal authorities and to claim that they followed an adequate standard of care in research. Liability risk has thus pushed federal rules onto whole continents of research where it would not otherwise be applicable.

My proposal will reduce the liability-based incentive for regulatory metastasis beyond federally sponsored research. While universities and researchers will still be subject to tort actions arising from harmful research, as they should be, at least they cannot be forced to adopt federal rules as a way to defend themselves. This might help foster a bit more experimentation and competition in the adoption of ethical guidelines for human-subjects research.

### CONCLUSION

Nobody wants to see a return of the days when medical researchers used prisoners in the place of lab animals to test the toxicity of cosmetics.<sup>70</sup> Nobody wants to see humans exposed to radiation without full disclosure of the risks, as the Atomic Energy Commission once did, leaving some of them sterile and others badly burned.<sup>71</sup> These horrors are appropriately prevented through a system of prior restraint on research.

But being too risk-averse, even when it comes to human subjects, could be harmful as well. Something important is being sacrificed when

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<sup>69</sup> Michelle M. Melo, David M. Studdert, & Troyen A. Brennan, *The Rise of Litigation in Human Subjects Research*, 139 ANNALS INTERNAL MED. 40, 41 (2003).

<sup>70</sup> Mistreatment of prison inmates in medical experimentation has been common. Sharona Hoffman, *Beneficial and Unusual Punishment: An Argument in Support of Prisoner Participation in Clinical Trials*, 33 IND. L. REV. 475, 482–88 (2000) (collecting examples).

<sup>71</sup> COLEMAN ET AL., *supra* note 2, at 44–45.

vague principles of “risk” and “benefits” are enforced by regulatory bodies subject to strong pro-regulatory pressures to forbid and restrict research in the social sciences about which they know little, and where the potential harm to human subjects is ordinarily quite minimal. The answer to our historic under-regulation of research is not overregulation.

It is probably too late in the day to rethink radically our approach to the approval of research involving humans. It is not too late, however, to consider a few modest steps that will help bring the IRB process more in line with our dual goals of protecting humans from unscrupulous researchers and protecting research from all-too-human regulators.

