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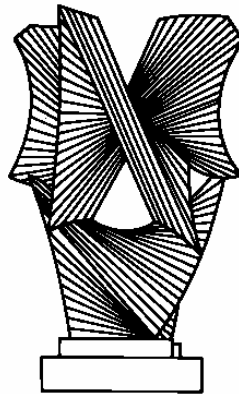
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## THE NEW CENSORSHIP: INSTITUTIONAL REVIEW BOARDS

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PHILIP HAMBURGER

THE NEW CENSORSHIP:  
INSTITUTIONAL REVIEW BOARDS

Do federal regulations on Institutional Review Boards violate the First Amendment? Do these regulations establish a new sort of censorship? And what does this reveal about the role of the Supreme Court?

Institutional Review Boards (so-called “IRBs”) license research in accord with federal policy. The federal government seeks to minimize the risk that research performed on human subjects will cause them harm, and the government therefore has adopted regulations that induce universities and other research institutions to establish IRBs.<sup>1</sup> In accordance with these regulations, a research institution typically creates at least one IRB and requires students, teachers, and other personnel to get the IRB’s permission before they conduct research on human subjects. Thus, a professor who wants to study human subjects must first submit a proposal to the IRB, which will review the proposal and evaluate its risk and on this basis will grant or deny him permission to do his research.<sup>2</sup> The professor must

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<sup>1</sup> See, for example, 45 CFR Part 46. All citations here to CFR refer to the 2004 version.

<sup>2</sup> See, for example, 45 CFR Part 46.

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get this prior permission not only if he wants to conduct a dangerous physiological experiment but also if he merely wants to ask individuals about their political opinions. The primary question here is whether the federal regulations establishing this system of licensing violate the First Amendment. The initial constitutional problem points to a second, more general concern, that government has developed a new kind of censorship. This, in turn, reveals a third, even more expansive danger, that the Supreme Court's doctrines on federal spending and on the First Amendment have undermined this Amendment's guarantee against licensing and have thereby weakened the capacity of the people to preserve their freedom from censorship.

The federal government adopted regulations on IRBs because research on human subjects can be dangerous. Much research on human subjects causes little or no harm, but there are grim examples of research that has gone awry, causing serious injury and even death. Although the risks of a research project cannot always be measured, they can often be anticipated and minimized, and to this end, it has long seemed essential that there be legal mechanisms to limit the risks to human subjects. The federal government began to use review boards for its own scientists in the 1950s, and the World Health Organization endorsed such committees in its *Declaration of Helsinki* in 1964.<sup>3</sup> The demands for IRBs gathered support after Henry K. Beecher published his prominent critique of medical studies in which researchers put subjects at risk without adequately seeking informed consent, and especially after the *New York Times* published an expose of the Tuskegee syphilis study.<sup>4</sup> In response to the anxieties about harm from research, the federal government could have relied upon approaches that did not involve licensing

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<sup>3</sup> World Health Organization, *Declaration of Helsinki*, 2 *British Med J* 177 (July 18, 1964). For the early history of IRBs in the federal government, see William J. Curran, *Governmental Regulation of the Use of Human Subjects in Medical Research: The Approach of Two Federal Agencies*, 98 *Daedalus* 542, 574–77 (1969); Robert J. Levine, *Ethics and Regulation of Clinical Research* 322–25 (1986).

<sup>4</sup> Henry K. Beecher, *Ethics and Clinical Research*, 274 *New Eng J Med* 1354 (1966). The Tuskegee study began in the early 1930s and aimed to examine the course of untreated syphilis in black men in Macon County, Alabama. Particularly after the 1972 *New York Times* article, the study came under severe criticism for misinforming the men that research was free medical treatment, for failing to seek informed consent, and for not informing the men about penicillin or giving it to them when this remedy became generally available for civilians after World War II. For this history and brief summaries of some of the more prominent research projects that came under criticism, see Levine, *Ethics and Regulation* at 69–72 (cited in note 3).

and that were more proportionate to the dangers of research. Instead, it began to adopt policies in the 1960s, and regulations in the 1970s, that systematically persuaded private and state institutions to adopt IRBs.<sup>5</sup> In some specialized contexts, the government directly required IRBs, but more generally it made IRB licensing a condition of its support for research, and this general use of IRBs to protect human subjects is the focus of this inquiry.<sup>6</sup>

The primary constitutional problem is the First Amendment's prohibition against licensing.<sup>7</sup> This Amendment generally forbids licensing of the press and, presumably, of speech.<sup>8</sup> In this regard, it responds to dangers that became evident in seventeenth-century England, where the Star Chamber issued regulations requiring persons to get permission from a licensor before they printed or caused to be printed any book or pamphlet. This licensing has come to be known as "censorship," and the First Amendment prohibits it. Of course, government frequently licenses conduct and products, as when the FDA licenses drugs, but the government cannot, consistently with the First Amendment, institute licensing of speech or of the press. Accordingly, it seems necessary to consider the constitutionality of the federal regulations on IRBs. These regulations establish mechanisms under which students, teachers, and others must get permission to conduct their research, and the regulations

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<sup>5</sup> In 1966, for example, the Surgeon General issued a policy statement "extending the requirements of 'prior review of research involving human beings' to all PHS grants," and he introduced the system of institutional assurances. Curran, 98 *Daedalus* at 577 (cited in note 3). For the introduction of the regulations in the early 1970s, see Thomas A. Huff, *The IRB as Deputy Sheriff: Proposed FDA Regulation of the Institutional Review Board*, 27 *Clinical Research* 103 (1979). For an overview of the history from the 1940s to the present, see National Research Council, *Protecting Participants and Facilitating Social and Behavioral Sciences Research*, ch 3 (2003).

<sup>6</sup> The government directly requires IRBs in two specialized regulatory regimes, which lie beyond the scope of the more general inquiry here. First, some statutes and regulations enforced by the Food and Drug Administration ("FDA") require the use of IRBs, and, second, the Privacy Rule under the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") requires the use of either Privacy Boards or IRBs. Whereas the federal government uses conditions on its support for research as its general means of securing IRB protection for human subjects, the laws associated with the FDA more narrowly require the use of IRBs to protect human subjects in exempted investigations, and the HIPAA Privacy Rule requires the use of IRBs or Privacy Boards to protect the privacy of medical information. They thus use IRBs in ways that extend beyond the government's standard regime for protecting human subjects, and because they therefore require slightly different analysis, they are left for separate consideration.

<sup>7</sup> Incidentally, it will be seen below that licensing by IRBs is not the only means of preventing injuries to human subjects. See text at notes 160–63.

<sup>8</sup> US Const, First Amendment (1791); Leonard Levy, *The Emergence of a Free Press* (1985).

thereby seem to be in tension with the First Amendment's prohibition against licensing. As it happens, there are other important constitutional questions about the regulations—questions about the enumeration of powers; about vagueness and overbreadth; about different types of speech; even about a possible right of research or inquiry. The most basic issue, however, is the licensing of speech or the press.<sup>9</sup>

Curiously, the First Amendment problems with IRBs are both familiar and largely unexamined. Over the past several decades, professors and students have frequently complained that IRBs abridge their liberty—both their freedom from censorship and their more general academic freedom.<sup>10</sup> Their complaints, however, have elicited little serious attention, and it is difficult to find systematic, scholarly studies that question the constitutionality of the federal regulations.<sup>11</sup> Indeed, among government regulators and members

<sup>9</sup> The licensing of speech, or of the press, is examined here largely without elaboration of the other constitutional issues. Similarly, this inquiry focuses on only the most prominent federal IRB regulation—the so-called Common Rule—and on its enforcement through conditions on government spending. See text at note 6. This essay thus leaves the other constitutional issues, other modes of securing compliance, other federal regulations, let alone the state IRB laws, to be explored elsewhere.

<sup>10</sup> Many academics, especially in the humanities and social sciences, have made such complaints, and although most do so in a rather diffuse manner, some are more effective. For example, an ethnographer, Jack Katz, writes: "It is a growing dilemma for the ethnographer whether to take a stand against IRBs' unannounced, presumably unintended, and increasing infringements of constitutionally protected inquiry and expression. IRBs act in the classic posture of censorship boards when they require prior approval of inquiries that would be the right of any U.S. resident to make. Prior[] restraints, as opposed to processes of review and sanctioning after the fact, impose especially troublesome chilling effects." Incidentally, he also notes: "We should remember that the Bill of Rights speaks not of 'journalism' but of freedoms of assembly (association), speech (making inquiries through questioning and observing practices that are routine in everyday social life) and press (publication)." Jack Katz, *To Participants in the UCLA, May 2002, Fieldwork Conference* (May 8, 2002), at [http://leroyneiman.sscnet.ucla.edu/katz5\\_8.htm](http://leroyneiman.sscnet.ucla.edu/katz5_8.htm).

<sup>11</sup> There have been only a few systematic, academic legal inquiries into the lawfulness of the federal regulations under the First Amendment. John Robertson defends the constitutionality of the laws on IRBs on both spending and First Amendment grounds. John Robertson, *The Law of Institutional Review Boards*, 26 *UCLA L Rev* 484 (1979); John Robertson, *The Scientist's Right to Research: A Constitutional Analysis*, 51 *S Cal L Rev* 1203, 1277 (1977). In another piece, he "show[s] that governmental regulation of social research through the IRB system . . . is constitutionally legitimate." John A. Robertson, *The Social Scientist's Right to Research and the IRB System*, in Tom L. Beauchamp et al, eds, *Ethical Issues in Social Science Research* 357 (1982).

In the law reviews, apparently only a student note argues that the current regulations are unconstitutional, and, revealingly, it does so only by suggesting that research is expressive conduct, which must be evaluated under *United States v O'Brien*, 391 US 367 (1968). Michael D. Davidson, Note, *First Amendment Protection for Biomedical Research*, 19 *Ariz L Rev* 893, 917–18 (1977). In a recent unpublished draft, however, Matthew Finkin argues against IRBs as prior restraints. "Pre-Approval of Social Science Research and the Erosion of Academic Freedom" (unpublished draft, cited with author's permission).

of IRBs, the constitutional issues raised by researchers tend to get almost casually dismissed.<sup>12</sup>

<sup>12</sup> One researcher states that there is an “absence in IRB culture of any recognition of First Amendment issues.” Jack Katz, *To Participants in the UCLA, May 2002, Fieldwork Conference* (May 8, 2002), at [http://leroyneiman.sscnet.ucla.edu/katz5\\_8.htm](http://leroyneiman.sscnet.ucla.edu/katz5_8.htm). In fact, the constitutional complaints about IRBs are well known, but they tend to get casually brushed aside with relatively little analysis, and even the formal defenses of the constitutionality of IRBs sometimes have a peculiarly dismissive tone.

The tone of the regulators may be observed in the recollection of the head of the office that would become the Office for Human Research Protections: “The charges were led by . . . [Ithiel de Sola] Pool . . . , who insisted that . . . our four pages of fine print in the *Federal Register* were about to lay waste to the First Amendment of the Constitution.” C. R. McCarthy, “Introduction: The IRB and Social and Behavioral Research,” in J. E. Sieber, ed., *NIH Readings on the Protection of Human Subjects in Behavioral and Social Science Research* 8–9 (1984), as quoted in National Research Council, *Protecting Participants* at 71 (cited in note 5).

Some defenders of IRBs dismiss the First Amendment concerns as rhetoric. For example, Robertson (who takes the constitutional issues more seriously than most commentators) is reported to have suggested that “scientists are fond of using the ‘rhetoric of rights’ to support the freedom of inquiry.” He apparently stated that research is protected by the First Amendment but that First Amendment rights are “negative rights” and that they therefore offer only limited protection against conditions on funding. Vivien B. Shelanski, “*Government Control of Science*,” Opening Session of the Second National Symposium on Genetics and the Law, Boston, May 21–23, 1979, 4 *Science, Technology, & Human Values* 46, 47 (1979). Levine writes: “Opponents of federally mandated IRB review and approval of research involving human subjects commonly refer to this activity as ‘prior restraint.’ This rhetorical device seems to support their claim that it is unconstitutional, a violation of the First Amendment. Actually, according to Tribe . . . the First Amendment is not an absolute bar to prior restraint, . . .” After acknowledging some countervailing arguments, he quickly concludes: “I have no wish to enter this debate. I do, however, wish that all concerned would cease to call IRB review prior restraint unless they intend the proper meaning of this term.” Levine, *Ethics and Regulation* at 359 (cited in note 3).

A prominent example of how the First Amendment problems get dismissed appears in a report published by the Association of American University Professors (“AAUP”), which ordinarily is devoted to protecting the freedom of academics. In opposition to arguments about “prior review,” the report states: “This position rests on the mistaken premise . . . that scholars have the right to be provided with federal funds to support their research without providing assurances that they will protect their human subjects.” In support of this position, it quotes: “If no right is violated by the imposition of a particular condition on federal research funds, then plainly no academic freedom is violated by the imposition of that condition on federal research funds. No one complains if a federal agency aims at ensuring that its available research funds be expended on scientifically valuable research; and no one complains if it establishes a fair system of peer review (a form of ‘prior review’) for assuring itself of the scientific value of a research proposal. HHS may certainly require assurance of the scientific value of a research project before funding it; we think HHS may also require assurance that the risks imposed by the research are reasonable before funding it.” AAUP, *Protecting Human Beings: Institutional Review Boards and Social Science Research*, *Academe: Bulletin of the AAUP* 55, 58–59 (May–June 2001). It should not have been difficult to discern that the government’s review of research proposals for purposes of determining its own action (whether in funding outside researchers or directing the work of internal researchers) reveals little about the constitutionality of laws setting up a system of licensing for human subjects research by students, faculty, and other personnel in universities and other research institutions across the country. As will be seen below, moreover, the suggestion that the government requires IRBs merely to avoid funding dangerous research is mistaken.

As for the “prior review” of research that is not federally funded, the report states: “The

IRBs have not elicited much constitutional concern in part because the federal regulations on IRBs adopt mild methods and appeal to popular moral sentiments, and this suggests the second problem here, that the regulations establish a new, soft kind of censorship. Instead of harshly imposing the force of law on individuals, this censorship seeks only the cooperation of institutions; instead of attempting to repress popular opinion, it appeals to the moral sensibilities of a majority. Indeed, rather than aim at political or religious ends, this censorship aspires to be bureaucratic, and rather than threaten civil liberties, it attempts to protect them. This is disarmingly unlike the censorship of the Star Chamber, and it is almost enough to make censorship attractive.<sup>13</sup>

With this mild and moral tenor, the new censorship seems to slip past both political and constitutional barriers. At the very least, this censorship escapes popular opposition. In addition, it appears to avoid constitutional obstacles—preeminently, those of the First Amendment. To be sure, the federal regulations on IRBs are unambiguously within the purview of the First Amendment, for although they concern research, they directly target and even specify speech and the press—for example, by defining “research” in terms of speech and the press.<sup>14</sup> In other ways, however, the federal regulations seem to escape the First Amendment. Under the Court’s doctrine on spending, Congress enjoys an expansive power to spend and place conditions on its spending, without clear limitations, and the federal regulations on IRBs take advantage of this uncertainty to introduce licensing not by force of law, but rather by means of

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absence of a direct financial connection between the government and the individual scholar . . . does not relieve the researcher of the professional obligation not to harm human subjects. Accordingly, a university’s effort to ensure that all researchers comply with its human-subject regulations does not offend academic freedom. . . .” *Id.* at 59. Leaving aside the attribution of professional obligations to researchers (for which, see note 161), a researcher’s moral duty to avoid harm sheds scarcely any light on the question of what method of enforcing his duties (whether moral or legal) the government can ask a university to impose.

<sup>13</sup> Of course, even the old censorship contained elements of the new. Especially in a free society, a government cannot easily license speech or the press without the cooperation of other institutions, and therefore already in the sixteenth and seventeenth centuries, the English government sought to enlist the assistance of organizations and individuals. For example, it delegated some licensing functions, as seen, to prelates, judges, and university officials, it relied on the Stationers Company (or printers’ association) for some enforcement, and it encouraged the English to support the licensing as part of a moral endeavor to prevent “abuses” in the press. The new censorship, however, takes the cooperation (including the moral emphasis and the delegation to other institutions) even further.

<sup>14</sup> See Part III below.



conditions on federal support for research—an approach that may seem, initially, to sidestep the First Amendment’s limit on the constraints of law. Similarly, under the Court’s First Amendment decisions, there is reason to think that this Amendment’s guarantee of speech and the press no longer establishes any absolute prohibition, and the federal regulations on IRBs make use of this opening to introduce licensing as necessary to protect human subjects—a moral end that may appear to outweigh the constitutional presumption against the means. In fact, as will be seen, the federal regulations on IRBs fail to satisfy the First Amendment, but they allow a casual observer to believe that they might get by, and this has been enough to make the new censorship legally plausible.<sup>15</sup>

Yet the new censorship escapes the First Amendment only because of a third problem: that the Court has undermined the First Amendment freedom of speech, or of the press, in ways that diminish the confidence of Americans that they have a right to be free from the new censorship. Shortly before proposing the Bill of Rights, James Madison wrote to Thomas Jefferson that in a nation in which the people control the government, a bill of rights would be valuable primarily because “[t]he political truths declared in that solemn manner acquire by degrees the character of fundamental maxims of free Government, and as they become incorporated with the national sentiment, counteract the impulses of interest and passion.”<sup>16</sup> In modern terms, the people would “internalize” the truths enumerated in the Bill of Rights, and even if a majority would not immediately restrain itself, it would, perhaps, when a minority appealed to the fundamental maxims of the Bill of Rights, to which Americans as a whole, including the majority, had become attached.

The Supreme Court, however, has developed and legitimized a Congressional spending power that seems to allow Congress to impose licensing through conditions on its spending, and having internalized this conception of a federal spending power only slightly limited by notions of unconstitutional conditions, observers often assume that if the government uses conditions on its spending to obtain IRBs, there is no clear or substantial First Amendment

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<sup>15</sup> Incidentally, the regulatory regimes associated with the FDA and HIPAA directly impose a requirement that one get permission without provoking opposition because, unlike the more general implementation of IRBs through federal support for research, they place their burdens on relatively narrow categories of institutions and individuals.

<sup>16</sup> James Madison, Letter to Thomas Jefferson (Oct 17, 1788), in Robert Rutland et al, eds, 11 *Papers of James Madison* 297 (1977).

objection.<sup>17</sup> The Court, moreover, in expanding the First Amendment freedom of speech, or of the press, has suggested that this freedom is never absolute—that even the Amendment’s prohibition on licensing is always subject to overriding government interests—and many commentators have therefore assumed that the moral purposes of IRBs can outweigh the constitutional objections.<sup>18</sup> In such ways, while the Court has expanded federal power and individual liberty, it has compromised one of the “fundamental maxims of free Government” in the enumeration of rights. It thus has weakened an essential mechanism by which a majority and the government might refrain from imposing the new censorship and by which minorities and individuals might resist it.<sup>19</sup> As it happens, the federal

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<sup>17</sup> See, for example, the quotations from the AAUP report in note 12. In the late 1970s, John Robertson wrote: “Constitutional rights are rights against government interference or restriction, not entitlements to a particular share of public resources,” and even as to IRB review of research not funded by the federal government, he stated that “[i]t is unlikely . . . that review of non-funded research as a condition of federal funding would be held to be an unconstitutional condition.” Robertson, 26 UCLA L Rev at 507, 509 484 (cited in note 11). In the early 1980s, he concluded that “Social scientists thus are treated no differently from journalists. Both are subject to employer constraints . . . both are subject to restrictions attached to grants of public funds. If the government gave grants to newspapers to foster investigative reporting, it could, as it does with human subject research funds, condition them on reporters having a publisher’s ethics committee approve their investigative techniques.” Robertson, in Beauchamp, *Ethical Issues in Social Science Research* at 363 (cited in note 11).

<sup>18</sup> See, for example, quotations from the AAUP Report in note 12. In 1979, Ithiel de Sola Pool wrote a short but prominent article pointing out that the proposed regulations on IRBs were a prior restraint on speech and the press and were therefore unconstitutional “censorship.” Ithiel de Sola Pool, *Protecting Human Subjects of Research: An Analysis on Proposed Amendments to HEW Policy*, 12 PS 452 (1979). The brief response published in the same journal summarily pointed out that the courts had abandoned any absolute conception of First Amendment rights: “The . . . important question . . . is whether the First Amendment provides an absolute right that takes precedence over other constitutional rights. (This seems to be Pool’s position, and it is one denied by the courts.)” Later, this response suggested that what was needed was “a complex balancing act.” Harvey Boulay, Richard Goldstein, and Betty Zisk, *Protecting Human Subjects of Research: Proposed Amendments to HEW Policy* 13 PS 452 (1980).

What appears to be the sole law review piece arguing against the constitutionality of IRBs similarly does not treat licensing as strictly forbidden, and after examining research as expressive conduct, it concludes that “because the Supreme Court’s approach to first amendment issues seems to vary from case to case, it is impossible to draw absolute conclusions pertaining to the proper standard of review for legislation which allegedly abridges researcher’s [*sic*] rights. The problem is compounded by the need to apply a variable standard to the different types of research depending on the extent to which they entail nonexpressive actions.” Its strongest conclusion is therefore that “the government bears the burden of proving regulatory necessity” and that “the government demonstrate a compelling interest in support of the regulation.” Davidson, 19 Ariz L Rev at 895, 917–18 (cited in note 11).

<sup>19</sup> For an illustration of how even a group that advocates freedom of speech in universities has succumbed, see the report of the AAUP quoted in note 12. See also text at note 189.

regulations on IRBs are probably unconstitutional even under the Court's spending and licensing doctrines. Yet through these doctrines, the Court has left the people with little sense that the new censorship is unconstitutional, and it has thereby diminished their capacity to preserve their liberty.

Lest this third point, about the role of the Court, seem insufficiently concrete, imagine that the Court had not created a spending power until it had developed a fully functional doctrine of unconstitutional conditions. Imagine, moreover, that the Court had not suggested that government interests could outweigh the First Amendment's core prohibition against laws licensing verbal speech or the press.<sup>20</sup> Then, Congress and the executive branch probably would not have imposed IRBs in the first place. The advocates of regulating research might not have even sought a system of licensing. At the very least, those who were censored would have been confident that their constitutional rights had been infringed and would have long ago defended themselves—initially in Congress, and then in court. Under the Supreme Court's doctrines, however, Americans have lost any clear sense that they have a right to be free of the new censorship.

The Court could have avoided lending legitimacy to the new censorship by taking greater care in developing its doctrines on spending and licensing. For example, if the Court had been more systematic in developing its doctrine of unconstitutional conditions, the spending power would not have created an end run around the First Amendment. In the context of the federal government, the doctrine of unconstitutional conditions is primarily a judicial response to the dangers arising from the judicial development of a Congressional spending power, and this attempt to contain the spending power may therefore be inherently unstable and even less susceptible of precision than most judicially developed constitutional law. Yet as IRBs illustrate, if the judges remain attached to a federal spending power, they must somehow bring strength and clarity to the limitations on this power, for otherwise Americans will be unable adequately to protect their liberty. Fortunately, as will be seen, the doctrine of unconstitutional conditions renders the federal regulations on IRBs unconstitutional, but this was not

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<sup>20</sup> By "verbal speech or the press," this article means the use of words, numbers, or other language of the sort traditionally associated with speech or printing presses. More generally, see text at notes 39–42.

clear enough to restrain the government from adopting the regulations, and the spending power as limited by the current, somewhat feeble doctrine of unconstitutional conditions has left those who might have resisted the censorship without a clear sense that they have a constitutional right against it.

The other doctrine in which the Court has unnecessarily created space for the new censorship concerns licensing. The Court sometimes lumps licensing together with other mechanisms—primarily judicial injunctions—under the rubric of “previous restraints.” Anxious to explain First Amendment limits on judicial injunctions, the Court suggests that injunctions are similar to licensing in that both mechanisms can impose pre-publication review on speech or the press.<sup>21</sup> The Court thus defends a freedom from some injunctions, but at the cost of obscuring the distinctiveness of licensing and depriving it of its central place in First Amendment doctrine. Indeed, by associating licensing with the other restraints, which are not absolutely prohibited, the Court can scarcely avoid the conclusion that licensing, like the other restraints, is only presumptively prohibited and that it can be justified by sufficiently substantial government interests.<sup>22</sup> Yet, as will be seen, the licensing of speech or of the press—at least licensing of the verbal core of speech or the press—is very different from other pre-publication restraints and is absolutely prohibited. Other pre-publication restraints, notably judicial injunctions, impose prior review, but they do not generally require persons to get permission before speaking, writing, printing, or publishing. In contrast, licensing makes it necessary for persons to get permission, and it thus is dangerous in different ways than other constraints on the press.<sup>23</sup> The First Amendment centrally and unequivocally forbids laws requiring that one get permission for verbal speech or the press, and even while the Court was developing broader, nonabsolute freedoms (for injunctions, post-publication restraints, and nonverbal speech and the press), it could have done more to preserve the unqualified character of this core freedom from licensing. The Court needs to restore the cen-

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<sup>21</sup> See text at note 31. Vincent Blasi observes that “[t]he Court no longer asks whether a challenge procedure amounts to the equivalent of a licensing system,” but instead inquires about “[p]rior restraint.” Vincent Blasi, *Toward a Theory of Prior Restraint: The Central Linkage*, 66 *Minn L Rev* 11, 12 (1981).

<sup>22</sup> See text at notes 36–38.

<sup>23</sup> For the dangers of licensing, see Thomas Emerson, *The Doctrine of Prior Restraint*, 20 *Law & Contemp Probs* 648 (1955).

trality of licensing in the First Amendment. It usually understands that licensing is distinctively prohibited, but it denies that there is any unequivocal freedom from licensing, and it thereby diminishes the capacity of Americans to preserve this freedom.

In sum, the federal regulations on IRBs would appear to violate the First Amendment. This will become apparent from six observations: (I) at least for verbal speech and the press, the First Amendment absolutely bars laws requiring licensing; (II) the federal regulations on IRBs set up a system of licensing; (III) these regulations target and even specify speech and the press as the object of their licensing, including verbal speech and the press; (IV) the federal government imposes this licensing by means of unconstitutional regulatory conditions on federal spending and by means of state tort law; (V) the injury arising from research on human subjects does not justify the licensing; (VI) the licensing causes serious injuries to researchers and their use of speech and the press. These observations reveal that the federal regulations on IRBs are constitutionally vulnerable. They further suggest that the regulations establish a new censorship, which dispels opposition through its mild and moral tenor, but which remains as unconstitutional as the old. Most broadly, they hint at the danger of Supreme Court doctrines that undermine enumerated rights—doctrines that allow those in power to believe they need not worry about abridging such rights and that leave those whose rights are abridged without confidence that they have constitutional grounds on which to protest.

## I. THE FIRST AMENDMENT

The First Amendment states that “Congress shall make no law . . . abridging the freedom of speech, or of the press,” and from its inception, it has been understood to bar the federal government from adopting licensing laws.<sup>24</sup> During the past century, the Amendment has more generally been interpreted to prohibit both pre- and post-publication restraints, and as a result of these expansive modern conceptions, the freedom of speech, or of the press, often seems contingent on government interests.<sup>25</sup> Nonethe-

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<sup>24</sup> US Const, First Amend (1791); *Lovell v Griffin*, 303 US 444, 451 (1938); Levy, *The Emergence of a Free Press* (cited in note 8); Philip Hamburger, *The Law of Seditious Libel and the Control of the Press*, 37 Stan L Rev 661 (1985).

<sup>25</sup> For the dynamic by which the expansion of a right can lead to diminished access, see Philip Hamburger, *More Is Less*, 90 Va L Rev 835 (2004).

less, the Amendment's traditional, core prohibition against licensing of verbal speech or the press remains absolute.

Licensing was the method of regulating the press that prevailed in sixteenth- and seventeenth-century England, where the Star Chamber attempted on behalf of the government to prevent "abuses" of the press by establishing a system of licensing printing.<sup>26</sup> The Star Chamber delegated to various specialized licensors—such as the judges, the Earl Marshall, the prelates, and university officials—the task of licensing manuscripts within their areas of specialization. The university officials, for example, shared with the prelates a jurisdiction over all books but especially those "of Divinity, Phisicke, Philosophie, [and] Poetry."<sup>27</sup> Although they could deny a license to a manuscript, they more often gave licenses, even if sometimes only after making deletions or other modifications.

The First Amendment has been understood from the time of its adoption to forbid the government from imposing this licensing of printing. In opposition to censorship, John Milton and others in seventeenth-century England argued for "the Liberty of unlicens'd Printing," and this liberty to use a printing press without prior permission became known as the freedom of the press.<sup>28</sup> In 1695, when John Locke joined the protests against licensing, the English government abandoned its licensing statute, and in the eighteenth century, both Englishmen and Americans claimed primarily this

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<sup>26</sup> *A Decree of Starre-Chamber; Concerning Printing*, sig A4[r] (1637). For the legal mechanisms used in seventeenth-century England to control the press, see Hamburger, 37 *Stan L Rev* 661 (cited in note 24).

<sup>27</sup> *A Decree of Starre-Chamber*, sig B3[r-v], § III (cited in note 26).

<sup>28</sup> John Milton, *Areopagitica: A Speech of Mr. John Milton for the Liberty of Unlicens'd Printing* 1 (1644). Like the licensors, Milton concerned himself with the licensing of printing rather than publication. Although publication or the sharing of a writing with another person was an element of the crime of seditious libel, unlicensed printing was what violated the licensing laws. Being in part a rejection of licensing, the First Amendment specifies the freedom of the *press*. Thus, the Amendment at its core protects the mere saying and printing of words, even if they are not shared with others; it most essentially concerns the words themselves, and cannot be confined to a freedom of publication or communication. This matters here because IRBs license a range of handwritten notes, printed surveys, tabulations of data, e-mails, and other informal materials. These are not publications in the lay sense. If prepared by a researcher for his own benefit, they may not be considered publications as a matter of law. Perhaps, moreover, they will not even be considered communications in a narrow or immediate sense. IRBs thus illustrate the importance of recalling that First Amendment doctrine has its foundations not merely in a freedom of publication or communication, but, more fundamentally, in a freedom of speech, or of the press.

freedom from licensing as their freedom of the press.<sup>29</sup> Similarly, although they were not as clear about their conception of freedom of speech, they evidently assumed that speech was also to be free from laws requiring that one get prior permission. Of course, many Americans were not unaware of the danger from injunctions and post-publication penalties, but when they discussed such matters, they usually assumed that the laws would employ these mechanisms against the injurious use of speech or the press, and they therefore tended to emphasize that the First Amendment protected against licensing. Thus, the licensing condemned by Milton and Locke was what the First Amendment's guarantee of speech and the press most clearly forbade.<sup>30</sup>

Today, however, this First Amendment freedom from licensing has expanded, first, into a freedom from prior restraints. According to the Supreme Court, the freedom from licensing should be understood more broadly to include, in addition, a freedom from some types of judicial injunctions. It thus seems to be not merely a freedom from licensing, but more generally a freedom from pre-publication restraints.<sup>31</sup>

Second, since its adoption, the First Amendment has come to prohibit a wide range of post-publication restraints on speech and the press—most notably, if these restraints discriminate on the basis of content or if they suffer from excessive vagueness or overbreadth. Content discrimination occurs with greatest clarity when a law penalizes a particular point of view, although also frequently when a law penalizes a subject matter or class of speaker.<sup>32</sup> Even if a law

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<sup>29</sup> John Locke, Common's Resolutions on the Licensing Bill (1695), Carl Stephenson and Frederick George Marcham, eds, *Sources of English Constitutional History* 619 (1937). As the Supreme Court has explained: "The struggle for the freedom of the press was primarily directed against the power of the licensor. It was against that power that John Milton directed his assault by his 'Appeal for the Liberty of Unlicensed Printing.' And the liberty of the press became initially a right to publish 'without a license what formerly could be published only with one.'" *Lovell v Griffin*, 303 US 444, 452 (1938) (note omitted). See also Levy, *The Emergence of a Free Press* (cited in note 8); Hamburger, 37 *Stan L Rev* at 661 (cited in note 24).

<sup>30</sup> US Const, First Amend (1791); Levy, *The Emergence of a Free Press* (cited in note 8).

<sup>31</sup> *Near v Minnesota*, 283 US 697 (1931). The conception of licensing as a pre-publication restraint drew upon the words of Blackstone in William Blackstone, *Commentaries*, \*151–52. Even in *Near*, however, the Court clearly understood that it had to depict the injunction in the case as analogous to licensing. See note 45.

<sup>32</sup> *Burson v Freeman*, 504 US 191 (1992); *Simon & Schuster, Inc. v Members of the New York State Crime Victims Board*, 502 US 105 (1991); *Boos v Barry*, 485 US 312 (1988); *Carey v Brown*, 447 US 455 (1980); *Police Dept v Mosley*, 408 US 92 (1972). Laws can violate the First Amendment either by discriminating among different speakers, types of speech,

regulates conduct that would not ordinarily be considered speech or the press, content discrimination can reveal that, in fact, the law does abridge speech or the press.<sup>33</sup> For example, although a law prohibiting the burning of cloth does not abridge this freedom, a law prohibiting the burning of the flag does.<sup>34</sup> In contrast to laws that penalize on the basis of content, the laws regulating speech or the press that are unduly vague or overbroad do not so directly abridge the freedom of speech or that of the press, but according to the Supreme Court, they can impermissibly discourage or “chill” expression.<sup>35</sup>

and points of view or by ecumenically suppressing speech or the press without regard to such differences. The suppression could be viewed as discrimination against speech and the press as a whole, just as the discrimination could be viewed as suppression. For purposes of content discrimination, the Court often seems to treat obscenity, deceit, and incitement as distinctions of conduct rather than content.

<sup>33</sup> The Court examines the interests of the government in order to determine whether a regulation of conduct is, in reality, a regulation of speech or the press that discriminates on the basis of conduct or that otherwise abridges the freedom of speech or the press. According to the Court in *O'Brien*, “a government regulation is sufficiently justified if it is within the constitutional power of the Government; if it furthers an important or substantial governmental interest; if the governmental interest is unrelated to the suppression of free expression; and if the incidental restriction of alleged First Amendment freedoms is no greater than is essential to the furtherance of that interest.” *United States v O'Brien*, 391 US 367, 377 (1968). Such a law must be narrowly tailored, but it does not have to be the least burdensome “imaginable.” *Ward v Rock Against Racism*, 491 US 781 (1989). Under this *O'Brien* test, even a statute for which “the governmental interest is unrelated to the suppression of free expression” can be held unconstitutional under a balancing test. (Incidentally, subsequent cases have suggested that the prohibited activity must be expressive in a manner more like burning a draft card than nudity. *Barnes v Glen Theatre, Inc.*, 501 US 560 (1991); *Arcara v Cloud Books, Inc.*, 478 US 697 (1986).)

More to the point here, if the governmental interest in a statute is related to the suppression of free expression, it is “outside of *O'Brien's* test, and we must ask whether this interest justifies” the application of the statute “under a more demanding standard”—in effect, strict scrutiny and its more severe weighing of government interests. *Texas v Johnson*, 491 US 397, 403 (1989). This emphasis, however, on finding a government interest in suppression of free exercise fails to capture the degree to which the Court also, perhaps, more directly examines legislation to see if it engages in content discrimination. A suggestion of this became apparent in *Eichman*, when the Court said that the statute contained “no explicit content-based limitation,” but it was “nevertheless clear that the Government’s asserted interest is ‘related “to the suppression of free expression” . . . and concerned with the content of such expression.’” *United States v Eichman*, 496 US 310, 315 (1990). See also John Hart Ely, *Flag Desecration: A Case Study in the Roles of Categorization and Balancing in First Amendment Analysis*, 88 Harv L Rev 1482 (1975).

<sup>34</sup> *United States v Eichman*, 496 US 310 (1990).

<sup>35</sup> A law constraining speech or the press is unconstitutionally vague if persons of “common intelligence must necessarily guess as its meaning and differ as to its application.” *Connally v General Construction Co.*, 269 US 385 (1926); *Coates v City of Cincinnati*, 402 US 611 (1971).

The Court has stated the overbreadth doctrine in terms of “substantial overbreadth,” *Broadrick v Oklahoma*, 413 US 601, 615 (1973), but the precise degree of overbreadth that matters remains elusive. *Virginia v Hicks*, 539 US 113 (2003); *Virginia v Black*, 538 US 343 (2003); *Watchtower Bible and Tract Society of New York, Inc. v Village of Stratton*, 536 US 127 (2002); *Ashcroft v Free Speech Coalition*, 535 US 564 (2002); *Brockett v Spokane*



These expansive conceptions of freedom from pre- and post-publication constraints have required the use of various balancing tests to protect government interests. The freedom from pre-publication restraint is so broad that it seems necessarily contingent on the countervailing interests of government, and the more expansive freedom from post-publication restraints seems all the more contingent. Accordingly, when the Supreme Court first treated the Amendment's prohibition on licensing as a barrier to pre-publication restraints, such as judicial injunctions, it stipulated various exceptions.<sup>36</sup> Similarly, when the Court began to treat the First Amendment as a bar against post-publication restraints, it qualified the constitutional right by weighing it against the government's concerns—an approach that today can involve either a general balancing test or a strict scrutiny search for a compelling government interest.<sup>37</sup> In these ways, all First Amendment claims

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*Arcades, Inc.*, 472 US 491 (1985); *Members of the City Council of the City of Los Angeles v Taxpayers for Vincent*, 466 US 789 (1984); *New York v Ferber*, 458 US 747 (1982); *Dombrowski v Pfister*, 380 US 479 (1965). In *Hicks*, the Court explained that “[r]arely, if ever, will an overbreadth challenge succeed against a law or regulation that is not specifically addressed to speech or to conduct necessarily associated with speech (such as picketing or demonstrating).” *Virginia v Hicks*, 539 US 113, 124 (2003). It will be seen that the federal regulations on IRBs focus on conduct necessarily associated with speech and, in addition, specify and otherwise target speech and the press.

Obviously, the vagueness doctrine has due process overtones, and overbreadth is ostensibly a standing doctrine. They are, however, largely substantive doctrines. For the substantive character of the overbreadth doctrine, see Henry Monaghan, *Overbreadth*, *Supreme Court Review* 1 (1981).

<sup>36</sup> *Near v Minnesota*, 283 US 697 (1931). For the way in which broadened definitions of rights often invite qualifications on access, see Hamburger, 90 Va L Rev 835 (cited in note 25).

Thomas Emerson observed the weakness of the Court's prior restraint doctrine in the late 1960s, when IRBs were coming into vogue: “[I]t is hard to say how much vitality the doctrine of prior restraint retains at the present time. . . . it has been applied loosely to areas beyond its original scope and limited drastically in some areas central to its original purpose. . . . When employed in this way the concept becomes so broad as to be worthless as a legal rule. . . . The result. . . is that, to a substantial extent, a ‘prior restraint’ now merely signifies a type of restriction that the courts will scrutinize with special care.” Thomas I. Emerson, *The System of Freedom of Expression* 511 (1970). Emerson did not recognize that the danger arose from the Court's tendency to generalize about prior restraint without retaining the distinctive category of licensing of verbal speech or the press, but his characterization of the result is suggestive.

<sup>37</sup> *Schenck v United States*, 249 US 47 (1919). For later cases, such as *United States v O'Brien*, 391 US 367 (1968), which elaborate the current doctrine, see note 33. As the Court explained in *R.A.V.*, “[e]ven the prohibition against content discrimination. . . is not absolute.” *R.A.V. v City of St. Paul, Minnesota*, 505 US 377, 387 (1992). Before the Court began to justify constitutional limits on injunctions and pre-publication restraints by blurring the distinction between them and licensing, it spoke about the freedom from licensing in sweeping terms. For example, Holmes wrote for the Court that “the main purpose of such constitutional provisions is ‘to prevent all such previous restraints upon publications as had been practised by other governments,’ and they do not prevent the

for freedom of speech, or of the press, have come to seem contingent on government interests, and even the freedom from licensing has become only a presumption, which can be outweighed by government interests. Yet the First Amendment's traditional bar against licensing was more clear-cut—indeed, it was absolute—and surely it should remain uncompromised.<sup>38</sup>

A third expansion of the freedoms of speech and the press has taken these freedoms beyond the verbal nucleus of “speech” and “the press” to all sorts of expressive conduct and uses of government property.<sup>39</sup> This expanded protection is necessarily somewhat contingent, and in recognition of this, the Court weighs government interests and even permits limited types of licensing. In particular, the Court allows government interests to justify laws licensing expressive conduct (such as nudity) or licensing access to what is understood to be common or public property (such as the airwaves or municipal pavements)—property to which the public has strong claims but for which government needs an orderly manner of division.<sup>40</sup> Sometimes, the Court even allows licensing of conduct that

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subsequent punishment of such as may be deemed contrary to the public welfare. The preliminary freedom extends as well to the false as to the true; the subsequent punishment may extend as well to the true as to the false.” *Patterson v Colorado*, 205 US 454, 462 (1907) (citations omitted). This passage is often taken to be significant for its permissive approach to subsequent punishment. More to the point here, however, it suggests the strength of the “preliminary freedom.” Indeed, although Holmes acknowledged much room for subsequent punishments, his words about “the main purpose” left at least some space for constitutional limits on such punishments.

<sup>38</sup> It is difficult to find eighteenth-century discussions of the freedom of the press from licensing that suggest it can be overcome by the weight of government interests. Indeed, the very concept of a freedom from licensing was based on the assumption that government could protect the interests of society and government after publication. In the mid-twentieth century, a well-known debate centered on the claim that the freedom of speech, or of the press, is absolute, but that debate focused on broader conceptions of the freedom of the press than the freedom under consideration here—the freedom from any law licensing verbal speech or the press. For a summary of part of the debate, see Alexander Meiklejohn, *The First Amendment Is an Absolute*, *Supreme Court Review* 245 (1961).

It has sometimes been noted that the Securities Act of 1933 establishes a system of licensing. The Act, on its face, forbids the sale or transportation of securities before a registration statement is in effect, but it uses the prohibition on the sale or transportation of securities to obtain licensing of registration statements. Securities Act of 1934, § 5(a). Obviously, if such licensing is constitutional, this would not necessarily imply the constitutionality of the licensing of research.

<sup>39</sup> For the conception of “verbal speech or the press” in this article, see note 20.

<sup>40</sup> In these ways, such property is very different from government funds. For the licensing of conduct in ways that indirectly burden speech or the press, see *FW/PBS v City of Dallas*, 493 US 215 (1990), concerning licensing of sexually oriented businesses. For examples of the licensing of access to common or public property, see *Cox v New Hampshire*, 312 US 569 (1941); *National Broadcasting Co. v United States*, 319 US 190 (1943); *Thomas v Chicago Park District*, 534 US 316 (2002).

lies just beyond the verbal core of speech and the press. For example, in *Freedman v Maryland*, the Court gave First Amendment protection to movies, but mindful of government interests in treating movies differently from more purely verbal speech or the press, it stated that the licensing of movies would be constitutional—at least “if it takes place under procedural safeguards designed to obviate the dangers of a censorship system.”<sup>41</sup> Such concessions to government interests may be necessary for the expansion of the freedom of speech, or of the press, beyond its traditional verbal nucleus, but these concessions do not diminish the First Amendment’s absolute protection for its core freedom from licensing of verbal speech or the press. Although contingent when expanded to protect against licensing of nonverbal speech and the press, the Amendment remains at its core an absolute bar against licensing of verbal speech or the press.<sup>42</sup>

Admittedly, the First Amendment’s unyielding prohibition on licensing of speech and the press has largely been left on the sidelines

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<sup>41</sup> *Freedman v Maryland*, 380 US 51 (1965). For recent decisions that apply modified versions of *Freedman*’s procedural requirements to the licensing of sexually oriented or adult businesses, see *City of Littleton, Colorado v Z.J. Gifts D-S, L.L.C.*, 124 S Ct 2219 (2004); *FW/PBS, Inc. v Dallas*, 493 US 215 (1990).

Incidentally, although the Court did not differentiate the sound track and the projected images, these two elements invite slightly different analysis. Imagine that the sound track of the movie were reduced to an audiotape, without any visual images: This sound track seems to fall unambiguously within the category of speech, and presumably, the government could not legislate that producers or theaters must get licenses for the words of sound tracks, even if it requires the licensors to use the highest possible procedural safeguards. (Of course, it could license emissions of noise above safe decibel levels, as long as it imposed this requirement generally rather than just on speech or the press.) In contrast to the words of the sound track, the images are less fully protected. Although the Supreme Court has come to understand visual displays as part of speech and the press, it has not given them the same degree of protection as merely verbal speech and thus has been willing to allow the government to license them. In this sense, the Court treats them more like conduct.

When defending expanded conceptions of rights, lawyers and judges are almost inevitably tempted to blur the distinction between the core freedom and the newer freedoms to which the core has been extended. Hamburger, 90 Va L Rev at 835 (cited in note 25). For example, in justifying its expanded conceptions of the freedom of speech and of the press, the Court blurs the distinction between speech and expressive conduct, and in lumping them together, it often seems to conclude that licensing is presumptively unconstitutional, but not absolutely so. This, however, should not be understood to mean that the core freedom from the licensing of verbal speech or the press is really as contingent as the freedom from the licensing of less narrowly verbal conduct, such as movies.

<sup>42</sup> The exceptions listed by the Supreme Court in *Near v Minnesota* in connection with judicial injunctions do not clearly apply to licensing, for although the government could enact a rule against publication of, for example, certain troop movements, and could obtain an injunction against an attempt to publish such information, this is not to say that it could enact a general rule requiring one to get permission before publishing information about troop movements. *Near v Minnesota*, 283 US 697, 716 (1931). See text at note 147.

of First Amendment theory. Although licensing or censorship of the press was a serious danger in the sixteenth and seventeenth centuries, the threats to freedom of speech, or of the press, in the past century have appeared to come mostly from other pre-publication restraints (mainly judicial injunctions) and from various post-publication restraints (such as laws penalizing political dissent). Licensing has therefore tended to seem a relatively narrow and even antiquated concept, which has been largely displaced by the broader and more up-to-date concepts of pre-publication and post-publication restraints. Yet as already suggested, beneath the surface formed by the concepts of pre- and post-publication restraints, the Supreme Court has continued to preserve at least some elements of a distinctively strong prohibition on licensing, and this poses the central constitutional problem for federal regulations on IRBs.<sup>43</sup>

Licensing is more severely prohibited than other First Amendment problems primarily because it undermines the ideal that one does not need permission to speak or print. It has sometimes been argued that licensing is forbidden because it restrains speech before publication, and on this assumption, it has not been clear whether pre-publication restraints are really more dangerous than post-publication restraints.<sup>44</sup> More fundamentally, however, licensing is

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<sup>43</sup> It is generally recognized that there is a particularly strong prohibition against prior restraints, but because of the injunction cases, neither courts nor commentators ordinarily concede that there is an even stronger prohibition against licensing. For example, in *Southeastern Promotions*, the Supreme Court wrote: "The presumption against prior restraints is heavier—and the degree of protection broader—than that against limits on expression imposed by criminal penalties. Behind the distinction is a theory deeply etched in our law: a free society prefers to punish the few who abuse rights of speech *after* they break the law than to throttle them and all others beforehand. . . . the line between legitimate and illegitimate speech is often so finely drawn that the risks of freewheeling censorship are formidable." *Southeastern Promotions, Ltd. v Conrad*, 420 US 538, 559–60 (1975).

In *Posadas de Puerto Rico Assoc. v Tourism Co.*, the Court upheld Puerto Rican regulations requiring licensing of gambling advertisements, but as the Court noted, the "prior restraint" argument "was not raised by appellant either below or in this Court," and the Court therefore "express[ed] no view" on this question. *Posadas de Puerto Rico Assoc. v Tourism Co.*, 478 US 328, 348 n 11 (1986). Even in its analysis of the regulations as commercial speech, the case has been much criticized. <sup>44</sup> *Liquormart, Inc. v Rhode Island*, 517 US 484 (1996); *Greater New Orleans Broadcasting Ass'n v United States*, 527 US 173 (1999).

<sup>44</sup> See, for example, Justice Frankfurter's opinion for the Court in *Kingsley Books, Inc. v Brown*, 354 US 436 (1957). Earlier, Paul Freund argued that "it will hardly do to place 'prior restraint' in a special category for condemnation. What is needed is a pragmatic assessment of its operation in the particular circumstances." Paul Freund, *The Supreme Court and Civil Liberties*, 4 Vand L Rev 533, 539 (1951). In contrast, Thomas Emerson argues that prior restraint is more dangerous. Emerson, 20 Law & Contemp Probs at 648 (cited in note 23).

More generally, the notion of prior restraint has come into dispute. Martin H. Redish,

a system by which government requires permission for speech or the press, and in this respect, it differs even from other pre-publication restraints, such as judicial injunctions, which interfere prior to publication but without establishing a general expectation that one must get permission.<sup>45</sup>

By requiring that one get permission, licensing laws reverse the ordinary presumption of liberty. Whereas a person is usually free to do as he pleases, as long as he does not violate a known rule of law, licensing laws leave him unfree, until the government or its surrogates give him permission. In matters of speech or the press, licensing encourages Americans to believe that they need permission to speak, print, or otherwise use language, and any such sense of dependence on a licensor's permission seems incompatible with the vigorous speech and press that are essential for protecting liberty. Government depends upon the authority of the people, but if government can make the people feel dependent on it for permission to use speech or the press, they can hardly be expected to assert their authority in limiting government and holding it to account.<sup>46</sup> In this way, the licensing of speech and the press not only reverses the ordinary presumption of liberty but also begins to invert the very relationship of the people to their government.

This central feature of licensing—that one needs permission—has not received much attention. Certainly, the need to get per-

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*The Proper Role of the Prior Restraint Doctrine in First Amendment Theory*, 70 Va L Rev 53 (1984); John Jeffries, *Rethinking Prior Restraint*, 92 Yale L J 409 (1982); Blasi, 66 Minn L Rev at 14 (cited in note 21); Owen M. Fiss, *The Civil Rights Injunction* 68–74 (1978); Stephen Barnett, *The Puzzle of Prior Restraint*, 29 Stan L Rev 539 (1977).

<sup>45</sup> This was almost recognized even in *Near v Minnesota*, in which the Court treated an injunction as analogous to licensing. Chief Justice Hughes argued for the Court that if the statute authorizing the injunction were constitutional, “it would be but a step to a complete system of censorship,” and “[t]he recognition of authority to impose previous restraint upon publication in order to protect the community . . . necessarily would carry with it the admission of the authority of the censor against which the constitutional barrier was erected.” *Near v Minnesota*, 283 US 697, 721 (1931). For more on the relationship between the freedom of speech, or of the press, and the authority of the people in relation to government, see Alexander Meiklejohn, “The First Amendment Is an Absolute,” *Supreme Court Review* 245, 254, 258, 265 (1961).

<sup>46</sup> For the relationship between the First Amendment and the character desirable in citizens, see Vincent Blasi, *Free Speech and Good Character: From Milton to Brandeis to the Present*, in Lee C. Bollinger and Geoffrey R. Stone, eds, *Eternally Vigilant: Free Speech in the Modern Era* 61 (2002)—although the argument here concerns a narrower portion of the First Amendment liberty and a narrower degree of individual independence than discussed by Blasi. In defending the extension of the prohibition against licensing to a prohibition of injunctions, Blasi focuses on the indignity of licensing rather than the central issues of permission, but he recognizes the implications of licensing for the relation between citizens and their government. Blasi, 66 Minn L Rev at 71 (cited in note 21).

mission for the use of speech or the press (in contrast to conduct or the use of government property) is more closely associated with the seventeenth century than the twenty-first. As revealed by IRBs, however, the danger that Americans need to get permission before speaking, reading, writing, printing, or publishing is far from obsolete.

## II. FEDERAL IRB REGULATIONS

An understanding of how the federal government runs up against the First Amendment's prohibition on licensing must be based on the details of the government's IRB regulations and policies. Put simply, the regulations establish a system under which persons hoping to conduct research on human subjects at almost all universities and other research institutions must first submit a research proposal to an IRB. The IRB then reviews the research and decides whether the inquiry can proceed. In particular, the IRB will forbid the research, approve it, or, most frequently, offer approval if aspects of it are abandoned or modified.<sup>47</sup> Thus, researchers must get permission, and the IRB can suppress the proposed research—either entire projects or portions of them. The regulations are also vague and overbroad—problems often associated with li-

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<sup>47</sup> This tripartite division developed already in the 1960s, when one observer wrote: “[A]s a practical matter, many committees probably operate in such a way that few applications are clearly and unequivocally turned down. The research protocol is probably returned for further explanation and revision until the problems are ironed out to the satisfaction of the investigator and the review committee. . . . If an impasse should result, the investigator might well be allowed to withdraw the application rather than have it stamped ‘disapproved.’” Curran, 98 *Daedalus* at 586 (cited in note 3). Levine makes similar assumptions but notes four different categories of decision—approved, approved contingent upon specific revisions, tabled, and disapproved. Levine, *Ethics and Regulation* at 332–34 (cited in note 3). He also emphasizes that the IRB “nearly never” labels a project “disapproved” but instead gives the researcher a chance to withdraw it. *Id.* at 333. On account of both the conditional approvals and the withdrawals, the small number of formal decisions to disapprove cannot be taken at face value. In its Terms for Federalwide Assurances, OHRP spells out the three types of decision and states the power of modification with unusual bluntness: “The IRB(s) will have authority to approve, require modifications in, or disapprove the covered human subject research.” OHRP, *Federalwide Assurance of Protection for Human Subjects*, Terms of the Federalwide Assurance for Institutions Within the United States, Part A.5, at <http://www.hhs.gov/ohrp/humansubjects/assurance/filasurt.htm>.

The power to modify can come in the form of either a contingent approval—that is, an approval subject to conditions—or a deferral with recommendations for changes. A large but uncertain number of the modifications focus on informed consent, which, as will be seen, can become a significant barrier to research.

censing.<sup>48</sup> It is, however, the licensing itself—the requirement that researchers get permission—that is the focus of this inquiry.

#### A. THE COMMON RULE

The basic regulatory scheme is known as the “Common Rule” because it has been adopted by seventeen federal departments and agencies—most prominently, the Department of Health and Human Services (“HHS”). Supplementary regulations establish specialized rules for research on vulnerable subjects, such as (in the HHS regulations) pregnant mothers, fetuses, neonates, children, and prisoners.<sup>49</sup> The Common Rule as adopted by HHS has particularly wide application, and therefore this essay concentrates on HHS’s version, but it does so to illustrate all the federal regulations that adopt or supplement the Common Rule. In these regulations, which are casually referred to here as the “federal regulations on IRBs,” the central requirement is that an IRB must review and decide whether to approve any “research” involving “human subjects.”<sup>50</sup>

A human subject is defined by the Common Rule as “a living individual” about whom an investigator conducting research obtains “data through intervention or interaction with the individual” or “identifiable private information.”<sup>51</sup> The rule thus relies upon privacy and the character of the information to determine if research has a human subject. The notion of “identifiable private

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<sup>48</sup> For example, the regulations are vague in allowing IRBs to make decisions without rules and even on the basis of “prevailing community standards and subjective determinations,” and they are overbroad in requiring IRBs to evaluate the mere risk of harm and thus requiring them to prevent much speech and the press that will not turn out to be injurious.

The overbreadth doctrine has been applied to permit facial challenges to licensing laws. In *City of Lakewood v Plain Dealer Publishing Co.*, a city ordinance gave the mayor discretion to grant or deny permits for newspaper vending machines on city sidewalks. Although he had not misused his powers, the Court held the ordinance unconstitutionally overbroad on the ground that “a facial challenge lies whenever a licensing law gives a government official or agency substantial power to discriminate based on the content or viewpoint of speech by suppressing disfavored speech or disliked speakers.” *City of Lakewood v Plain Dealer Publishing Co.*, 486 US 750 (1988). See also *Forsyth County, Ga. v Nationalist Movement*, 505 US 123 (1992), in which a county permit ordinance allowing the county administrator to adjust fees up to \$1,000 a day was held unconstitutionally overbroad.

<sup>49</sup> 66 Fed Reg 56775; 43 id 53655; 48 id 9818; 56 id 28032.

<sup>50</sup> 45 CFR Part 46. For the current statutory authorization for the HHS regulations, see 42 USC § 289 (2004). For descriptions of some early IRBs, see Levine, *Ethics and Regulation* at 328–41 (cited in note 3), and the sources cited at id 327.

<sup>51</sup> 45 CFR § 46.102(f).

information” is particularly expansive and unclear, for it is understood to go beyond confidential medical records and other information acquired within a fiduciary duty to include other, more loosely private information, but how far it goes in this direction is not specified. For example, it may, perhaps, include information in a manuscript autobiography that an author shares with a scholar of literature, and it may include what a person says publicly in front of a limited audience, such as in a classroom.<sup>52</sup>

Research is defined as a “systematic investigation” that is designed to develop or contribute to “generalizable knowledge.”<sup>53</sup> The regulations thereby adopt the scientific model of research, in which a researcher systematically and self-consciously tests a hypothesis or at least seeks evidence that may eventually lead to the formulation of a general statement. Most academic inquiry, however, is systematic in one way or another by the standards of the researcher’s discipline, and almost all serious research can be understood to test or contribute to knowledge that is generalizable at one level or another. To be sure, in the humanities and social sciences, the investigation may not be obviously systematic, and the generalizable conclusions may be so understated as to be evident only to initiates. Nonetheless, as defined by the Common Rule, research can reasonably be understood to include more than just the inquiry that openly adopts the scientific model. For example, in medicine, HHS’s Office for Human Research Protections (“OHRP”) has stated that quality improvement studies can be subject to IRBs, and in the humanities and social sciences, IRBs enjoy jurisdiction over history and other largely nonscientific inquiry.<sup>54</sup>

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<sup>52</sup> The latter interpretation has been taken by IRBs at, for example, Reed College and the University of Illinois. Reed College Human Subjects Research Committee (IRB), *Summary of Review Categories and Procedures*, p 4 (2003–04); David Wright, *Creative Non-fiction and the Academy: A Cautionary Tale*, 10 *Qualitative Inquiry* 202, 204–05 (2004).

<sup>53</sup> 45 CFR § 46.102(d).

<sup>54</sup> For the quality improvement studies, see J. Lynn, *When Does Quality Improvement Count as Research? Human Subject Protection and Theories of Knowledge*, 13 *Quality and Safety in Health Care* 67 (2004); Kristina C. Borrer, Compliance Oversight Coordinator, HHS, Letter to Dennis Swanson and Associate Vice Chancellor Dr. Juhl, University of Pittsburgh (April 4, 2002). For more on quality improvement studies, see text at notes 183–84. The reach of IRBs over the humanities and social sciences can be illustrated by an IRB at Florida State University that claimed jurisdiction over all of the humanities, including literature, religion, and music. Christopher Shea, *Don’t Talk to the Humans: The Crackdown on Social Science Research*, 10 *Lingua Franca* 26, 29 (2000). See also the view of the National Bioethics Advisory Commission, discussed in AAUP, *Protecting Human Beings*, *Academe: Bulletin of the AAUP* at 58 (cited in note 12).



With a broad sense of its general jurisdiction over human subjects “research,” at least one IRB has even attempted to license a literary essay. This occurred at the University of Illinois, where a professor of creative literature asked his students to tell stories about themselves in ways that adopted the techniques of creative writing. The approach is known as “creative nonfiction” because it self-consciously explores the subjective character of attempts to depict the truth. The professor subsequently wrote an essay about this teaching experience, in which he himself used the methods of creative nonfiction, and in which he used fictional names when referring to the students. After the piece was accepted by the *Kenyon Review*, the IRB charged him with “bad research practices” for failing to get the permission of the students before making allusions to them and their descriptions of their experiences.<sup>55</sup> Of particular concern to the Executive Secretary of the IRB was that the professor’s “article discussed the moral dilemmas” he faced “when a student in a creative writing class submitted an essay suggesting the student had taken part in a gang-related murder some years earlier.” On this account, “the IRB chair threatened to prevent publication of the article” if the professor “didn’t withdraw it from [the] *Kenyon Review*.” After the professor’s colleagues came to his defense and persuaded the IRB to back down, he got his work published, but these events suggest how the expansive definition of “research” leaves some IRBs with a sense that even in the humanities they have a power to examine merely verbal “research” before it is undertaken, let alone published.<sup>56</sup>

When considering whether to approve research projects, IRBs must weigh risks and benefits. In particular, they must determine that “[r]isks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result.”<sup>57</sup> The Common Rule

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<sup>55</sup> Wright, 10 *Qualitative Inquiry* 202, 204–05 (cited in note 52).

<sup>56</sup> E-mail message from Professor Dennis Baron (Oct 20, 2004) (who at the time of the incident was head of the English Department). Part of this account is confirmed by other e-mails. In particular, only minutes after the Executive Secretary finally called Wright to explain that the IRB would end its investigation, Wright wrote an e-mail to various colleagues in which he explained that the Executive Secretary had “called to let me know that the IRB ‘considers action unnecessary’ in this case. it ‘doesn’t fit the category’ and is ‘not worth pursuing from an IRB standpoint.’ he added that, likewise, the IRB ‘won’t pursue the *Kenyon Review*’ to have them remove the essay from their publication. (hurrah.)” E-mail message from David Wright to five colleagues (May 10, 2002).

<sup>57</sup> 45 CFR § 46.111(a)(2).

thus gives IRBs some principles with which to evaluate research, but it does not give them a rule or even a loose standard with which to determine what combination of risk and benefit is permissible.<sup>58</sup> An IRB must therefore rely on its own judgment. Indeed, the Common Rule offers its principles only as the minimum, and an IRB may in addition apply its own institution's moral standards.<sup>59</sup> Moreover, at least one member of each IRB must be unaffiliated with the institution that established the IRB, and this member is expected to represent the "perspective" of the "local community."<sup>60</sup> Overall, as explained by OHRP, an IRB must make "a judgment that often depends upon prevailing community standards and subjective determinations of risk and benefit. Consequently, different IRBs may arrive at different assessments of a particular risk/benefit ratio."<sup>61</sup>

In order to weigh the risks and benefits of research, IRBs need to review the details of a researcher's procedures. For example, when a research project (in medicine or the social sciences) involves a survey or interview, IRBs tend to ask the researcher to submit his questions ahead of time in writing so that the IRB can review the risks they may create. After reviewing and sometimes modifying the questions, IRBs require the researcher to adhere to these written questions. A researcher therefore cannot shift his line of questioning, follow up on points raised by the subjects, or engage in normal conversations.

The federal government encourages IRBs to calculate the risks of marginal harms. When the federal government asks universities and other institutions to give assurances that they have IRBs, it suggests that they establish IRBs on the principles of the *Belmont Report*—issued in 1979 by the National Commission for the Pro-

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<sup>58</sup> The "risk" to be considered in the approval of research is undefined, for as the OHRP *Guidebook* acknowledges, "[f]ederal regulations define only 'minimal risk'—the standard for expedited review. OHRP, *Institutional Review Board Guidebook*, ch III, Part A.

<sup>59</sup> 45 CFR § 46.102(h). See also Levine, *Ethics and Regulation* at 342 (cited in note 3).

<sup>60</sup> OHRP, *Institutional Review Board Guidebook*, ch I, Part B. For the membership requirement, see 45 CFR § 46.107(d).

<sup>61</sup> OHRP, *Institutional Review Board Guidebook*, ch III, Part A. Much research has established the variability of IRB determinations. See, for example, Mary Terrell White and Jennifer Gamm, *Informed Consent for Research on Stored Blood and Tissue Samples: A Survey of Institutional Review Board Practices*, 9 *Accountability in Research* 1 (2002); Jon Mark Hirshon, Scott D. Krugman, et al, *Variability in Institutional Review Board Assessment of Minimal-Risk Research*, 9 *Academic Emergency Med* 1417 (2002); Thomas O. Stair, Caitlin R. Reed, et al, *Variation in Institutional Review Board Responses to a Standard Protocol for a Multicenter Clinical Trial*, 8 *Academic Emergency Med* 636 (2001).

tection of Human Subjects of Biomedical and Behavioral Research.<sup>62</sup> According to this report, IRBs need to anticipate a broad range of harms, including legal, economic, social, psychological, and “other possible kinds” as yet undefined.<sup>63</sup> In explaining to IRBs how they should evaluate such harms, the National Science Foundation advises that risks of “legal harm,” “financial harm,” “moral harm,” social “stigma,” mental “upset,” or “worry” can be sufficient reasons to deny permission to do research.<sup>64</sup> Furthermore, the government reminds IRBs to be careful about the injuries arising from the study of “sensitive” topics. For example, the *Institutional Review Board Guidebook*—published by OHRP—suggests that IRBs need to consider the emotional harms arising from research and explains: “Stress and feelings of guilt or embarrassment may arise simply from thinking or talking about one’s own behavior or attitudes on sensitive topics such as drug use, sexual preferences, selfishness, and violence.”<sup>65</sup> In this way, the govern-

<sup>62</sup> HHS, *Federal Wide Assurance (FWA) for the Protection of Human Subjects for Domestic (U.S.) Institutions*, p 1 (version date 03/20/2002). Alternatively, institutions can negotiate for some other statement of principles.

<sup>63</sup> National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, *Belmont Report*, Part C.2 (1979). Increasingly, some institutions now expand upon the “respect for persons” discussed by the *Belmont Report* (in Part B.1) and insist that IRBs should attend to “*Dignitary harm*,” which “can result when individuals are treated as means to an end and not as people deserving respect for their own values and preferences.” National Research Council, *Protecting Participants* at 28 (cited in note 5). In this spirit, Columbia University, for example, informs its faculty that the “primary responsibility” of its IRB “is to protect the rights, privacy and dignity of human research participants.” E-mail from Provost Alan Brinkley and Executive Vice President for Research to Faculty, Administrators, and Students at the Morningside Campus (Oct 15, 2004).

<sup>64</sup> National Science Foundation, Division of Institution and Award Support, *Frequently Asked Questions and Vignettes*, at <http://www.nsf.gov/bfa/dias/policy/hsfaqs.htm>. In contrast, the Kalven Report states: “The mission of the university is the discovery, improvement, and dissemination of knowledge. Its domain of inquiry and scrutiny includes all aspects and all values of society. A university faithful to its mission will provide enduring challenges to social values, policies, practices, institutions. By design and by effect, it is the institution which creates discontent with the existing social arrangements and proposes new ones. In brief, a good university, like Socrates, will be upsetting.” Kalven Committee, *Report on the University’s Role in Political and Social Action* (1967), at <http://www.uchicago.edu/docs/policies/provostoffice/kalverpt.pdf>.

<sup>65</sup> OHRP, *Institutional Review Board Guidebook*, ch III, Part A. Bradford Gray notes the early history of the sensitivity requirement: “The 1974 regulations made no reference to the sensitivity of the questions asked in research. Some IRBs, however, apparently have made the sensitivity of the questions asked in social or psychological research a factor in their risk-benefit judgments. The 1981 regulations may encourage this practice by making the collection of ‘sensitive aspects of an individual’s behavior such as illegal conduct, drug use, sexual behavior, or use of alcohol’ a factor in determining whether certain social and behavioral research will [be] exempt from the regulations.” He adds: “The possibility is troublesome for First Amendment reasons . . .”; Bradford H. Gray, *The Regulatory Context*

ment leaves IRBs in no doubt that research on “sensitive” topics (including research involving nothing more than asking questions) should get a particularly thorough examination.

The federal regulations even require that IRB members be chosen for their sensitivity to “community” attitudes. Each IRB, according to the Common Rule, must “be sufficiently qualified through the experience and expertise of its members, and the diversity of the members, including considerations of race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects.”<sup>66</sup> It is a mere curiosity that the decisions of an IRB are called its “advice and counsel” and that diversity is valued so that it can “promote respect” for such advice and counsel. More pertinent for constitutional analysis is the requirement of “sensitivity” to “community attitudes” (and other “such issues,” whatever they may be).<sup>67</sup>

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of *Social and Behavioral Research*, in Beauchamp, *Ethical Issues in Social Science Research* at 348–49 (cited in note 11).

<sup>66</sup> 45 CFR § 46.107(a).

<sup>67</sup> Incidentally, the regulations also require IRBs to ensure that the researcher’s selection of subjects is “equitable,” thus subjecting to censorship his decision about whom he will study. The regulations explain: “In order to approve research covered by this policy the IRB shall determine that . . . Selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.” 45 CFR § 46.111(a)(3).

There is a long history of academics studying the impoverished, the weak, and the oppressed—both to draw attention to their needs and to explore the intellectual questions that can be understood only by examining such groups. The *Belmont Report*, however, examines the selection of subjects as a matter of “justice” and asks: “Who ought to receive the benefits of research and bear its burdens? This is a question of justice, in the sense of ‘fairness in distribution.’” After alluding briefly to the Tuskegee syphilis study, it concludes that “against this historical background, . . . conceptions of justice are relevant to research involving human subjects,” and it elaborates that “the selection of research subjects needs to be scrutinized in order to determine whether some classes (e.g., welfare patients, particular racial and ethnic minorities, or persons confined to institutions) are being systematically selected simply because of their easy availability, their compromised position, or their manipulability, rather than for reasons directly related to the problem being studied.” National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, *Belmont Report*, Part B.3 (1979). These concerns are reasonable, but they are only a few of many reasonable considerations relevant to the selection of research subjects. None of this, moreover, explains why the selection of subjects is a matter of general government regulation, for although the government can choose to fund only such studies as examine subjects who meet its criteria, its legislative interests in preserving equal rights surely do not extend to controlling the selection of evidence in intellectual inquiries. Most essentially, however, even the strongest claims about justice would not warrant the requirement that researchers must get prior permission from licensors.

## B. INFORMED CONSENT

The federal regulations require researchers to obtain informed consent, which means that researchers must get permission not only from the IRB but also from the persons they study. The regulations state that, in general, “no investigator may involve a human being as a subject in research covered by this policy unless the investigator has obtained the legally effective informed consent of the subject,” and the regulations require this consent to be “documented by the use of a written consent form approved by the IRB and signed by the subject.”<sup>68</sup>

The regulations borrow these informed consent requirements from medicine. Doctors have a Hippocratic duty and a duty to avoid negligent injury, and in any case, they need to avoid committing a battery against their patients, and thus on grounds of both morals and prudence, they typically have reason to keep their patients informed and to get their consent. The federal regulations, however, more broadly require that informed consent be obtained by researchers, most of whom are not doctors.

Like journalists, researchers who are not doctors usually do not owe a specially high standard of care to their subjects. Indeed, researchers sometimes, quite legitimately, have an almost adversarial relationship to their subjects. Nonetheless, under the regulations, even researchers who merely inquire about political opinion or observe public behavior must often preface their interviews or observations with warnings about the dangers of talking to them or of allowing them to observe, and they must obtain signed documents evidencing the consent of the subjects. By requiring researchers to begin their colloquies not with a question, but with a printed warning and a request for a signature, the regulations discourage persons from talking to researchers and often probably skew the results.

Informed consent thus has the very opposite effect among researchers as among doctors. For doctors in their relationship to their patients, and for others (including researchers) who engage in physical contact that might be considered a battery, consent—together with the information necessary for it—is, at the very least, a prudent precaution, and the need for this consent stimulates the

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<sup>68</sup> 45 CFR § 46.116; 45 CFR § 46.117(a).

flow of information.<sup>69</sup> In contrast, when informed consent is generally required of researchers in their relationship to the rest of society (regardless of whether they would otherwise be committing a battery), the requirement of informed consent is a barrier to the transmission of information and even the asking of ordinary questions. Nor should this be a surprise: It is one thing to choose to get permission to do what would otherwise be an intentional physical tort; it is another to be required to get permission to engage in inquiry. As imposed on research, informed consent thus becomes a democratized licensing system, whereby intellectuals must get permission from individuals before talking with them, before observing them, and even before reading about them.

IRBs compound the problem of informed consent by requiring researchers to get prior IRB approval for their informed consent forms and by rewriting these forms to make them more onerous. When IRBs expect that the research will cause stress to the subjects or will be controversial, they increase their scrutiny of informed consent and tend to ask the researchers to give their subjects extra strong warnings about the risks of participation.<sup>70</sup> The largest single class of modifications to research probably involve changes in informed consent, and although the changes are often small, they almost always impede consent.

Incidentally, both the informed consent requirement and the need for IRB approval apply not only to research requiring intervention or interaction with human subjects but also research that reexamines data collected in earlier research, if it contains

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<sup>69</sup> Obviously, however, this is not to say that (in the absence of IRB regulations) the same amount of information must be provided by doctors conducting research on their patients and persons conducting research outside of a doctor-patient relationship.

<sup>70</sup> Most IRBs have the good sense not to advertise their approach to controversial research, but at Florida State University, the IRB candidly states that “full committee review is required when . . . research is of a controversial nature.” Florida State University, Office of Research, *Human Subjects Committee*, at <http://www.research.fsu.edu/humansubjects/applications/full.html>. The IRB even asks researchers questions such as: “Is the research area controversial and is there a possibility your project will generate public concern? If so, please explain?” Florida State University, *Human Subjects Application to the Institutional Review Board for Research Involving Human Subjects*, at <http://www.research.fsu.edu/humansubjects/applications/documents/irbapp1299.txt>, quoted by Christopher Shea, *Don't Talk to the Humans: The Crackdown on Social Science Research*, 10 *Lingua Franca* 26, 29 (2000).

IRBs can in some instances waive the requirement of informed consent or at least that concerning documentation of informed consent, but they are notoriously hesitant to grant a waiver and frequently do so only if the researcher agrees not to collect information about the identity of the subjects or about sensitive matters. Yet if the researcher uses informed consent of the stringent sort required by many IRBs or if he accepts the demand that he obtain signed documentation of the consent, he is less likely to collect useful information.

“identifiable private information.” As already noted, private information is understood to include much information that is not proprietary, subject to a fiduciary duty, otherwise confidential, or even very personal.<sup>71</sup> Scholars who wish to examine such data after a research project is complete must typically secure further informed consent for the new use of the data and must get additional approval from an IRB.

### C. EXCEPTIONS AND EXEMPTIONS

To make the indeterminate breadth of the licensing more manageable, the regulations carve out various exceptions and exemptions, but these do not spare researchers from having to get permission. One of the exceptions is “[e]xpedited review.” The Common Rule makes expedited review available for a project if it does not go beyond various commonplace procedures listed by HHS, such as the use of surveys or the collection of blood samples by venipuncture. Yet even this research is eligible for expedited review only if the IRB determines that it involves “no more than minimal risk.”<sup>72</sup>

The exemptions are broader. For example, there are exemptions for reading publicly available documents and for surveys, interviews, or observations of public officials. The exemption of research on public officials apparently rests on the assumption that this would be political speech, but it is oddly narrow, for it refers to “elected or appointed public officials”—the latter being usually understood to include only appointees who are public figures. Of course, it is also strangely narrow because research on persons

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<sup>71</sup> 45 CFR § 102(f)(2). For example, “[p]rivate information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place.” *Id.* To recognize the breadth of this concept of private information, consider its application to the research that might be done in a restaurant: Private information would include ethnographic observations and linguistic observations about the language used by waiters and waitresses. Accordingly, if the researcher would learn the identity of the persons (which would be very likely in a small town), and if he aimed to develop or contribute to generalizable knowledge (which would be very likely if he were an academic), his research would be subject to approval by an IRB, which would seek to protect the subjects from the usual array of legal, economic, social, and mental harms.

<sup>72</sup> 45 CFR § 46.110(b)(1). In addition, some “minor changes in previously approved research” can receive expedited review. 45 CFR § 46.110(b)(2). The Common Rule defines minimal risk to be when “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.” 45 CFR § 46.102(i).

who are not officials (including the poor, ill, and oppressed) can be equally political. The regulations further exempt research consisting of a researcher's "survey procedures," "interview procedures," and "observation of public behavior," but not if the identity of the subject will be identifiable from the researcher's records and the disclosure of the information could harm the subject—for example, in his employability or reputation.<sup>73</sup> Accordingly, this research is not exempt if it will elicit controversial opinions. As the National Science Foundation explains, such research is exempt only if the "information would not cause harm to the individual if it were known"—"[f]or example, recording observations of everyday public behavior, or interviewing people about non-controversial opinions or preferences."<sup>74</sup>

These exemptions, however, do not really allow researchers to escape the licensing, because the government expects the IRBs to determine whether a research project falls within the exemptions, thus even making exempt research subject to the prior judgment of the IRB. In the words of OHRP, it "recommends that institutions adopt clear procedures under which the IRB (or an authority other than the investigator) determines whether proposed research is exempt from the human subjects regulations."<sup>75</sup> The government ex-

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<sup>73</sup> 45 CFR § 46.101(b)(2). Compared to the rest of the regulations, the harm element is stated narrowly here, but it remains very broad: "Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), 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." *Id.*

<sup>74</sup> National Science Foundation, Division of Institution and Award Support, *Frequently Asked Questions and Vignettes*, at <http://www.nsf.gov/bfa/dias/policy/hsfaqs.htm>.

<sup>75</sup> OHRP, *Guidance on Written IRB Procedures*, Additional OHRP Guidance, Part D(1) (July 11, 2002), at <http://www.hhs.gov/ohrp/humansubjects/guidance/irbgd702.htm>. Indeed, this is sometimes required in an institution's assurance—as when the University of Chicago assures the government: "All human subject research which is exempt under Section 101(b)(1–6) or 101(i) will be conducted in accord with . . . this Institution's administrative procedures to ensure valid claims of exemption." University of Chicago, *Multiple Project Assurance of Compliance with DHHS Regulations for Protection of Human Research Subjects* 3, Part III.B. The ethnographer Jack Katz complains that "the requirement to apply to receive a certification as exempt guts the protections" of "the exemption criteria." Jack Katz, *To Participants in the UCLA, May 2002, Fieldwork Conference* (May 8, 2002), at [http://leroyneiman.sscnet.ucla.edu/katz5\\_8.htm](http://leroyneiman.sscnet.ucla.edu/katz5_8.htm).

Incidentally, to avoid unnecessary delays, IRBs can publish general determinations that some types of information (for example, publicly available data sets) are exempt, but even when researchers confine their work to such information, IRBs feel obliged under the regulations to require the researchers to "register" their research projects with the IRB. For example, the University of Chicago's Social and Behavioral Sciences IRB emphasizes



pects researchers to get an IRB's permission even for exempt research because the extent of the exemptions is not always clear and the government does not trust researchers to exercise good judgment. For example, the exemption for observations or surveys of elected or appointed public officials does not clearly extend to any but the highest-level appointees, and therefore an IRB needs to pre-examine all research on public officials to ensure that research extending beyond the narrow exemption will undergo the IRB's full process of approval, modification, or denial.<sup>76</sup>

#### D. CONSEQUENCES

The IRBs do not formally impose "penalties" on students, faculty, or other researchers for failing to conform to the regulations. They certainly, however, impose consequences.

IRBs frequently approve research only after requesting modifications, and IRBs thereby, in effect, suppress the modified aspects of the research.<sup>77</sup> For example, if the questions in a survey or interview are likely to elicit what an IRB considers confidential, sensitive, or private information, it will sometimes require researchers to omit or alter their questions. More frequently, IRBs give approval on the condition that the researcher not collect names or other identifying information about the subjects. In a similar spirit, IRBs sometimes require researchers to assure the IRB that they will not disclose and thus not publish the infor-

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that such "researchers do need to register their research" with the IRB. University of Chicago, Social and Behavioral Sciences IRB, *Policy on Public Use Data Sets*, at <http://humansubjects.uchicago.edu/sbsirb/publicpolicy.html>. For example, the University of Chicago lists as exempt the data published on the website of the U.S. Bureau of the Census, but even under this dispensation, a researcher working from the public census data must register his research by submitting information about it to the IRB.

<sup>76</sup> Another reason that the regulations require researchers get permission even for exempt research is that the government encourages IRBs to apply not only the federal regulations but also the ethical principles of its institution, and IRBs can do this only if they review exempt research as well as that which requires approval. From this perspective, the National Science Foundation advises IRBs: "When the subjects are public officials or candidates for public office, the research is exempt even when identifiers are included or disclosure might be harmful. However, all research should be bound by professional ethics and respect for respondents to guard their privacy whether or not the research is exempt (unless the participants understand that their information may be made public and permission is granted)." National Science Foundation, Division of Institution and Award Support, *Frequently Asked Questions and Vignettes*, at <http://www.nsf.gov/bfa/dias/policy/hfaq.htm>.

<sup>77</sup> For example, an IRB will write to a researcher that specified "problems were identified and need to be addressed in an amendment resubmission in order for the project to proceed." Letter from IRB to investigator.

mation, and IRBs frequently use informed consent forms to get researchers to make such statements.<sup>78</sup> Indeed, by requiring excessively somber warnings in informed consent forms—even those for social science research—IRBs can ensure low participation, and in this way can force a halt to research they find objectionable, without formally denying approval.

IRBs also routinely require researchers to destroy data or information after they have used it. IRBs often ask researchers to strip identifying information from data and even sometimes ask that they eventually destroy the codes that link the identifying information to the rest of the data. IRBs occasionally even require researchers to dispose of all their data, and they regularly instruct researchers to destroy video and audio tapes.<sup>79</sup> In the words of the federal regulations, an IRB must determine that “[w]hen appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.”<sup>80</sup>

If research needs approval and does not get it, the IRB can stop the research, and if the research departs from a condition imposed by an IRB, the IRB can “terminate approval.”<sup>81</sup> From the IRB’s

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<sup>78</sup> IRBs also sometimes require researchers to obtain certificates of confidentiality—that is, federal certificates that purportedly allow researchers “to refuse to disclose identifying information on research participants in any civil, criminal, administrative, legislative, or other proceeding, whether at the federal, state, or local level.” NIH has made clear that it “would like to encourage” the use of these certificates. NIH, Office of Extramural Research, *Certificates of Confidentiality Kiosk*, at <http://grants1.nih.gov/grants/policy/coc/>.

<sup>79</sup> This destroys the possibility of later verifying transcriptions or other information drawn from the recordings.

<sup>80</sup> 45 CFR § 46.111(a)(6). At some universities, IRBs allow researchers to place the identifying information in the hands of third parties so that replication remains possible, but if the information is kept in two places, it is unlikely that researchers will be able to locate both parts after one or two decades have passed. The National Science Foundation goes so far as to state that even without a request from an IRB, a professor has an obligation to destroy data—for example, if a student becomes a research subject and reveals “some sanctioned behavior,” such as “plagiarism on the part of the student,” then “[t]o protect the student, the record should be erased immediately.” National Science Foundation, Division of Institution and Award Support, *Frequently Asked Questions and Vignettes*, at <http://www.nsf.gov/bfa/dias/policy/hsfaqs.htm>.

IRBs also license the reuse of data, and thus researchers who seek data already collected and available at an institution need to get IRB approval, even though this is really just a question of sharing information or publication. For example, an IRB at one institution recently wrote to some investigators: “Upon receipt of a security protocol, the . . . IRB will authorize the release of data. If data is to be linked with identifiers, a document attesting that the appropriate security procedures are in place must be submitted along with the names, titles, and affiliations of the individuals who will have access to the linked data. Each person with access to the linked data must provide certification of having taken human subject protections training and must sign a statement [that] names of any research subjects will be protected.” Letter from IRB to investigators.

<sup>81</sup> 45 CFR § 46.113.

perspective, it takes these actions to prevent harm to human subjects rather than to penalize researchers, but the implications extend further than the research.<sup>82</sup> According to OHRP, “[w]hen unapproved research is discovered, the IRB and the institution should” not only “act promptly to halt the research” but should also “address the question of the investigator’s fitness to conduct human subject research.”<sup>83</sup> If the IRB finds him unfit (even if merely for failing to ask for prior permission to study), it can prevent him from doing other research on human subjects.<sup>84</sup> More typically, the IRB will simply take into account a researcher’s prior “virtue” or “track record” of cooperation with the IRB when making decisions about his proposals.<sup>85</sup>

IRBs often discourage publication in ways that go beyond their mechanisms for securing nondisclosure of information. Some university IRBs have intervened even after research or other inquiry has been completed, and thus have directly interfered with publication (such as at George Washington, Illinois, and Pittsburgh). Most IRBs, however, leave control of publication to others.<sup>86</sup> Many

<sup>82</sup> Of course, there is also evidence that IRBs act to avoid federal consequences for their institution. See Yvonna S. Lincoln and William G. Tierney, *Qualitative Research and Institutional Review Boards*, 10 *Qualitative Inquiry* 219, 225 (2004).

<sup>83</sup> OHRP, *Institutional Review Board Guidebook*, ch I, Part D. Strikingly, it adds: “Beyond the obvious need to protect the rights and welfare of research subjects, the credibility of the IRB is clearly at stake.” *Id.*

<sup>84</sup> Indeed, the oldest independent IRB in the country declares: “IRBs have the authority to approve, require modifications to, or disapprove the proposed study protocols and consent forms for research which will involve human subjects. In addition, IRBs must review and approve or disapprove the investigator for the research.” Western Institutional Review Board, *About Us*, at <http://www.wirb.com/>.

<sup>85</sup> As Robert Levine states, “many IRBs take the investigator’s ‘virtue’ into account in making decisions about protocols. For example, Shannon and Ockene report on their IRB’s disapproval of a low risk protocol based, in part, on the fact that the investigator had a poor relationship with the IRB . . . . In the same paper, they report their IRB’s approval of a high risk protocol; one important factor was that the investigator had ‘an excellent track record in terms of trustworthiness, exemplified by his willingness to report immediately any problem in research by notifying the appropriate people.’ Moreover, ‘within the medical center . . . he was perceived to be skilled and trustworthy.’” Levine, *Ethics and Regulation* at 27 (cited in note 3).

<sup>86</sup> For Illinois, see David Wright, *Creative Nonfiction and the Academy: A Cautionary Tale*, 10 *Qualitative Inquiry* 202, 204–05 (2004), discussed at notes 55–56. At George Washington, after researchers obtained approval for experiments related to human cloning, the IRB later discovered that they had already done the research when they got approval, and as Harold Edgar and David Rothman explain: “When it learned of this breach, the IRB penalized the investigators, compelling them to withdraw an abstract of their findings.” Harold Edgar and David J. Rothman, *The Institutional Review Board and Beyond: Future Challenges to the Ethics of Human Experimentation*, 73 *Milbank Quarterly* 489, 499 (1995). At the University of Pittsburgh, the Senior Vice Chancellor for the Health Sciences

journals have so deeply absorbed the ethos of licensing that they will not publish work unless it has been licensed by an IRB, and in some fields, a scholar who does not have IRB permission may have difficulty finding a reputable journal to publish his research.<sup>87</sup> Taking advantage of this, IRBs often warn students and professors that they need IRB permission for their research if they hope to get it published.<sup>88</sup> Under pressure from OHRP to prevent violations of IRB regulations, some IRBs match their approvals against publications by the faculty to check that their faculty have obtained IRB approval for their research, and some scholars therefore hesitate to publish or draw attention to licensed research even after it is written. They understand that if the IRB learns they did not get prior approval, they might in the future have difficulty getting permission for a project. Increasing the disincentive for publishing unapproved work, universities sometimes warn of “serious consequences” for those who do not follow the IRB rules.<sup>89</sup>

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required personnel in his division to submit their manuscripts to him. Upon getting a piece accepted in a peer-reviewed journal, a researcher was required to send him a copy of the manuscript so that an individual in his office could review it for compliance with IRB and related licensing rules, and, at least in theory, the Vice Chancellor would have a manuscript pulled if it did not conform. Not surprisingly, after a number of years of such review, manuscripts tended to comply with the licensing rules, and the Chancellor ended this experiment.

<sup>87</sup> In this connection, the International Committee of Medical Journal Editors includes in its *Uniform Requirements for Manuscripts Submitted to Biomedical Journals* a requirement that: “When reporting experiments on human subjects, authors should indicate whether the procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation . . . .” International Committee of Medical Journal Editors, *Uniform Requirements for Manuscripts Submitted to Biomedical Journals*, Part II.F, at <http://www.icmje.org/#protect>. For a brief account of the history of this sort of policy among journals, see Levine, *Ethics and Regulation* at 27–31 (cited in note 3).

<sup>88</sup> Although these warnings usually occur in private communications between IRBs and individual researchers, they can also appear in print. After posing the question, “What’s the worst that can happen if I don’t request IRB approval?” one IRB explains: “Articles may not be published: Many professional journals require evidence of IRB approval when considering articles for publication.” University of Alaska Fairbanks, Institutional Review Board, *Ensuring the Rights and Welfare of Human Participants in Research* 11, at <http://www.auf.edu/irb/faqs.html>.

<sup>89</sup> University of Chicago, Social and Behavioral Sciences Institutional Review Board, *Frequently Asked Questions 2*, at <http://humansubjects.uchicago.edu/sbsirb/faq.html> (dated 2/13/2003). See also, for example, e-mail message from Provost Alan Brinkley and Executive Vice President for Research to Faculty, Administrators, and Students at the Morningside Campus (Oct 15, 2004). At a recent meeting held by the Northwestern University IRB, when a representative of the IRB referred to such consequences, a law professor “asked what would happen if I went ahead without approval, and I was told that there would be disciplinary action at the highest levels; I could be subject to severe sanctions.” He also said that nonconforming “students could have their diplomas withheld; faculty might even be dismissed.” Conversation with Professor Cynthia Bowman, Northwestern University Law School (Dec 10, 2004).

More generally, researchers recognize that IRB licensing is conducted under authority or color of federal law, and they therefore fear that they would be violating federal policy if they published without IRB approval.

The practical implications of IRBs can be illustrated by a hypothetical history student who wants to study the participation of women in the 1964 campaign for equal voting rights. If she hopes to write to some of the women to get their accounts of their experiences, she must first consult an IRB for “approval” of the project, including the specific questions she plans to ask the women. If the student wants only to read about the women in books available in the university library, she need not consult the IRB, but if she obtains from one of the women letters she received from another woman describing their activities in 1964, the student cannot read the correspondence for her research unless she first gets the IRB’s approval.<sup>90</sup> If the IRB is concerned that either of the women may be “upset” or may suffer any social “stigma” from the student’s writing or publishing of her paper, it can ask the student to warn the women of the dangers and can require her to get their permission before she reads the letters. It can also ask the student not to identify the women in her paper or her publication. It can additionally ask the student, after she has finished her project, to destroy any portions of her notes that mention their identity.

Incidentally, the student herself cannot ask for IRB approval because students might not be sufficiently responsive to IRB requests. Thus, at most universities, the “principal investigator” must be a faculty member. The professor is therefore required to claim a role that he in fact does not have, and the student must, in effect, get the permission of both a teacher and the IRB. So stringent is the licensing requirement that if the student needs “approval” for her research and proceeds without it, she cannot get approval retroactively, even if her research clearly created no more than minimal risk. At best, she can get a statement from the IRB that her research would have been approved if submitted before its inception (a statement that can ameliorate some of the difficulties of getting journals to accept unapproved work). If she

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<sup>90</sup> Of course, she could read the letters if not doing research on the women, which raises an initial question as to whether the licensing concerns private information or intellectual inquiry.

avoids these problems by getting prior approval, she must act on it promptly, lest it expire, at which point the IRB will peremptorily instruct her that (in the words of one university IRB) “no research related activities . . . can take place until the IRB has approved the continuation of research.”<sup>91</sup>

In these ways, the federal regulations on IRBs set up a system of licensing. The next step is to consider whether the regulations interfere with speech or the press, and after that, to inquire whether they amount to the sort of federal action that violates the First Amendment.

### III. LICENSING OF SPEECH AND THE PRESS

The regulations require IRB licensing of “research,” and it may therefore be thought that they license conduct rather than speech or the press.<sup>92</sup> Certainly, many laws regulate conduct in ways that indirectly burden speech or the press, without violating the First Amendment.<sup>93</sup> As it happens, however, although the IRB regulations appear to focus on conduct, they discriminate on the basis of content and thus target speech and the press. At key points, moreover, they candidly require IRBs to license the verbal core of speech and the press. Thus, in one way or another, the regulations take aim at speech and the press, as can be observed in six illustrations.<sup>94</sup>

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<sup>91</sup> Communication from a Midwestern IRB to an investigator (2004), given by the investigator to the author.

<sup>92</sup> It is possible that the Amendment protects not merely the freedoms of speech and the press but also a freedom of research or inquiry. The licensing of research is more intrusive and, perhaps, more dangerous than the licensing of speech or press, for it bars not merely the reduction of ideas to speech or print, but even the development of ideas. Here, however, there is no need to pursue this line of reasoning, for the federal regulations target and even specify speech and the press.

<sup>93</sup> See note 33.

<sup>94</sup> Doctrinally, even to the extent the IRB regulations concern conduct, they engage in content discrimination and thus amount to the licensing of speech and the press under *O'Brien*. Of course, the *O'Brien* test is a measure of whether a post-publication restraint violates the First Amendment rather than whether a law licensing conduct really licenses speech or the press, but to the extent the *O'Brien* test establishes a method of discerning content discrimination, it is relevant. Under this test, it is an open question whether the regulation of research “is within the constitutional power of the Government,” and of particular significance, it is dubious whether the IRB regulations further a governmental interest “unrelated to the suppression of free expression.” *United States v O'Brien*, 391 US 367, 377 (1968). See also note 33. Indeed, the regulation of research, as such, necessarily suppresses expression—whether in the research or in the publication of its results.

Incidentally, *O'Brien's* focus on the government's interest and the relation of this interest to suppression may not always be adequate to the task of discerning whether licensing of

First, the IRB regulations impose licensing on research at research institutions, and they thereby discriminate against inquiry and publication. Research is conduct that involves inquiry or the pursuit of curiosity, and when done at a research institution (whether a private firm or a university), it almost always leads to some publication or at least internal communication about it. This in itself does not necessarily protect the research, but in imposing licensing on research at research institutions, the government licenses, not the proximate causes of harm, but rather the inquiry and publication inherent in institutional research. In this way, the regulations concerning IRBs differ from those regarding FDA drug licensing. The FDA licenses the sale of new drugs against the background of a general federal prohibition on the marketing of new drugs. In contrast, the government imposes IRB licensing on research at institutions, while simultaneously leaving the same conduct unconstrained if done not as part of such research. It thus imposes licensing not on any particularly dangerous substance or activity, but on the pursuit of curiosity and publication that takes place at universities and other research institutions.

Imagine if Congress were to prohibit journalists from investigating and asking questions, unless they first obtained permission from a Newspaper Review Board. In particular, imagine that they had to get permission from a board of journalists and community members, who were to ensure that each journalist would disclose his identity, warn persons of the dangers of talking to him, get a signed consent form, engage in no deceit, intrude on no one's

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conduct is really a licensing of speech or the press. A government interest related to suppression was clear enough in seventeenth-century England, but it may not always be apparent under a popularly elected government seeking popular ends. For example, the new censorship attempts to satisfy popular moral anxieties about the risks of research, and, in this context, the government's interest is not likely to seem related to the suppression of free expression. More generally, in its deference to government interests, the *O'Brien* test is necessarily incomplete. As Madison explained in *Federalist* No. 44, the enumeration of powers was an enumeration of the "objects" of government or what *O'Brien* calls a "governmental interest." *Federalist* 44, in Jacob E. Cooke, ed, *The Federalist* 304 (1961). In contrast, the enumeration of rights defines exceptions to the powers, and therefore an examination of the legitimacy of the government's object or interest will not always be an adequate measure of the abridgement of the right.

A further, curious twist is that content discrimination in the regulation's treatment of conduct may amount to an express regulation of speech and the press. It will be seen below that the IRB regulations expressly define "research" in terms of speech and the press, and within this context, the regulatory distinctions concerning the conduct involved in research are merely further refinements of the express licensing of the speech and press involved in "research."

privacy, and otherwise cause no harm.<sup>95</sup> Imagine further that that Congress asked Newspaper Review Boards to prevent journalists from causing “upset,” “worry,” social “stigma,” “moral harm,” or any legal or economic loss.<sup>96</sup> Even to the extent these harms are within the constitutional reach of law, the government cannot impose its regulation of such harms only on journalists, and especially not by requiring them to get approval before they do their investigation. So, too, for research and researchers.

Second, in establishing IRB licensing, federal regulations single out for constraint the pursuit of a particular conception of knowledge, and this similarly reveals that the regulations license speech and the press. In requiring the licensing of “research,” and in defining research as a “systematic investigation” designed to produce “generalizable knowledge,” the regulations specify modern, empirical, scientific method and constrain it in its most important application, human beings. The modern, empirical, scientific conception of knowledge, especially as applied to human beings, created much of the modern world by dismantling medieval scholasticism. Even today, it continues to be contested when it challenges traditional religious notions of truth—for example, in debates about evolution and the verity of scripture, and in controversies about abortion and about conception as the beginning of human life. More broadly, even among scientists, the empirical, scientific conception of knowledge stimulates anxieties about its consequences for human beings, whether in health, morals, politics, social relations, or the environment. Yet this does not mean that government can constitutionally discriminate against those who pursue the modern, empirical conception of knowledge. In particular, when government regulations specify or otherwise target this conception of knowledge for licensing, they discriminate on the basis of content. The government could just as well impose licensing on scholars who engage in elenctic dialogue about the nature of man on the ground that this puts interlocutors at risk of social stigma and mental upset. If this targeting of Platonists and their method would violate the First Amendment, so does the

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<sup>95</sup> This is not beyond the imagination of the defenders of IRBs. See, for example, Roberson’s comments on the subject in note 17.

<sup>96</sup> National Science Foundation, Division of Institution and Award Support, *Frequently Asked Questions and Vignettes*, at <http://www.nsf.gov/bfa/dias/policy/hsfaqs.htm>.



targeting of researchers who explore knowledge about human beings by means of direct empirical study.

Monkeys illustrate the danger. The government can license the handling of monkeys, without violating the First Amendment. Similarly, it can license the application of drugs to monkeys. Yet it cannot license the handling of monkeys only in modern scientific research, any more than it could license the handling of these primates only in biblically oriented research.<sup>97</sup> Whether with regard to monkeys or men, the law cannot single out one conception of knowledge for constraint—least of all, for licensing.

Third, the regulations require IRBs to evaluate the risks and benefits of research and thus require IRBs to weigh the value of the particular scientific methods proposed by researchers. The regulations even require IRBs to weigh the methodology of projects that rely exclusively upon observation, reading, speaking, writing, and printing. One of the government's purposes in creating IRBs was to "improve the quality of a research protocol," and its regulations expressly require IRBs to ensure that "[r]isks to subjects are minimized" by the use of "procedures which are consistent with sound research design." Moreover, the regulations require IRBs to weigh the risks of research against the benefits, and IRBs therefore cannot escape the obligation to consider the quality of the research and its methodology.<sup>98</sup> As OHRP explains: "Specification of quality standards in the conduct of research is an important function of the institutional leadership. Insistence upon well-conceived and -conducted research should be evident both in written policies and in actions of institutional officials. . . . Approval procedures should be devised such that the institution supports only well-designed and properly executed research." To ensure that IRBs appreciate their methodological obligation, OHRP cautions: "Research that is conducted so poorly as to be invalid exposes subjects and the institution to unnecessary risk."<sup>99</sup> The regulations thus require IRBs to become arbiters of the value of different research methods, including merely verbal methods, and the regulations thereby subject methodology to a process that

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<sup>97</sup> In fact, there are Institutional Animal Care and Use Committees, but they can be left for another day.

<sup>98</sup> For the government's purposes, see HEW, FDA, Standards for Institutional Review Boards for Clinical Investigations, 43 Fed Reg 35188 (Aug 8, 1978) (re NIH's requirements for IRBs). For the regulations, see 45 CFR § 46.111(1) & (2).

<sup>99</sup> OHRP, *Institutional Review Board Guidebook*, ch I, Part B.

inevitably discriminates against unconventional or unpopular approaches.<sup>100</sup> Few matters are more contested in academia than methodology, but IRBs enjoy power over methods, and they often return proposals to researchers with requests for methodological changes—in effect, suppressing the method that the researchers initially proposed.

In each of these three examples, the regulations focus on what could be considered conduct, but they do so in ways that discriminate on the basis of content, and they thus target speech and the press. The regulations, however, go even further, for in the remainder of the six illustrations given here, it will be seen that the regulations candidly target verbal speech and the press as the objects of the licensing.

Fourth, the IRB regulations define the licensed conduct so broadly as to impose licensing on substantial amounts of conduct that consists solely of noninjurious reading, observing, analyzing, speaking, writing, or printing. Many research projects consist of little more than these activities. For example, much research (in fields including medicine, politics, and increasingly law) consists of making otherwise lawful observations, printing and distributing surveys, tabulating the results, and analyzing them. Indeed, many research projects only involve reading and analyzing preexisting data. Although the fact that injurious conduct consists exclusively of various forms of speech or of the press does not automatically give it constitutional protection from post-publication penalties, the IRB licensing is not a post-publication restraint, and in any case, research is not itself an injury. Of course, IRB licensing is an attempt to prevent harm from research, but rather than punish actual injury, it restricts proposed research because of the mere risk or possibility that it may eventually produce injury. By lumping all research together, the regulations require IRBs to interfere with much entirely

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<sup>100</sup> Some commentators complain of the “monitoring, censoring, and outright disapproval of projects that use qualitative research, phenomenological approaches, and other alternative frameworks for knowing and knowledge.” Lincoln and Tierney, 10 *Qualitative Inquiry* at 220 (cited in note 82). “The issues—frequently cited as bases for rejection—seem to be nonquantitative or experimental research methods (i.e., qualitative methods), new paradigms for inquiry (e.g., phenomenological, feminist, post-modern, Foucauldian, and/or constructivist), and lack of fit with traditional rigor criteria (e.g., generalizability, replicability, objectivity).” *Id.* See also *id.* at 230.

Of course, the government and any board upon which it relies are free to consider methodology when making decisions about research by the government’s own employees, about giving money to outside researchers, or about giving researchers access to its facilities or to persons whom it has in its custody.

harmless reading, observing, analyzing, speaking, writing, and printing—even though these things have not yet caused any injury and in most instances will probably not do so. This “overbreadth” reveals that the regulations impose licensing directly on speech and the press—including much purely verbal speech and the press.<sup>101</sup>

Fifth, the government requires IRBs, in evaluating the risks and benefits of research, to weigh the risks and benefits of publication. Although the licensing of publication is not the goal of the federal government, the failure of a researcher to obtain a license to do research has profound consequences for her ability to publish—a connection that the government clearly understands and that academic institutions and their IRBs sometimes exploit by warning faculty and students that if they do not first get approval, they may have difficulty publishing their work.<sup>102</sup> More directly, the government’s own regulations reveal the role of IRBs in licensing publication, for in evaluating the risks of a research project, an IRB must consider whether “[r]isks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result.”<sup>103</sup> Thus, on the one hand, an IRB must take into account the risk arising from publication of the research (including the risks of worry, upset, moral harm, and other injuries not ordinarily cognizable at law or under the First Amendment). On the other hand, the IRB must consider “the importance of the knowledge” that the researcher hopes to obtain and publish—as if IRBs were the arbiters of what is important enough to be studied and published.<sup>104</sup> This judgment about the potential “risks and benefits” of doing research, including the possible “risks and benefits” of publication, makes the IRBs licensors or censors of the press in its most traditional verbal form. Although IRBs license research, they do so by considering the danger and value of publication.<sup>105</sup>

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<sup>101</sup> The overbreadth may be of constitutional interest on its own, but it is of significance here because it reveals the direct licensing of speech and the press. For the substantial overbreadth test, see note 35.

<sup>102</sup> See notes 87–88.

<sup>103</sup> 45 CFR § 46.111(a)(2).

<sup>104</sup> *Id.*

<sup>105</sup> The regulations apparently recognize that this inclusion of the risks and benefits of publication in IRB evaluations runs up against the First Amendment, for the regulations promptly add: “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

Sixth, and most fundamentally, the regulations define “research” in terms of speech and the press, and thus when requiring IRBs to license research, the regulations directly make speech and the press the object of the licensing. The regulations define research as “systematic investigation . . . designed to develop or contribute to generalizable knowledge,” and as a result, they apply only to the inquiry that is designed to advance “generalizable” knowledge. Although knowledge can perhaps be generalizable without being yet reduced to a statement, generalizable knowledge is the knowledge that has at least the potential to be reduced to a statement. The definition of research in terms of “generalizable knowledge” makes sense if research is understood in terms of modern scientific method, which seeks to develop knowledge in the form of statements that are sufficiently general that they can be applied or tested elsewhere. Yet by adopting this definition, the regulations select for licensing not injury, nor mere inquiry or the pursuit of curiosity, but rather such inquiry as is designed to make possible a statement with wider application or significance. The regulations thus candidly constrain verbal speech and the press—indeed, precisely the sort that is apt to be important.

Finally, it must be emphasized that nothing in the First Amendment stands in the way of the government’s adopting laws prohibiting physical injury or even licensing dangerous activities. But this is precisely what the government has not done. By using licensing, it regulates the risk of injury from research rather than the injury itself, and because the risk will usually not become a reality, the regulation of this mere possibility is highly overinclusive. This overinclusive regulation of the mere risk of injury is all the more distant from a lawful prohibition on injury because it includes the risk of harms—such as “upset,” social “stigma,” and “moral harm”—that are the ordinary consequence of free discussion and publication. If legally cognizable harms were its sole concern, the government could rely upon the general rules against negligence or could adopt rules against specific, substantive types of injury. The government

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policy) as among those research risks that fall within the purview of its authority.” 45 CFR § 46.111(a)(2). The First Amendment, however, forbids the licensing of speech and the press, not just the long-term application of speech and press for public policy.

The degree to which doctors view IRBs as licensors of publications is evident from the growing tendency of doctors who do innovative medical procedures to seek IRB approval, in case they afterward wish to publish an account of their work. The innovative character of the procedures does not make them “research,” but the doctors assume that it is prudent to get IRB approval if publication is likely.

could even (within its enumerated powers) license dangerous activities, as it does with the distribution and development of pharmaceuticals. It cannot, however, establish licensing for “research” that it defines in its regulations to include a vast amount of harmless speech and the press. Nor can it adopt licensing regulations that target the curiosity of researchers, the consequences of their publications, their scientific empiricism, their methodologies, or their attempts to reach generally stated conclusions, as if these were particularly dangerous circumstances. Although the government regulations require the licensing of “research” to prevent researchers from doing harm, they neither penalize any actual injury nor license a genuinely dangerous activity, but instead single out speech and the press for licensing.<sup>106</sup>

#### IV. FEDERAL ACTION

The government’s regulations on IRBs run afoul of the First Amendment only to the extent that they impose licensing of speech or the press by force of law, and it is not immediately clear whether they do this. Rather than bluntly require the use of IRBs, the government seems ordinarily to adopt milder approaches: For research receiving its support, the government requires institutions to use IRBs as a condition of government support, and for other research, which is not federally funded, the government simply invites institutions to use IRBs voluntarily.<sup>107</sup> On closer examination, however, the government does not make the regulations merely conditional and optional. In particular, there is reason to worry that the government imposes unconstitutional conditions and co-opts the force of state law.

In analyzing these two issues, it is useful to keep in mind that what matters for the First Amendment is whether the government has legislated beyond its constitutional limits rather than the degree

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<sup>106</sup> For the safety of research in general, see Levine, *Ethics and Regulation* at 39–40 (cited in note 3). See also text at notes 152–57.

<sup>107</sup> For the conditions, see 45 CFR § 46.101(a). The regulations refer to human subjects research “supported” by the government so as to include even research that gets only the most minimal support, such as the loan of a book, but this essay refers interchangeably to “support,” “funds,” and “grants” because this has been the practical application of the regulations thus far. Nonetheless, the regulations’ emphasis on support is significant. See note 130.

For the optional adoption of IRBs, see HHS, *Federalwide Assurance (FWA) for the Protection of Human Subjects for Domestic (U.S.) Institutions 2* (version date 03/20/2002). For the required uses of IRBs in connection with the FDA and HIPAA, see note 6.

of government coercion or the existence of institutional or individual consent. When contracting or otherwise dealing with the government, a person can waive a particular exercise of a constitutional right, including the right of speech, or the press. Such consent, however, cannot authorize the federal government to legislate or adopt policies beyond its constitutional powers. The First Amendment is particularly explicit about this, for in focusing on legislation, it specifies that Congress shall make no law abridging the freedom of speech, or of the press. Accordingly, as illustrated by notions of overbreadth, the mere making of such a law is unconstitutional.<sup>108</sup> It does not matter whether the law specifies a harsh or mild penalty or whether a person's exercise of his speech or press rights has yet been subjected to any penalty. Nor does it matter whether an affected individual has consented. The government's simple act of making the law is enough to violate the Constitution, and accordingly, in evaluating the constitutionality of the federal regulations on IRBs, coercion and consent are not necessarily relevant considerations.

#### A. UNCONSTITUTIONAL CONDITIONS

The first way in which the federal regulations on IRBs conflict with the First Amendment is through the government's use of unconstitutional conditions. Formally, the regulations impose conditions on government support for research. In reality, however, the government goes further, for it uses these conditions to exercise regulatory power over speech and the press. In this way—through the regulatory use of conditions—the government appears to have made a law that violates the First Amendment.<sup>109</sup>

If understood primarily as a response to the structural problem arising from the judicial development of a federal spending power,

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<sup>108</sup> To be precise, the point is evident in the assumption about Congressional power that can be discerned in ideas about overbreadth. Obviously, this is not to say that anyone will necessarily have standing, for this is a different question. For more expansive implications of the assumption about Congressional power, see Michael C. Dorf, *Facial Challenges to State and Federal Statutes*, 46 *Stan L Rev* 235 (1994).

<sup>109</sup> The literature on unconstitutional conditions is substantial. Some salient articles are Seth F. Kreimer, *Allocational Sanctions: The Problem of Negative Rights in a Positive State*, 132 *U Pa L Rev* 1293 (1984); Richard Epstein, *Unconstitutional Conditions, State Power, and the Limits of Consent*, 102 *Harv L Rev* 4 (1988); Kathleen Sullivan, *Unconstitutional Conditions*, 102 *Harv L Rev* 413 (1989); Lynn Baker, *The Prices of Rights: Toward a Positive Theory of Unconstitutional Conditions*, 75 *Cornell L Rev* 1184 (1990); Lynn Baker, *Constitutional Federal Spending After Lopez*, 95 *Colum L Rev* 1911 (1995).

the doctrine of unconstitutional conditions must focus on the distinction between purchases and regulation. Of course, the doctrine could be understood more broadly as a solution to the full range of injustices arising from government benefits or privileges—for example, it could be understood to apply to state spending and to include equal protection issues—but on the more modest and manageable assumption that the distinct and central problem of federal spending requires a distinct doctrinal response, the doctrine will be more narrowly understood here mostly as a solution to this federal problem. Perhaps state spending also requires a doctrine of unconstitutional conditions, but as will be seen, the doctrine as applied to federal spending is particularly necessary because of the structural problems created by the judges.<sup>110</sup> The basic frame-

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<sup>110</sup> Conditions on state spending need not be treated in the same way as conditions on federal spending. With respect to a federal spending power, the judicially created doctrine of unconstitutional conditions is necessary as a means of limiting the structural dangers that the judiciary itself stimulated through its development of a federal spending power. In contrast, with respect to state spending, the need for a doctrine of unconstitutional conditions is less clear, and any such doctrine perhaps need not be as strong, for the states have always had a general power to spend, and therefore the states' imposition of conditions on their spending does not so clearly create a structural problem. In short, the traditional power of a state to spend does not raise the same structural dangers as the federal power to spend, and because the judiciary created the federal problem, they have a particular responsibility to cure it. Other issues can also be distinguished from those on federal spending—particularly equal protection questions and related public forum issues. If the Equal Protection Clause of the Fourteenth Amendment provides for equal privileges as well as equal protection of natural rights, then there is no reason to think of the equal protection cases in terms of a doctrine of unconstitutional conditions. For example, in *Southeastern Promotions, Ltd. v Conrad*, 420 US 538, 559–60 (1975). Of course, whether the use of a municipal auditorium is really equivalent to the use of a public park is rather doubtful. One need only imagine an application by the Ku Klux Klan to use a city auditorium for a musical called *Robes*. What matters here, however, is simply that this problem is more easily understood in terms of equal protection than in terms of unconstitutional conditions. If, nonetheless, it is treated as an unconstitutional conditions problem, it is not clear that it should be understood in terms of the same doctrine as is applied to federal spending.

Even as applied to federal spending, the so-called doctrine of unconstitutional conditions should probably be viewed as two separate doctrines. On the one hand, when Congress spends (whether under its enumerated powers or under a spending power), it surely cannot purchase rights the Constitution allocates elsewhere—this being a limit arising from the assumption that Congress has only such powers as granted to it in the Constitution. On the other hand, in response to its expansion of federal power, especially its creation of a federal spending power, the Court should recognize that Congress sometimes uses spending that is more clearly authorized by the Court than the Constitution to regulate in ways that evade the enumerated limitations on federal power, and the Court should therefore conceive of this regulatory spending as subject to these limitations—at least, that is, those enumerated in the Bill of Rights. See note 115. To avoid unnecessary complexity, however, this essay treats these two doctrines together as the doctrine of unconstitutional conditions applicable to federal spending.

work of the doctrine was laid out two decades ago by Seth Kreimer, who distinguishes between threats and offers—threats being subject to the regular constitutional limitations, and offers not being subject to constitutional limitation, unless they deprive individuals of inalienable rights.<sup>111</sup> The general outline of this analysis captures the structural problem raised by federal spending, but as will be seen, each component of the analysis could, perhaps, be understood in terms that more closely match this problem—that is, in terms of regulation and purchases, regulation being subject to the usual constitutional limitations on federal constraints, and purchases not being subject to such limitations, unless they are purchases of rights that the Constitution allocates elsewhere.

The doctrine of unconstitutional conditions limits the government's ability to use its spending in ways that evade the Constitution's limitations. The Bill of Rights typically places limitations on constraints rather than privileges—that is, on the force of law rather than on the government's distribution of money and other benefits. Although the Establishment Clause of the First Amendment directly limits the government's distribution of privileges, most guarantees in the Bill of Rights, including the guarantee of speech and the press, merely limit the government's constraints. Congress has accordingly sometimes evaded the constitutional limitations on its imposition of constraints by placing conditions on its distribution of privileges. In particular, when Congress acts by means of its spending, it can achieve the effect of a constraint without formally resorting to the constraining force of law, and it can thus avoid compliance with the constitutional limits on constraints of law in both the enumeration of Congressional powers and the Bill of Rights.

The Court acknowledges this reality in its doctrine of unconstitutional conditions. As a distinct constitutional requirement, the doctrine of unconstitutional conditions is rather tenuous, for it lacks its own foundation in the text and is at best ill-defined and amorphous. Nonetheless, as an acknowledgment of the reality of government spending and how it is used, the doctrine is valuable. It recognizes that even though government spending does not formally violate the Constitution's limits on the government's imposition of constraints, such spending may still, in reality, con-

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<sup>111</sup> Kreimer, 132 U Pa L Rev at 1301 (cited in note 109).



stitute a means of constraint and thus a means of accomplishing what the Constitution forbids.

This inquiry into the realities of the matter is necessary because the spending power itself is a judicial creation. Ordinarily, there would be little reason to go beyond the formal prohibitions of the Constitution, and where the First Amendment prohibits only government restraints, there is usually no need to consider whether government spending is, in reality, a restraint. Yet when Congress and the Supreme Court took a Hamiltonian approach to the taxing power and carved out a spending power, they developed Congress's power in a way that was not clearly limited—not even by most of the Bill of Rights. In fact, the so-called Spending Clause was written as a limitation on the taxing power and was carefully drafted so that it would not imply a general power to spend—thus leaving Congress to spend only as permitted under its other powers.<sup>112</sup> The Supreme Court, however, long ago held that Congress has a general spending power as part of its power to tax, and the Court therefore found itself in the awkward situation of having

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<sup>112</sup> For the history of the Spending or General Welfare Clause, see Jeffrey T. Renz, *What Spending Clause? (Or the President's Paramour): An Examination of the Views of Hamilton, Madison, and Story on Article I, Section 8, Clause 1 of the United States Constitution*, 33 *John Marshall L Rev* 81 (1999). The crucial evidence, which Renz only notes in passing, is that there was a surreptitious attempt to create a separate spending power by adding a semicolon in the middle of the first paragraph of Section 8 of Article I of the Constitution. *Id.* at 105. On September 4, 1787, the Committee of Eleven reported to the Convention a draft of what became Section 8 that read: "The Legislature shall have power to lay and collect taxes, duties, imposts, and excises, to pay the debts and provide for the common defence and general welfare of the United States." *Journal* (Sept 4, 1787), Max Farrand, 2 *Records of the Federal Convention* 493 (1937). On September 12, the Committee on Style reported a version of this paragraph, and on the next day, it distributed a printed version of its report. John Quincy Adams's *Memoirs* (Jan 11, 1823), Farrand, 3 *Records* 457 Appendix CCXLIV. In this printed report, however, there was not a comma, but a semicolon after the word "excises"—so that "to pay the debts and provide for the common defence and general welfare of the United States" became an additional power, conjoined to the power to tax, rather than merely a limitation on it. *Id.* at 594 (Report, Sept 12, 1787). The Convention, however, recognized this alteration and rejected it. At stake was simply the addition and removal of a single dot above a comma. Rarely has so much rested on so small a point.

Its importance was recognized already in early debates about the Constitution. For example, in 1798, Albert Gallatin told the House of Representatives, "he was well informed that those words had originally been inserted in the Constitution as a limitation to the power of laying taxes. After the limitation had been agreed to, and the Constitution was completed, a member of the Convention, (he was one of the members who represented the State of Pennsylvania [i.e., Gouverneur Morris]) being one of a committee of revision and arrangement, attempted to throw these words into a distinct paragraph, so as to create not a limitation, but a distinct power. The trick, however, was discovered by a member from Connecticut, now deceased, and the words restored as they now stand." Albert Gallatin in the House of Representatives (June 19, 1798), 3 *Records* 378 Appendix CCLXXXI.

conceded to Congress a power that is not clearly limited, whether by the enumeration of Congressional powers or most of the enumeration of rights.<sup>113</sup> For example, Congress has no power to impose constraints on speech or the press, let alone research, and the First Amendment bars constraints that abridge the freedom of speech, or of the press, but if Congress has a general power to spend subject to conditions, it can use conditions on its spending to regulate speech and the press without limitation by either the enumerated powers or the enumerated rights. This is an enormous structural problem. Having legitimated this escape from the Constitution's formal limitations, the judges can surely place some limits on Congress's use of it. Among other things, they should inquire whether, in reality, the conditions on spending are being used to constrain in a manner analogous to the force of law, and if so, whether they are being used to impose constraints of a sort forbidden by the Constitution.

This understanding that a condition can serve as a constraint is essential for preventing the judicially developed spending power from becoming an end run around the guarantee of speech and press in the First Amendment. The Bill of Rights created, as Madison explained, "particular exceptions to the grant of power," and thus the First Amendment unequivocally limits any Congressional power to spend.<sup>114</sup> Although in developing a spending power, the Court allowed Congress to escape the limitations specified in the enumeration of Congress's powers, it apparently is not willing to let Congress use the spending power as a path around the First Amendment.<sup>115</sup>

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<sup>113</sup> The attempts of the Justices to resolve this conundrum are evident in *United States v. Butler*, 297 US 1, 66 (1936), and *South Dakota v. Dole*, 483 US 203 (1987).

<sup>114</sup> Madison's speech of June 8, 1789 (as reported in *Congressional Register*), in Helen E. Veit, Kenneth R. Bowling, et al, eds, *Creating the Bill of Rights* 83 (1991).

<sup>115</sup> In *South Dakota v. Dole*, the Court stated that "we have noted that other constitutional provisions may provide an independent bar to the conditional grant of federal funds." *South Dakota v. Dole*, 483 US 203, 208 (1987). In *League of Women Voters*, it held a federal condition unconstitutional under the First Amendment. *FCC v. League of Women Voters*, 468 US 364 (1984). In *Rust*, the Court acknowledged that there were circumstances in which the First Amendment limited conditions on federal spending. *Rust v. Sullivan*, 500 US 173, 194 (1991).

Although for purposes of this inquiry, it is only necessary to focus on the Constitution's enumerated rights, the reasons for the doctrine of unconstitutional conditions suggests that any spending power should also be limited by the enumerated powers. Certainly, the legislative and judicial creation of a spending power permits an end run around the enumerated powers as much as around the enumerated rights. As the Court candidly admitted in *Dole*, "objectives not thought to be within Article I's 'enumerated legislative fields' . . .

To understand when Congressional spending violates the First Amendment's guarantee of freedom of speech, or of the press, it is first necessary to distinguish (as suggested by Lynn Baker) between purchases and regulation.<sup>116</sup> If the doctrine of unconstitutional conditions is understood broadly as a cure for the unjust distribution of government privileges, then this distinction may be inadequate, but if the doctrine is understood more narrowly as an attempt to contain the structural damage done by judicial acceptance of a spending power, then the most basic question is whether the government has merely made an expenditure for a benefit defined by a condition or has, in reality, used the condition to create a substitute for the constraining force of law. In less abstract terms, the issue is whether the government's conditional spending amounts to a purchase or a regulation.

Conditions on mere purchases are generally constitutional, unless they are attempts to purchase rights that the Constitution allocates to others. Whether Congress acts under its enumerated powers or under a spending power, it is free to place conditions on its purchases, such as its contracts for goods and services, including speech or the press.<sup>117</sup> Nonetheless, such purchases are

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may nevertheless be attained through the use of the spending power and the conditional grant of federal funds." *South Dakota v Dole*, 483 US 203, 207 (1987). With this in mind, Lynn Baker, not unlike James Madison, argues that any regulatory use of the spending power should be limited not only by the enumeration of rights but also by the enumeration of Congressional powers. Baker, *Conditional Federal Spending*, 95 Colum L Rev at 1935 (cited in note 109).

Yet the use of enumerated Congressional powers to limit the spending power is questionable, for if there is a spending power, it is not evident why it would be limited by the other, more clearly enumerated powers. For example, there is no reason to think that the Commerce Clause is limited by any other enumerated power in Article I, Section 8 of the Constitution. (Of course, each grant of power must be interpreted in accord with the whole of the Constitution, including other grants of power, but the other grants thereby reveal the scope of the commerce power; they do not limit it.) In these circumstances, even if the doctrine of unconstitutional conditions brings the Bill of Rights to bear against the federal spending power, it cannot easily apply the enumeration of powers to limit this power. It would seem, therefore, that the Court's latter-day creation of a "spending power" threatens to unravel the limited character of American government, and the doctrine of unconstitutional conditions probably cannot adequately repair the damage. This point, however, need not be pursued here.

<sup>116</sup> Lynn Baker draws a distinction between regulatory and reimbursement spending. *Id.* at 1954.

<sup>117</sup> *National Endowment for the Arts v Finley*, 524 US 566 (1998); *United States v American Library Association, Inc.*, 539 US 194 (2003). In *Rust*, the Court noted that it was "not the case of a general law singling out a disfavored group on the basis of speech content, but a case of the Government refusing to fund activities, including speech, which are specifically excluded from the scope of the project funded." *Rust v Sullivan*, 500 US 173, 194–95 (1991). The government in *Rust* "used private speakers to transmit specific information pertaining to its own program." *Rosenberger v Rector and Visitors of University of Virginia*,

limited by the Constitution if Congress attempts to purchase what the Constitution elsewhere carves out from Congressional power.<sup>118</sup> This minimal limitation on purchases is not merely a response to the creation of a spending power; rather, it arises from the fact that the Constitution gives Congress limited powers, and presumably Congress cannot purchase a power over rights that the Constitution gives to others. Congress thus can reach an agreement with a person for him to waive a particular exercise of one of his rights, but it cannot purchase the right in general or even a significant part of it.<sup>119</sup> To take two clear-cut examples, although

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515 US 819, 833 (1995).

Incidentally, in *Finley*, the Court stated that “when the Government is acting as patron rather than as sovereign, the consequences of imprecision are not constitutionally severe.” *National Endowment for the Arts v Finley*, 524 US 566, 589 (1998). As will be seen, however, when the government uses conditions on spending as a means of regulation, it is acting as a sovereign.

<sup>118</sup> Kathleen Sullivan takes such a view, although she takes it much more broadly than it is understood here, and she combines it with a theory of strict scrutiny. Her central point, however, is very apt even for this article’s limited version of the doctrine of unconstitutional conditions—that “[t]he doctrine of unconstitutional conditions holds that government may not grant a benefit on the condition that the beneficiary surrender a constitutional right, even if the government may withhold that benefit altogether.” Sullivan, 102 Harv L Rev at 413 (cited in note 109).

<sup>119</sup> The two categories can be illustrated by some of the cases. For example, *Rust* involved the waiver of a particular exercise of the right of freedom of speech rather than a purchase of the right in general, as the Court seemed to appreciate when it pointed out that the regulation placed the condition on the program rather than the grantee. The Court explained that the regulations “do not force the Title X grantee to give up abortion-related speech; they merely require that the grantee keep such activities separate and distinct from Title X activities. Title X expressly distinguishes between a Title X *grantee* and a Title X *project*. . . . The Title X *grantee* can continue to perform abortions, provide abortion-related services, and engage in abortion advocacy; it simply is required to conduct these activities through programs that are separate and independent from the project that receives Title X funds.” *Rust v Sullivan*, 500 US 173, 197 (1991). (The Court then added: “In contrast, our ‘unconstitutional conditions’ cases involve situations in which the government has placed a condition on the *recipient* of the subsidy rather than on a particular program or service, thus effectively prohibiting the recipient from engaging in the protected conduct outside the scope of the federally-funded program.” *Id.*) For other examples of nonregulatory conditions involving only a waiver of a particular exercise of a right, see *Regan v Taxation with Representation or Washington*, 461 US 540 (1983); *Snepp v United States*, 440 US 507 (1980).

*League of Women Voters* is an example of the purchase of a right in general or at least a substantial portion of it. In this case, the Court overturned a condition that required noncommercial educational stations to avoid editorializing, which amounted to a large part of their First Amendment right of speech and press. *FCC v League of Women Voters*, 468 US 364 (1984). At the very least, this condition amounted to a purchase of a right that the Constitution denies to the federal government. In addition, as will be seen in note 130, it could be viewed as a regulation, but this point can wait.

A more complex case is *Legal Services Corporation v Velazquez*, 531 US 533 (2001). The Court held unconstitutional the government’s condition on its funding of the Legal Services Corporation that the corporation not engage in representation involving an effort to amend or otherwise challenge the validity of existing welfare law. Even if this was not

Congress can purchase a federal employee's waiver of his freedom of speech as to information acquired in his employment relationship, it cannot purchase a general sacrifice of his freedom of speech as to all matters in all of his relationships. This bar against Congress's purchase of a right the Constitution allocates to others is not a severe limit, and otherwise, Congress is free to place conditions on its purchases.

In contrast, Congress sometimes uses a condition on its spending to create what is really a means of regulation, and in these instances, it faces more substantial limitations. The spending power is not an excuse for regulating in a manner forbidden by the Constitution, and therefore if, in reality, Congress is regulating, it cannot do so in a way that violates the Bill of Rights. As the Supreme Court stated in *South Dakota v Dole*, the government can use conditions to define what it is purchasing, and it can also use conditions to regulate, but "other constitutional provisions may provide an independent bar to the conditional grant of federal funds"—not least, it may be presumed, when the federal government uses conditions to regulate in a manner inconsistent with the First Amendment.<sup>120</sup>

#### B. UNCONSTITUTIONAL CONDITIONS AND IRBS

The application of the unconstitutional conditions doctrine to the federal IRB regulations must follow their structure. The regulations most basically create an "ethical principles" condition. On

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a large part of the corporation's right of speech, or that of their clients, the condition limited the ability of the judges to hear arguments from the corporation's lawyers questioning the constitutionality of welfare laws. In this way, according to the Court, it "threatens severe impairment of the judicial function." *Id.* at 546. Thus, the condition was, perhaps, an attempt to purchase a right allocated by the Constitution to the judiciary itself. Alternatively, however, the condition could be viewed as being, in reality, a regulation—indeed, one that abridged the freedom of speech of the poor.

Another unusual case is *United Public Workers v Mitchell*, 330 US 75 (1947). The Hatch Act made it unlawful for most federal executive branch employees to take any active part in political management or in political campaigns, and in *Mitchell*, the Court upheld this. Yet although the statute had the effect of placing a condition on federal employment, it was, more fundamentally, a direct regulation.

As observed in note 110, the cases on federal spending as a means of regulation should probably be understood as distinct from the cases on state spending or on equal protection. The cases on state spending respond to issues somewhat different from the structural problem of a judicially created federal spending power and therefore should not be viewed as involving the same doctrine of unconstitutional conditions. Moreover, cases based on equal protection doctrine are perhaps most concretely understood in terms of equal protection rather than unconstitutional conditions.

<sup>120</sup> *South Dakota v Dole*, 483 US 203, 208 (1987).

this foundation, they then add an IRB licensing condition.

The “ethical principles” condition derives from the statement in the IRB regulations that an institution can receive federal support for human subjects research only if it gives the government “[a] statement of principles governing the institution in the discharge of its responsibilities for protecting the rights and welfare of human subjects of research conducted at or sponsored by the institution, regardless of whether the research is subject to Federal regulation.” The regulations add that “[t]his may include an appropriate existing code, declaration, or statement of ethical principles, or a statement formulated by the institution itself.”<sup>121</sup> Accordingly, before giving support for research at an institution, the government asks the institution to assure the government “that all of its activities related to human subject research, regardless of funding source, will be guided by . . . ethical principles.” In particular, it requires the institution to choose between the ethical principles in either the *Belmont Report* (which sets out ethical principles and guidelines for protecting human subjects, and which assumes the existence of IRBs) or ethical principles elaborated in another document, as negotiated between the institution and the government.<sup>122</sup> The government in this way uses its funding of some research to get “ethical principles” for other research.

By leveraging its conditions on federally supported human subjects research to control the “ethical principles” of all human subjects research, the government reveals that it is not simply specifying the sort of research it is willing to fund, but is attempting generally to regulate the ethics of human subjects research. If as suggested in Part III, the federal regulations on IRBs define “research” in terms of speech and the press, then this regulatory use of a condition to impose “ethical principles” on research is troubling. The problem is partly that Congress is using its spending to regulate speech and the press, over which Congress does not have regulatory power.<sup>123</sup> Even more pointedly, Congress appears

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<sup>121</sup> 45 CFR § 46.103(b)(1).

<sup>122</sup> HHS, *Federalwide Assurance (FWA) for the Protection of Human Subjects for Domestic (U.S.) Institutions*, p 1 (version date 03/20/2002). Apparently, relatively few American research institutions have negotiated an alternative statement of ethical principles.

<sup>123</sup> For the limits on Congressional power, see *United States v Lopez*, 515 US 549 (1995). For Congress’s lack of power over speech or the press, see Philip Hamburger, *Natural Rights and Positive Law: A Comment on Professor McAfee’s Paper*, 16 SIU L J, 307, 310–11 (1992).

to be using conditions to regulate speech and the press in a manner incompatible with the First Amendment.

In particular, the requirement of “ethical principles” in “research” is a form of content discrimination. In many areas of research, ethical principles are continually contested, and in some fields, such as the humanities and social sciences, supposedly unethical modes of inquiry (such as not disclosing one’s identity, taking a person unawares, and causing offense or disgust) are often crucial means of expressing challenges to conventional assumptions, including ethical principles.<sup>124</sup> The content discrimination is all the more problematic when the “ethical principles” condition is applied to purely verbal research—whether in the hard sciences, the soft ones, or the humanities—for in verbal research, a provocative and apparently unethical form of inquiry (including aggressive questioning about sensitive and embarrassing issues, deceit of the sort that does not clearly give rise to legal liability, and the exposure of “private” information and the identity of the human subject) is the very essence of the research. One need only imagine, for example, how a professor could usefully study members of the Ku Klux Klan or high-ranking corporate officials if he had to get their informed consent, if he could not engage in ruses to gain their trust, or if he could not later publish private information that caused emotional and even financial and legal harm.<sup>125</sup>

<sup>124</sup> Incidentally, Justice Frankfurter wrote: “No field of education is so thoroughly comprehended by man that new discoveries cannot yet be made. Particularly is that true in the social sciences, where few, if any, principles are accepted as absolutes.” *Sweezy v New Hampshire*, 354 US 234, 250 (1957).

<sup>125</sup> The example of a Klansman is used by Linda Shopes, *Institutional Review Boards Have a Chilling Effect on Oral History*, *Perspectives* 62 (Sept 2000); Cary Nelson, *Can E.T. Phone Home?* 89 *Academe* 30 (2003). Incidentally, note that there are distinctions among proprietary information, information as to which one has a fiduciary duty, and information that is private merely in the sense that it was shared in a meeting rather than on prime time television.

The stifling implications of the “ethical principles” condition are also evident from its application to research on human subjects who are public officials. Research on these human subjects is at least “exempt” from needing IRB approval. Yet even leaving aside that the exemption must nonetheless be confirmed by the IRB, the “ethical principles” condition remains in place and thus limits aggressive questioning of public officials. As the National Science Foundation advises IRBs: “When the subjects are public officials or candidates for public office, the research is exempt even when identifiers are included or disclosure might be harmful. However, all research should be bound by professional ethics and respect for respondents to guard their privacy whether or not the research is exempt (unless the participants understand that their information may be made public and permission is granted).” National Science Foundation, Division of Institution and Award Support, *Frequently Asked Questions and Vignettes*, at <http://www.nsf.gov/bfa/dias/policy/hfaq.htm>.

Thus, in using its funding for some research to secure “ethical principles” for all research at an institution, the government employs its spending to regulate—indeed, to regulate in a manner that apparently violates the First Amendment.

In addition, the government imposes an IRB condition: It requires institutions receiving its support for human subjects research to establish IRBs—at least for the supported research—and this condition is, in reality, a means of regulation. As noted above, whereas a condition that is not regulatory can violate a person’s freedom of speech, or of the press, only if the condition is a purchase of a substantial portion of this right, a condition that amounts, in reality, to a regulation can violate the First Amendment in the same way as any other regulation.

Although the IRB condition applies only to federally funded research, its breadth suggests that it is regulatory. The government makes IRBs a condition of all types of research on human subjects that it supports, even though much of the research is not at all dangerous. If the government merely wanted to avoid supporting dangerous research, it could easily distinguish dangerous physiological research from largely harmless inquiries, such as social science surveys and historical research, which do not ordinarily cause legally cognizable injuries. At the very least, it could leave all purely verbal research beyond the jurisdiction of the IRBs. Instead, it makes IRBs a condition of all human subjects research that it supports. The breadth of this condition suggests that it cannot be understood as a narrow attempt by the government to protect its legitimate interests in preserving proprietary information, supporting a particular point of view, or not funding dangerous activities. It looks like a regulation rather than a purchase.<sup>126</sup>

The regulatory character of the condition requiring IRBs for federally supported research becomes further evident from the fact that it is part of a wider scheme to pressure research institutions to employ IRBs for all research, regardless of the source of fund-

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<sup>126</sup> For similar reasons, the current authorizing statute (like the original National Research Act of 1974) is also probably unconstitutional. The current act states, in part: “The Secretary shall by regulation require that each entity which applies for a grant, . . . for any project or program which involves the conduct of biomedical or behavioral research involving human subjects submit . . . assurances . . . that it has established (in accordance with regulations . . .) a board (to be known as an ‘Institutional Review Board’) to review biomedical and behavioral research involving human subjects conducted at or supported by such entity in order to protect the rights of the human subjects of such research.” 42 USC § 289.



ing. The history of the IRB movement makes this clear, for the goal and effect was to adopt licensing as a means of protecting human subjects in all research rather than simply to ensure that the federal government did not support dangerous research.<sup>127</sup> As might be expected, therefore, the proposed draft of the federal regulations published in 1979 by the Department of Health, Education, and Welfare (“HEW”) would have “require[d] IRB review and approval of research involving human subjects, even if it is not supported by Department funds.”<sup>128</sup> When faced with protests against this federal condition—one of the few half-successful attempts of academics to limit such censorship—the government adopted the predecessors of the current regulations, which simply employed less direct mechanisms to achieve the same end.<sup>129</sup> For

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<sup>127</sup> The necessity of pursuing the goal of general regulation though the limited jurisdiction of Congress and its relevant committee was frequently made explicit. For example, in 1974, the Committee Report on the National Research Act, Pub L 93-348, stated: “It is the Committee’s belief that the establishment of such a commission [the National Commission for the Protection of Human Subjects] is essential to the development of a system where human subjects of biomedical and behavioral research are adequately protected. The Committee agrees with those witnesses who testified that the scope of the inquiry, findings, and procedure of such a national commission should cover all biomedical and behavioral research involving human subjects. But the Committee also recognizes that its jurisdiction is limited to those programs and activities defined in the Public Health Service Act, the Community Mental Health Centers Act and the Developmental Disabilities Act, and that further expansion would be a complicated matter . . .” 2 *United States Congressional and Administrative News*, 93d Cong, 2d Session 1974, 3653. See also National Research Act, Pub L 93-48 (July 12, 1974). In 1978, the National Commission for the Protection of Human Subjects recommended that federal law should be enacted or amended to allow HEW “to promulgate regulations governing ethical review of all research involving human subjects that is subject to federal regulation.” National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, *Report and Recommendations: Institutional Review Boards 3* (DHEW Publication No 78-0008) (1978).

Today, the National Science Foundation answers the question “What are the overall goals of the federal policy (the Common Rule)?” by stating generally: “The major goal is to limit harms to participants in research. That means no one should suffer harm just because they became involved as subjects or respondents in a research project. Institutions engaged in research should foster a culture of ethical research.” National Science Foundation, Division of Institution and Award Support, *Frequently Asked Questions and Vignettes*, at <http://www.nsf.gov/bfa/dias/policy/hsfaqs.htm>.

<sup>128</sup> Proposed Regulations Amending Basic HEW Policy for Protection of Human Research Subjects, 44 Fed Reg 47688 (Aug 14, 1979).

<sup>129</sup> The head of the organization that drafted the regulations and that later became OHRP has explained that the government responded to the First Amendment objections raised by Pool and others simply by adopting less direct means of achieving the same regulatory ends: “Friendly champions of social and behavioral sciences showed us how to back away from our unpopular positions while continuing to offer what we felt were reasonable protections for the dignity and rights of subjects involved in social and behavioral research—to say nothing of saving the face and the jobs of OPRR staff.” C. R. McCarthy, *Introduction: The IRB and Social and Behavioral Research*, in J. E. Sieber, ed, *NIH*

example, the regulations apply the “ethical principles” condition to *all* research at an institution and thus commit the institution to the ethical foundations for IRBs, regardless of the source of support for the research. Moreover, as will be seen shortly, federal administrators have often refused to accept assurances that do not impose IRBs on all research, regardless of funding, and the federal regulations co-opt the force of state law to pressure institutions to adopt IRB licensing for all research, even if not federally funded. In these circumstances, the condition that institutions must use IRBs for federally supported research is, in reality, just part of a broader scheme of regulation. As noted in Part III, the federal regulations directly target and even specify speech and the press, and because they regulate speech and the press by means of licensing, they appear to violate the First Amendment.<sup>130</sup>

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*Readings on the Protection of Human Subjects in Behavioral and Social Science Research* 8–9 (1984), as quoted in National Research Council, *Protecting Participants* 71 (cited in note 5).

<sup>130</sup> Of course, there are other possible indicia that a condition on spending is, in reality, a regulation—for example, the reach of the spending, the degree of coercion, the nexus of the condition to the spending or whether it is germane, and the disproportionality between the condition and the spending. See, for example, *FCC v League of Women Voters*, 468 US 364, 399–401 (1984), for the Court’s assumption that the disparity between the support and the condition was significant. It is not clear, however, that any of these considerations should alone be dispositive.

Some of the indicia mentioned in this footnote are slightly relevant to IRB regulations but not as much as those mentioned in the text. If the federal government funded most of the human subjects research in a broad field of inquiry, such as medicine or biology, this would, perhaps, be an indication that the condition is regulatory. Moreover, the IRB condition seems disproportionate because the federal regulations place the condition not on funding, but on any support, however minor. 45 CFR § 46.101(a).

As for the degree of coercion, the coercive effect of conditions is not necessarily an indication that they are regulatory, but coercion is certainly very much evident in the federal government’s relationship to universities. This power is partly a matter of funding. It is also, however, created by the cross-conditioning of grants through “assurances” from institutions rather than researchers. OHRP reminds institutions of this cross-conditioning through its site visits and the implicit threat of a shutdown. OHRP can suspend an institution’s assurance of its compliance even if only one researcher covered by the assurance is found to be out of compliance. If the institution elects to assure the government that it follows the regulations for research not supported by the government, then OHRP can even suspend the assurance for a compliance failure by a researcher working without any federal funding. As many social science researchers—for example, historians—cannot reasonably do their research without departing from IRB requirements, OHRP can easily find violations, and therefore its site visits are viewed with trepidation. Most violations are nothing more than failures to follow the licensing procedures. Even when a noncomplying researcher does cause serious harm, the government ordinarily has little reason to assume that other, unrelated research at the institution is causing any injury, and the additional problems it finds are usually only procedural. Accordingly, when OHRP responds to serious injuries in a research project by threatening to shut down all federally funded research at the institution, it makes an utterly disproportionate in terrorem threat. In the late 1990s, the predecessor of OHRP briefly shut down research at about a half dozen institutions, and since then its site visits have carried an implicit and sometimes explicit threat of a shutdown. In the words of a former head of this office, “[t]he suspensions

Thus far, it has been assumed here that a condition will be unconstitutional if the government uses it to regulate in a way that violates the First Amendment, but the constitutional test for regulatory conditions may, perhaps, be more sensitive than this. In particular, it has been questioned whether the government can use a condition to require licensing in even a single grant for university researchers, if the condition is likely to invite a more general imposition of such conditions.<sup>131</sup> In 1991, in *Stanford v Sullivan*, NIH had awarded a grant to researchers at Stanford University on the condition that they “obtain government approval before publishing or otherwise publicly discussing preliminary research results.” When the university challenged this condition, a U.S. District Court held the condition unconstitutional under the First Amendment, explaining that otherwise, “the result would be an invitation to censorship wherever government funds flow, and . . . thus . . . an enormous threat to the First Amendment rights of American citizens and to a free society.”<sup>132</sup> Apparently, therefore, the IRB condition is vulnerable as an unconstitutional regulation and even, perhaps, as an invitation to unconstitutional regulation.

### C. CO-OPTING STATE LAW

The second sort of federal action evident in the federal regulations on IRBs is that they co-opt the force of state law. Although

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created a crisis of confidence and a climate of fear.” Greg Koski, *Beyond Compliance . . . Is It Too Much to Ask?* 25 *Ethics & Human Research* 5 (2003).

Incidentally, one effect of this climate of fear is to give force to the guidance, advice, and recommendations of OHRP. Although couched in mild terms, these attempts to counsel institutions seem more like commands. Indeed, OHRP uses its site visits and the threat of shutdowns to get institutions, including universities, to impose education requirements on their teachers, students, and other personnel who study human subjects. These required classes include indoctrination on the importance of IRBs and the need to cooperate with them. The reach of the education requirements can be illustrated by an e-mail sent by Columbia University to all of the faculty, students, and administrators at its main campus, in which the Provost admonished: “All personnel involved in the conduct of human research must take and pass the appropriate human subject research training course before embarking on such research.” Indeed, “[c]onducting human subjects research without appropriate training and review could have serious consequences.” E-mail from Provost Alan Brinkley and Executive Vice President for Research to Faculty, Administrators, and Students at the Morningside Campus (Oct 15, 2004).

<sup>131</sup> A condition on a single grant would also probably be unconstitutional, even if it did not attempt to regulate beyond the limits on federal power, if it generally deprived an individual of a right—for example, if it required a person to give up his right to a jury trial not merely in a particular case but in all cases in which he might one day be a party. This, however, is not clearly the problem here.

<sup>132</sup> *Stanford v Sullivan*, 773 F Supp 472, 473, 478 (1991).

the federal regulations do not directly require IRBs, they take advantage of state law to achieve the same end—even for research that is not federally supported.

The commitment of institutions to adhere to the federal regulations on IRBs is said to be “[o]ptional” for research not funded by the federal government.<sup>133</sup> When the government asks an institution to provide an assurance that all of its federally supported research will comply with the government’s “Terms of Assurance” and thus with its IRB regulations, the government also asks the institution to indicate whether it “elects” to apply the federal regulations on IRBs “to all of its human subject research regardless of source of support.”<sup>134</sup> Thus, whereas for government-supported research, the use of IRBs is a condition, for other research, the government merely suggests that institutions voluntarily commit to using them. Although the government makes this suggestion under the heading of “[o]ptional,” it clearly assumes that IRBs are the conventional method by which institutions should ensure their adherence to “ethical principles” and that its regulations are the appropriate standard for IRBs, even for research not supported by the government.<sup>135</sup> Moreover, it hopes institutions will elect to adhere to the federal regulations for such research, because this makes an institution subject to enforcement by OHRP for any breach of the assurance, regardless of the funding. With these aspirations in mind, the government has not always viewed the election as optional. For example, in the 1970s, HEW regulations threatened to deny funding to institutions that did not follow this department’s IRB policies for all human subjects research, regardless of the source of funding.<sup>136</sup> For a while in the 1990s,

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<sup>133</sup> See, for example, HHS, *Federalwide Assurance (FWA) for the Protection of Human Subjects for Domestic (U.S.) Institutions*, p 2 (version date 03/20/2002).

<sup>134</sup> See, for example, *id.* Under the HHS regulations, institutions can choose to assure the government that they will adhere to Subpart A—the Common Rule—or Subparts A, B, C, and D. *Id.*

<sup>135</sup> For the heading, see, for example, *id.*

<sup>136</sup> Robertson wrote in 1979: “DHEW requires institutions to commit themselves to review all research, regardless of funding, in the sense that failure to conform to the DHEW policy in nonfunded research may be taken into account ‘in evaluating applications or proposals for support of activities covered by this part.’ 45 CFR § 46.121(b) (1977). Strictly speaking, such review is not a requirement for a general assurance, though failure to include it could mean as a practical matter no funding.” Robertson, 26 UCLA L Rev at 499 (cited in note 11). Incidentally, early in the 1970s, before the adoption of the regulations, HEW employed a more general approach, which did not focus as closely on the assurance. For example, in the 1971 “Yellow Book,” HEW stated: “If, in the judgment

moreover, the predecessor of OHRP apparently declined to accept assurances in which institutions failed to make the election. As dryly put by one observer, if you declined, “you were urged strongly” to reconsider.<sup>137</sup> This was an additional unconstitutional condition, and partly as a result, in the late 1990s, almost all American colleges and universities that had a so-called Multiple Project Assurance made the election. Since 2000, however, the election has become more optional, and OHRP now more clearly accepts assurances that decline to apply the regulations to research unsupported by the federal government.<sup>138</sup>

In fact, strong arm tactics are no longer necessary, because once the government had elevated IRBs as the standard method of avoiding research injuries, it could rely on state tort law to induce research institutions to use IRBs. By establishing IRB licensing as the standard method of preventing research injuries, the government made IRB licensing an attractive means for institutions to limit state tort liability, and the government has thereby created

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of the Secretary, an institution fails to discharge its responsibilities for the protection of the rights and welfare of the individuals in its care, whether or not DHEW funds are involved, he may question whether the institution and the individuals concerned should remain eligible to receive future DHEW funds for activities involving human subjects.” *The Institutional Guide to DHEW Policy on Protection of Human Subjects* 17 (DHEW Pub No (NIH) 72-102) (1971).

<sup>137</sup> Conversation with former head of a university IRB. Prior to December 2000, the standard form of assurance for an institution at which many persons conducted research was the so-called Multiple Project Assurance, and of the just under five hundred institutions that had given such an assurance, only about a half dozen (by one account only five) had not elected to apply the Common Rule to all of their human subjects research, regardless of the source of funding. Indeed, the government’s sample Multiple Project Assurance stated: “MPA institutions generally elect to comply with all Subparts of 45 CFR 46 for any research conducted under their auspices (i.e., regardless of the source of support). . . . This has been taken into account in working the sample text”—that is, the form did not even leave space to opt out of the election. Division of Human Subjects Protections, Office for Protection from Research Risks, NIH, DHHS, *Sample Language for a DHHS Multiple Project Assurance . . . in Accordance with the Federal Policy (Effective August 19, 1991)* (June 1999 version), at <http://www.hhs.gov/ohrp/humansubjects/assurance/mpa.htm>. Today, approximately 75 percent of major domestic research institutions are said to commit themselves to adhere to the Common Rule, and some observers speculate that more than 90 percent and perhaps almost all of American colleges and universities make this election, although this is unclear, because the numbers are not currently available from OHRP.

<sup>138</sup> Even today, however, it is not clear whether a major institution can make such an election without some bargaining. The election still matters as a mechanism for allowing OHRP to enforce the regulations as to research the government does not support. The government, however, does not care as much as it used to whether institutions make the election, because institutions now have another reason to use IRBs, under at least equivalent standards, for research on human subjects, regardless of the election, and regardless of the source of funding. Accordingly, many institutions now consider the election little more than a technicality about OHRP’s jurisdiction—that is about reporting requirements and enforcement.

powerful pressures on institutions to adopt IRB licensing for all human subjects research conducted under their auspices. Institutions have good reason to worry about the legal risks of failing to adopt IRBs for all of their human subjects research. Of course, an institution need not accept federal grants. Moreover, even if it does accept federal support, it can choose its own methods of enforcing “ethical principles” in its non-federally-funded research—for example, by instituting IRBs less severe than those stipulated in the federal regulations, or by establishing clear rules and subsequent penalties. Yet IRB licensing—particularly IRB licensing of the severity specified in the federal regulations—clearly has the government’s approval as the appropriate method of ensuring ethical research, and this licensing therefore offers institutions, if not an entirely safe harbor, at least a safer harbor than not using such IRBs. To be precise, if an institution does not use IRBs, or if it uses an IRB less intrusive than those required by the federal regulations, the institution must worry that it will be accused by a litigant of adopting a less careful and thus less reasonable means of ensuring adherence to “ethical principles” or otherwise preventing harm. Accordingly, against the background of state tort law, institutions fear they will be held liable for their failure to use licensing—whether for federally funded research or other research.<sup>139</sup> Indeed, they must be vigilant not only in estab-

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<sup>139</sup> The AAUP Report explains: “Consider the following: a privately funded research project is carried out at a university, one of the human subjects claims to have been harmed by the research, and the subject sues the university. Consider further that the university’s IRB does not review research that is not funded by the government. The litigant will almost certainly argue that the university’s failure to review privately funded research while it reviews government-funded research is proof that it acted unreasonably. Conversely, if the university’s IRB has approved the research, the university will cite that fact as evidence of its reasonableness in permitting the research to go forward. Whatever the merits of these arguments, the university’s legally prudent course of action, so the lawyers will advise, is for its policy to apply to all research on human subjects, irrespective of the source of funding. An aversion to legal risks may also help explain the actual decision of IRBs, to the extent that they seek to protect the institution (and perhaps themselves as well) from lawsuits that allege mistreatment of human research subjects.” The Report adds that “no university is likely to want to explain to either the government or the public why its commitment to avoid harming the human subjects of research is limited by the source of funding for the research. This prospect is even less attractive as IRBs expand their authority in response to concerns that the government must do more to protect human research subjects.” AAUP, *Protecting Human Beings*, *Academe: Bulletin of the AAUP* at 60 (cited in note 12).

Indeed, it has been argued that “research institutions must increasingly take a conservative approach to granting licenses for social research because IRB approval is one criterion for determining whether the university is culpable, with the researcher for harm to subjects.” Lauren H. Seiler and James M. Murtha, *Federal Regulation of Social Research: Is “Prior Review” Posing a Threat to Academic Freedom?* 53 *Freedom at Issue* 26, 29.

lishing licensing but also in doing it thoroughly. As OHRP explains when reminding IRBs to evaluate methodologies, “[r]esearch that is conducted so poorly as to be invalid exposes subjects and the institution to unnecessary risk.”<sup>140</sup> No institution’s legal counsel, risk management officer, or insurer can ignore this legal risk. As a result, the government’s choice has become that of private and state institutions.<sup>141</sup>

This would not be of so much concern if the federal government had merely published safety standards and encouraged institutions to adopt them. Certainly, the First Amendment does not prevent government from using its powers of persuasion and even its spending and regulatory powers to encourage institutions to adopt what it considers reasonable means of avoiding harm. Here, however, the government has advocated a mechanism that it is constitutionally forbidden from imposing, it has employed unconstitutional conditions to ensure wide use and acceptance of this mechanism, and it has relied upon this wide use and acceptance to trigger liability under state tort law for institutions that do not adopt the mechanism for all of their research. In sum, rather than use the force of federal law to require the licensing, the federal government has substituted, first, the regulatory force of the conditions on its spending and, second, the force of state law.

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<sup>140</sup> OHRP, *Institutional Review Board Guidebook*, ch I, Part B. The government has long understood that if it could use federal funding to make IRB review “widespread,” it could establish this as the standard of care for all research on human subjects. In 1978, when discussing the tort liability of researchers, the National Commission for Protection of Human Subjects revealed its understanding of the effect of the federal regulations on the law of negligence: “In negligence per se jurisdictions, violation of IRB rules could be taken as evidence of negligence. In other jurisdictions, the widespread use of IRBs in the research community may create a standard of care for the conduct of all research.” National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, *Report and Recommendations* 86 (cited in note 127).

<sup>141</sup> A small number of universities, including the University of Chicago, have declined to assure the federal government that they will apply the Common Rule or the other IRB regulations to research not supported by the government. Yet this does not mean that such universities can afford to abandon the licensing system—just that they can avoid reporting to OHRP and can avoid its oversight with respect to research not funded by the federal government. Indeed, the University of Chicago answers the question “Why is my research subject to review?” by explaining that it has negotiated an assurance with OHRP and that, “[i]n addition, federal laws require this protection. In order for the University to fulfill its responsibility, all human subjects research conducted under its auspices must receive appropriate review and approval.” University of Chicago, Social and Behavioral Sciences IRB, *Frequently Asked Questions*, at <http://humansubjects.uchicago.edu/sbsirb/faq.html>.

## D. THE GOVERNMENT'S USE OF SURROGATES

This discussion of unconstitutional federal action must close by noting that the federal government's delegation of licensing to other institutions does not insulate it from its responsibility under the First Amendment. On the contrary, the delegation to surrogates confirms that the government is using its conditions and other pressures to regulate, in this instance by the forbidden method of licensing.<sup>142</sup>

In some parts of the world, governments regularly pay or coerce private groups to carry out policies the government cannot openly pursue. These governments have liberal constitutions that protect the freedoms of speech and of the press, and technically, in accord with their constitutions, these governments respect such rights. In practice, however, these governments reward and pressure private groups to do what the government cannot. Somewhat similarly, the federal government has not imposed IRB licensing, but instead has pressured private and state institutions do so. It has thereby established licensing that it itself cannot constitutionally adopt by pressing the institutions to act as its surrogates.

The regulatory and unconstitutional character of this use of surrogates is evident from *Rust v Sullivan*, in which the Supreme Court noted the devolution of regulation that might occur through the government's conditions on its grants.<sup>143</sup> Congress had funded family planning services on the condition that the projects receiving the funding not counsel or otherwise encourage abortion as a method of family planning. This condition limited both the entities that provided the services and the doctors who worked for them, and in *Rust*, the Court upheld the condition. This result was not altogether surprising, for the government funded the services on which it placed the condition, and the doctors did not clearly have more than an ordinary contractual or employment relation to the providers of the services. Accordingly, the Court could treat the problem as a conventional instance of a condition on purchased services and could bypass the more serious problem of the government's use of surrogates to limit freedom.

This issue about surrogates, however, is inescapable for IRBs,

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<sup>142</sup> Among the recent discussions of the danger that the delegation of governmental power can become a means of evading constitutional limitations, see Gillian Metzger, *Privatization as Delegation*, 103 Colum L Rev 1367, 1432, 1462 (2003).

<sup>143</sup> *Rust v Sullivan*, 500 US 173, 176 (1991).



because the government uses conditions and more forceful legal pressure to establish IRBs as a means of regulation, and it does so in institutions that otherwise leave much freedom of speech and press to their personnel. Students, teachers, and even many commercial researchers necessarily enjoy an intellectual freedom that prevents them from being simply identified with their institutions. Anticipating this sort of problem, the Court in *Rust* explained that “the university is a traditional sphere of free expression so fundamental to the functioning of our society that the Government’s ability to control speech within that sphere by means of conditions attached to the expenditure of Government funds is restricted by the vagueness and overbreadth doctrines of the First Amendment.”<sup>144</sup> Thus, the intellectual independence of researchers in relation to their employers may transform ordinary conditions on grants into unconstitutional conditions by clarifying that the government is using its grants to obtain regulation through surrogates. Far from insulating the government, its devolution of licensing to universities confirms that in pressuring them with conditions and legal liability, it is making them instruments for imposing regulation—indeed, an unconstitutional kind of regulation: the licensing of speech and the press.

#### V. INJURY IS NOT A JUSTIFICATION

It may be thought that even if the IRB regulations would ordinarily be unconstitutional, they are justified by the distinctive magnitude and frequency of the injuries caused by research on human subjects. For decades, the danger to human subjects has seemed to make IRBs a moral necessity, and certainly research injuries can be very serious. Yet they do not justify unconstitutional licensing. Even if the First Amendment is not understood to create an absolute guarantee against the licensing of speech or the press, the licensing established by the federal regulations on IRBs is a

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<sup>144</sup> Id. See also *Sweezy v New Hampshire*, 354 US 234, 250 (1957). The Court recently echoed this sort of claim about the distinctive freedom enjoyed in universities when it decided *Grutter v Bollinger*, 539 US 1, 17 (2003). Yet it is difficult to understand why some Americans enjoy greater First Amendment freedoms than others simply because they are fortunate enough to attend or work at institutions of higher learning. Instead, what seems to underlie the Court’s concerns is the danger that the government is purchasing not merely products or services but also the use of institutions to regulate others.

disproportionate response to the danger of research on human subjects.<sup>145</sup>

The amount of injury that could, perhaps, justify a law licensing verbal speech and the press is not clear, because the precedents tend to involve injunctions.<sup>146</sup> To be sure, there are cases on laws licensing common space or expressive conduct—even conduct (such as showing a movie) that comes close to the verbal core of speech and the press. Yet the Supreme Court cases on laws concerning prior review of verbal speech or the press typically involve injunctions rather than licensing. In 1931, when discussing judicial injunctions in *Near v Minnesota*, Chief Justice Hughes wrote that prior restraints could be constitutional if used against the dangers of national security, obscenity, and violence or insurrection. Yet he apparently was speaking of judicial injunctions rather than licensing, as suggested by his illustration that “a government might prevent actual obstruction to its recruiting service or the publication of the sailing dates of transports or the number and location of troops.”<sup>147</sup> His reference to preventing “actual” obstruction suggests that he was thinking of injunctions rather than a system of licensing, which would ordinarily have the more general effect of limiting the risk of obstruction. Similarly, in 1979, when the government obtained an injunction against the *Progressive Magazine* to prevent it from publishing information about how to construct a thermonuclear weapon, the question was not licensing, but merely an injunction, and the constitutionality even of this injunction has been questioned.<sup>148</sup> The Supreme Court, however, has shied away from upholding the constitutionality of licensing under laws that target, not expressive conduct, nor access to common property, but the verbal core of speech or the press.<sup>149</sup> Ac-

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<sup>145</sup> In terms of the Court’s doctrines, the government’s interests in preventing research harms do not overcome the presumption against licensing, and the IRB regulations are not narrowly tailored to this objective.

<sup>146</sup> See discussion of *Freedman v Maryland*, 380 US 51 (1965), at note 41.

<sup>147</sup> *Near v Minnesota*, 283 US 697, 716 (1931).

<sup>148</sup> *United States v The Progressive, Inc.*, 467 F Supp 990 (WD Wis 1979); L. A. Powe, *The H-Bomb Injunction*, 61 U Colo L Rev 55, 61 (1990).

<sup>149</sup> As noted earlier, the cases that seem to uphold such licensing turn out to involve licensing of conduct or of access to common or public property. See text at note 40. Although *Posadas* involved a regulation that required licensing of verbal speech and the press, the Court explained that the question of prior review did not come before it. See note 43. Another distinction concerns nonregulatory conditions involving only a waiver of a particular exercise of a right, as in *Snepp*. See note 119.

cordingly, in considering regulations that specify verbal speech and the press as the object of licensing, it is not evident what danger would be so great as to warrant putting aside the First Amendment's central prohibition on such laws.

Many commentators defend IRBs by suggesting that they are necessary to prevent a repetition of the violations of rights associated with Nuremberg and Tuskegee. The Nuremberg Code was a list of ten requirements for ethical research on human beings that the Military Tribunal at Nuremberg adopted in 1947 in its trial of the doctors who experimented on the inmates of Nazi concentration camps. In the context of these experiments, IRBs seem to enjoy the overwhelming moral legitimacy that comes with opposing the Nazi experiments. Yet because of the character of these experiments, their goals, and their context, they reveal little about the dangers of research in a free society. In contrast, the Tuskegee syphilis study is at least a relevant exemplar of what can go wrong in American research. Even allusions to Tuskegee, however, cannot transform censorship into a necessary, moral, or constitutional solution. It is one thing to protect "vulnerable populations."<sup>150</sup> It is another to protect them by violating one of the most significant guarantees of liberty in the Bill of Rights. The use of IRBs is particularly regrettable because, as will be seen, there are other, entirely constitutional means of limiting the harms from research.<sup>151</sup>

In general, licensing of speech and the press is disproportionate to the injuries arising from human subjects research. Leaving aside, for a moment, the relative risks of research, the total amount of injury seems too mundane to overcome the presumption of unconstitutionality. Although the injuries done by research can be serious, the total amount of such injury (whether before or after the wide-scale adoption of IRBs in the 1970s and 1980s) has been far less than the harm arising from many entirely ordinary activ-

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<sup>150</sup> 45 CFR § 46.111(a)(2).

<sup>151</sup> See text at notes 160–63. If an academic attempted today to expose another Tuskegee study, it is not clear whether he could get approval from an IRB. Even if he could get approval, the IRB would be so concerned about the risk to the reputations of the patients and the doctors that it would probably create severe obstacles by requiring informed consent for any interviews and by protecting the identities of the patients and doctors. Were the academic to collect any useful information under these conditions, he might therefore end up exposing an unspeakable study by unnamed persons concerning an unmentionable disease in an undisclosed location. If the location were not disclosed, however, most IRBs would probably allow the researcher to name the disease.

ities, such as roller-blading or simply walking. For example, deaths and lasting disabilities from experimentation have never been common in America, even without IRBs, but deaths and permanent disabilities from walking (whether from collisions or less dramatic accidents) are numerous. The almost negligible overall harm from research on human subjects reveals little about the relative risk of the research, but it does raise a question as to why the research requires licensing.<sup>152</sup> Adding to this disproportionality is the very method of licensing. Whatever the frequency of serious injuries from research, the harms are hypothetical at the time of licensing.<sup>153</sup> Therefore, to the extent the government relies upon licensing to prevent injury, it inevitably deters and prevents many interactions, communications, and other instances of research that would not have been injurious.

As for the relative risk of research, it does not appear to be unusually high. Even in 1966, when IRBs were still novel and therefore could not have been the explanation for an absence of harm, the Surgeon General acknowledged that “there is a large range of social and behavioral research in which no personal risk

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<sup>152</sup> A 1979 survey showed that “fewer than 2% of sociology or IRB chairs evidenced firsthand or indirect knowledge of harmful items,” but that 25 percent of IRB chairs “found it necessary to deny permission to a survey research project because of the sensitive nature of items in a questionnaire or interview schedule.” Seiler and Murtha, 53 *Freedom of Information Act* at 30 (cited in note 139), also quoted by Ithiel de Sola Pool, *Response*, 13 *PS* 203, 204 (1980).

There are very limited useful data about research risks in the 1950s and 1960s. Moreover, such evidence as exists is not very helpful for understanding the degree to which special regulation, let alone the use of IRBs, is necessary, for the context of research has changed dramatically. Today, for example, researchers are much more self-conscious about informed consent and about the danger of legal liability. What would reveal the effect of IRBs would be a large-scale controlled experiment involving similar research, some with IRBs, and some without. In the absence of such a study, it is difficult to know whether IRBs substantially diminish research harms. The advocates of IRBs, however, had little interest in such an experiment in the 1960s, and now that IRBs are required, the experiment can no longer be done.

Revealingly, some of the most notorious instances of unethical research in the mid-twentieth century were reviewed by ethics committees. For example, according to a report of the National Research Council, “[t]he Willowbrook study had been reviewed by an ethics committee, and the Tuskegee study apparently had also had such a review, but neither study was stopped until the media reports and subsequent public reactions.” National Research Council, *Protecting Participants* at 63 (cited in note 5). Evidently, IRBs can be only as effective as the substantive principles of their time and community, and what was needed to avoid or at least end the problems at Tuskegee and Willowbrook was not IRB licensing, but better principles.

<sup>153</sup> Although the risk to a group of human subjects in a particular research project is not necessarily hypothetical, the actual harm to any particular subject is almost always hypothetical.

to the subject is involved.”<sup>154</sup> Moreover, in examining a wider range of research (including medical studies), a distinguished defender of IRBs, Robert Levine, raises serious doubts. He observes that although “[m]uch of the literature on the ethics of research . . . reflects the widely held and, until recently, unexamined assumption that playing the role of research subject is a highly perilous business,” and although this assumption was “clearly evident in the legislative history” of the 1970s, “some empirical data have become available that indicate that, in general, it is not particularly hazardous to be a research subject.”<sup>155</sup>

Writing in 1981, on the basis of risk studies done when the IRB regime was significantly less intrusive than it became over the following decades, Levine found that the risk from being a research subject was not especially hazardous. Some evidence suggested that even in the relatively risky category of “‘therapeutic research’ . . . the risk of either disability (temporary or permanent) or of fatality was substantially less than the risk of similar unfortunate outcomes in other medical settings involving no research.” He concluded that “the role of research subject is not particularly hazardous in general,” and “arguments for policies designed to restrict research

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<sup>154</sup> As quoted by Gray, *Ethical Issues in Social Science Research* at 331 (cited in note 65). Astonishingly, the Surgeon General made this statement about the absence of risk in much social and behavioral research when issuing a “clarification” that “the requirement of institutional review ‘applies to all investigations that involve human subjects, including investigations in the behavioral and social sciences.’” *Id.* Although IRBs often concern themselves with the stress that may be caused by questions, a 1979 study of the harm to survey respondents from the stressful content of questions revealed little such harm. The study asked sociology and IRB chairs if they knew of “harmful items from: 1) their own research, 2) professional literature, 3) word of mouth, or even a rumor. . . . Among 270 responding sociology and IRB chairs, five each reported knowledge of one case of an interview which led to results they considered of substance. None of these cases involved physical injury. All were judged harmful on the basis of emotional reactions during the course of an interview or subsequent to it.” This was less than 2 percent of such chairs. Seiler and Murtha, 53 *Freedom at Issue* at 29–30 (cited in note 139).

<sup>155</sup> Levine, *Ethics and Regulation* at 39 (cited in note 3).

When defenders of IRBs speak of “risk,” they often refer to a few, isolated instances of severe harm or to widespread but much less serious types of physical discomfort or mental distress. Levine notes the curiosity that “[b]iomedical researchers have contributed importantly to this incorrect belief [that research is distinctively hazardous].” He explains: “To many members of the public and to many commentators on research involving human subjects who are not themselves researchers, the word ‘risk’ seems to carry the implication that there is a possibility of some dreadful consequence; this is made to seem even more terrifying when it is acknowledged that, in some cases, the very nature of this dreadful consequence cannot be anticipated. And yet, it is so much more common that, when biomedical researchers discuss risk, they mean a possibility that there might be something like a bruise after a venipuncture.” *Id.*

generally because it is hazardous are without warrant.”<sup>156</sup> Of course, some particular research projects are relatively hazardous, and Levine had to work from studies done after the introduction of IRBs, but overall, the risk from research on human subjects appears to be quite mundane, and therefore the remedy of licensing is disproportionate.<sup>157</sup>

There have been, furthermore, many complaints that IRBs are not very effective in preventing injury. Even many proponents of IRBs worry about this problem, though their response is to seek improvements in the IRB system. For example, after studying IRBs, HHS’s Office of Inspector General questions “the effectiveness of the IRB system” and therefore proposes that it be made more rigorous. In one study of clinical trials, the office “discovered inadequacies related to IRB oversight in each case.”<sup>158</sup> There is, in fact, reason to believe that IRBs have not been the primary obstacle to research harms and that, instead, “the most important reason that the record is so good and that there have been so few

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<sup>156</sup> Robert J. Levine, *Ethics and Regulation of Clinical Research* 25–26 (1981). He adds: “Equally unsupported are arguments that, because research is generally safe, there is no need for any restriction.” *Id.* Similarly, see Levine, *Ethics and Regulation* at 39–40 (cited in note 3). At issue, however, is not whether there should be “any restriction,” but rather whether the restriction should consist of unconstitutional licensing.

E. L. Pattullo also notes that the regulation of harms to human subjects “cannot be accounted for by the record of injury to subjects. Of 2384 research projects surveyed in 1974–1974, 3 per cent were reported to have caused harmful effects to a total of 158 subjects, with most of the harm characterized as ‘trivial or only temporarily disabling.’ Given the size of the research enterprise (\$8 billion of health-related research in 1980) and the number of subjects involved annually, the incidence of injury appears extremely small.” E. L. Pattullo, *Institutional Review Boards and the Freedom to Take Risks*, *New Eng J Med* 1156 (Oct 28, 1982). He also writes that “there was not much of a problem to begin with. Despite the handful of horror stories, the record of the professions in protecting their human subjects is remarkably good.” E. L. Pattullo, *Institutional Review Boards and Social Research: A Disruptive, Subjective Perspective, Retrospective and Prospective*, in Joan E. Sieber, *NIH Readings on the Protection of Human Subjects in Behavioral and Social Science Research* 10, 13–14 (1984).

<sup>157</sup> Unfortunately, in the 1960s, as already noted, there was little interest in systematically collecting empirical evidence about the relative safety of research with and without IRBs, and now that IRBs are pervasive, it is difficult to obtain such information. See note 152.

<sup>158</sup> HHS, OIG, *Institutional Review Boards: A Time for Reform* vi, 1 (1998). See also HHS, OIG, *Institutional Review Boards: Their Role in Reviewing Approved Research* (1998). Nonetheless, many officials and others have recently suggested that the government should require IRBs for all research on human subjects. For example, a recent commission led by a former president of Princeton, Harold Shapiro, states: “No one should participate in research unless independent review concludes that the risks are reasonable in relation to the potential benefits.” National Bioethics Advisory Commission, *Ethical and Policy Issues in Research Involving Human Participants, Summary 2* (2001).

injuries is that most researchers are keenly aware of the potential for injury and take great care to avoid it.”<sup>159</sup>

IRB licensing is all the more disproportionate as a response to research injuries because there are other, more clearly constitutional mechanisms for preventing harms from research. The federal government can weigh the risks of research when authorizing its own researchers to pursue their investigations, when granting funds to outside researchers, and when controlling access to persons in the government’s custody and to government facilities (such as military bases and prisons).<sup>160</sup> In addition, the federal

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<sup>159</sup> Levine, *Ethics and Regulation* at 40 (cited in note 3).

A recent study of the risks of Phase 1 clinical trials of anticancer drugs reveals that death rates have decreased, and, on this basis, it purports to provide evidence that IRBs reduce risks. Examining reports of trials conducted during periods at the beginning and the end of the 1990s (1991–94 and 1999–2002), the study observes that the odds of a patient dying from experimental treatment become less than one-tenth of what the odds had been earlier. Thomas G. Roberts et al, *Trends in the Risks and Benefits to Patients with Cancer Participating in Phase 1 Clinical Trials*, 292 JAMA 2130 (Nov 3, 2004). In speculating about the causes of the decline, the authors note that the drugs administered in the trials have become considerably less toxic. Secondarily, they point to “better supportive care,” increased “oversight by IRBs,” and publication bias (as their samples came from published studies). *Id.* at 2138. They conclude that the increased supervision of IRBs may have contributed to the decline in deaths.

This study, however, reveals little about the need for IRBs. First, even if, perhaps, IRBs may have been a contributing factor in the decreased death rate, the study does not measure the efficacy of IRBs. Far better for this purpose would be a controlled experiment. See notes 152 and 157. Second, from the report of the study, it would appear that the data are just as consistent with changes in the toxicity of the drugs used in cancer trials, let alone other changes that occurred in medicine during the 1990s. As the authors suggest, changes in drugs were almost surely the primary cause of the decrease. Third, even if the evidence showed that IRBs significantly reduce risks in Phase 1 cancer trials, this evidence would be of little significance in evaluating the merits of IRBs without information as to whether or not IRBs impede the development of cancer treatments and thus create risks—perhaps risks for the very same patients they seek to protect. Fourth, although it is quite possible that evidence will one day show that IRBs reduce risks in research as obviously dangerous as Phase 1 cancer trials, this is of little help in determining whether IRBs reduce risks in other, less dangerous research, including much medical research. Fifth, the government can make laws requiring licensing for the use of dangerous drugs, without licensing research or otherwise legislating on speech or the press.

More generally, although “phase 1 cancer trials are considered among the most risky in all of medicine,” it is curious that the benefits of using IRBs even for this sort of study remain a matter of speculation. *Id.* at 2139. Modern medicine is based on evidence and scientific methods of proof, and IRBs bar or modify research that does not adequately meet these standards. The value of IRBs themselves, however, has never been examined in a manner that satisfies such criteria. It is curious that so many persons who uphold the demanding standards of modern scientific method assume the value of IRBs as a matter of faith.

<sup>160</sup> Curran observed in 1969 that “the NIH staff and study sections have always given attention to ethical issues in project applications, both before and after adoption of the 1966 guidelines. . . . Often the issue would be inextricably woven into the general issue of the merits of the application.” Curran, 98 *Daedalus* at 587 (cited in note 3).

government can perhaps license some particularly injurious types of physical conduct (at least within the extent of its powers), as long as it does not target researchers or otherwise aim its licensing at speech or the press. More broadly, the law can impose after the fact liability for harm and can do so even for harm caused by speech or the press—again, as long as the law remains within the parameters of the First Amendment. Even without special regulation, researchers can generally be held liable for negligently harming others. Under this standard, researchers would ordinarily find themselves in a position similar to that of journalists, but some—most clearly, physicians studying their own patients—would find themselves under a higher duty of care.<sup>161</sup> Although such an approach will not prevent all injury, it discourages harm in a way that does not violate the First Amendment.<sup>162</sup> Of course,

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<sup>161</sup> It is difficult and constitutionally problematic to argue that researchers in general owe a duty to their subjects analogous to that of doctors to their patients. Versions of such an argument can be found in the *Belmont Report* and elsewhere. National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, *Belmont Report*, Part B.2 (1979); *Grimes v Kennedy Krieger Inst., Inc.*, 782 A2d 807, 858 (Md 2001). Others suggest the possibility of a more general fiduciary duty. Angela R. Holder, *Do Researchers and Subjects Have a Fiduciary Relationship?* 4 IRB: Ethics and Human Research 6–7 (1982); Richard Delgado and Helen Leskovic, *Informed Consent in Human Experimentation: Bridging the Gap Between Ethical Thought and Current Practice*, 34 UCLA L Rev 67, 107–12 (1986); Roger L. Jansson, *Researcher Liability for Negligence in Human Subject Research: Informed Consent and Researcher Malpractice Actions*, 78 Wash L Rev 229 (2003). Yet in many instances, this approach to researchers is not unlike attributing to journalists a professional duty to treat the subjects of their investigations in a manner that does no harm and that even helps them—as if journalists had a professional duty to show respect and to avoid causing distress, upset, or moral, economic, legal, or reputational harm. Such notions about a researcher’s professional duty, enforced by federal law, are simply incompatible with the First Amendment.

Incidentally, at least for research by doctors, some commentators may consider a negligence standard too harsh. Certainly, many doctors seem to think it too severe in actions for medical malpractice.

<sup>162</sup> The shadow of the censorship will linger even if the regulations are held unconstitutional. The government has spent several decades and much money pressing universities to impose IRBs and requiring academics to undergo “education” or indoctrination about the importance of IRB licensing. Moreover, the government has elevated IRBs as the standard means of reducing the risk of research injuries. Accordingly, with or without federal regulations, research institutions will continue to cling to IRBs as a means of limiting their tort liability for the negligence of their researchers.

This damage to the traditions of independence among academics will not easily be repaired. Ideally, after the government expended so much effort and money to get IRBs, it might now spend an equal amount to persuade institutions to get rid of them. More practicably, because of the role of tort law in inducing institutions to adopt IRBs, it is worth noting some possible limits on negligence.

First, institutions do not and should not all have equal control over their personnel, and they therefore should not, perhaps, be equally vulnerable for the negligence of their personnel. Although the law holds a business corporation responsible for the negligence of its servants or agents within the scope of their employment, it is not clear that the law



this is not to say that the mere application of negligence doctrine is a perfect solution. The point is simply that a plausible and lawful response to research injuries already exists in the legal system, and this makes it difficult to conclude that a fear of research injuries can justify the extraordinary response of imposing licensing.<sup>163</sup>

In calculating the value of IRBs, one could take into account their prevention of the harms of offense, embarrassment, or other mental discomfort arising from research. Yet from a legal perspective, these are so trivial, immeasurable, or subjective as to be not typically cognizable at common law. For example, the negligent infliction of mental distress does not ordinarily create liability, unless it is in-

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should equally hold academic institutions responsible for the negligence of all of their personnel in all facets of their academic conduct. For example, students are not servants or agents of their university, and perhaps teachers are not ordinarily servants or agents in all aspects of their teaching, research, or public service. It may seem odd to consider them independent contractors in the business sense, but they have long enjoyed an equivalent independence in an intellectual sense. With this in mind, the Supreme Court has repeatedly observed the independence enjoyed by teachers, students, and other academic personnel in academic institutions. See, for example, *Sweezy v New Hampshire*, 354 US 234, 250 (1957); *Rust v Sullivan*, 500 US 173, 176 (1991); *Grutter v Bollinger*, 539 US 1, 17 (2003). To be sure, there is no academic freedom clause in the Constitution, but in light of the fact and tradition of academic independence, a court could, perhaps, recognize a common law presumption that neither the government nor an academic institution has a power to control academic personnel in their realm of academic freedom, including their research, unless an institution or the government clearly undertakes to control such matters, and that therefore the law does not attribute to the institutions the negligence of their personnel in this sphere of independence. For example, universities reward professors for their public service, but if a professor serves on the board of a charitable organization and breaches his fiduciary duties, he will be held liable, and the university will not be vulnerable on his account. The same should be true of his teaching and research. A professor doing research or teaching as part of a distinctively institutional project (such as an alumni fund-raising event) might be a servant and agent for these purposes, but he is not so clearly a servant or agent for his other research or teaching. In particular, he might be a servant and an agent for purposes of teaching or conducting research in accord with his contractual duties, but not as to his choices in teaching and doing research within the sphere of his independence. In these decisions, he should be understood to stand on his own.

Second, it may be doubted whether state law can give any advantageous legal significance to an academic institution's licensing of speech or the press. If state law treats institutional licensing of speech or the press as a stronger defense against claims of negligence than other precautions, it creates legal incentives for institutions to require such licensing, and it thus in effect penalizes institutions that do not adopt licensing. If the states thereby pressure institutions to become surrogates for imposing censorship, this may violate the Fourteenth Amendment to the extent this Amendment applies First Amendment freedoms to the states. *Gitlow v New York*, 268 US 652 (1925). At the very least, it probably violates state constitutional guarantees of freedom of speech or of the press.

<sup>163</sup> Obviously, the mechanism for discouraging harm need not be the same as the mechanism for compensating injuries. As it happens, most institutions are sufficiently concerned about their reputation that they usually are eager to compensate for injuries, and this may be the reason there have been so few legal actions.

cidental to a physical injury or occurs in unusually personal circumstances. Not only much of the mental harm but also many of the moral, social, legal, and economic harms that IRBs aim to prevent are little more than the unavoidable costs of the freedom of speech or of the press, and to this extent, the government cannot penalize or prevent them. Such injury is ordinarily beyond government intervention even after the injury has occurred, and it can therefore hardly justify interference beforehand, when its occurrence is merely speculative.<sup>164</sup>

Lest it be thought that research on human subjects poses a special risk that requires licensing, it should be recalled that journalism and medical treatment can create at least equal risks for human subjects without needing prior permission. A journalist who investigates a corrupt corporate officer or a corrupt judge may hope to cause his discomfort, ignominy, and punishment but would have little hope of attaining this desirable end if she had to conform to an IRB's consideration of every question she planned to ask the officer or judge. Similarly, doctors often develop new treatments and use drugs and medical devices for "off label" purposes, and they need this freedom to help their patients. Far from being considered threats to society that require a board's advance permission, the novel treatments given by these doctors are merely the most interesting of the innumerable, little experiments by which doctors every day figure out a diagnosis, prescribe a course of treatment,

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<sup>164</sup> In *Cohen v California*, 403 US 15 (1971), the Court overturned a conviction for the "offensive conduct" of wearing a jacket displaying the words "Fuck the Draft" and explained that the words were not directed to an individual and thus, however offensive in general, were not fighting words. More recently in *Texas v Johnson*, 491 US 397 (1989), the Court explained that "a primary 'function of free speech under our system of government is to invite dispute,'" *id.* at 408 (quoting *Terminiello*), and that "[i]f there is a bedrock principle underlying the First Amendment, it is that the Government may not prohibit the expression of an idea simply because society finds the idea itself offensive or disagreeable." *Id.* at 414. See also, for example, *R.A.V. v City of St. Paul, Minnesota*, 505 US 377 (1992); *Boos v Barry*, 485 US 312 (1988); *Terminiello v Chicago*, 337 US 1 (1949); *Chaplinsky v New Hampshire*, 315 US 568 (1942).

Recognizing that the actual harm done by research may not warrant licensing, some commentators add that IRBs are necessary to give potential research subjects the confidence to participate in research, and that this matters both for promoting research and for ensuring that racial minorities participate and thus get the benefits of research. Such arguments, however, raise many questions. For example, it is by no means clear that licensing is the best way to encourage confidence among potential human subjects. Even if it were, the government's alleged interest in raising the reputation of research among human subjects seems a rather dubious basis for justifying the licensing forbidden by the First Amendment. If the research itself does not do the extraordinary harm that might justify licensing, the mere reputation of the research for doing harm cannot justify it.

observe the results, and then adjust their treatment and, sometimes, their diagnosis. Surgeons often engage in innovative procedures that are risky for their patients, and although they make decisions leading to numerous injuries and deaths each year, they are free to reach their own judgments as to whether they should consult with other specialists or whether they should proceed on their own.<sup>165</sup> Journalists and doctors thus sometimes cause harm, and if it is of a sort cognizable by law, they must face the consequences—but only *after* there is an injury. In both journalism and medicine, harms similar to those arising from research are not thought to require licensing, and it is therefore difficult to justify licensing for research.<sup>166</sup>

## VI. THE INJURIES CAUSED BY IRBs

Laws that abridge the freedom of speech, or of the press, are unconstitutional without proof of particular injury, but it is not necessary to insist on this point, for IRB licensing does much harm. The licensing injures researchers, their use of speech and the press, and their pursuit of knowledge.

IRBs delay research. The delays are inevitable for many reasons—for example, because IRBs usually meet only monthly or quarterly, because IRBs frequently will not approve a proposal at the first meeting at which it comes up (and sometimes will not even get to the proposal), and because IRBs often will have questions for the researcher or requests for modification. Sometimes, repeated exchanges with the researcher are necessary. Accordingly, for social science research at most institutions, a several-month wait is typical.<sup>167</sup>

Although delay may not seem a particularly serious injury, researchers usually have reason to think otherwise. If a social science

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<sup>165</sup> Surgeons tend to get IRB approval for their work only when they expect they will want to publish about it.

<sup>166</sup> Of course, doctors are licensed, but the relevant point here is that their treatments are not.

<sup>167</sup> Conversation with Tom W. Smith, Director of the General Social Survey at the National Opinion Research Center (Dec 10, 2004). Four to six weeks is considered rapid at most institutions. *Id.* According to one estimate, “institutional review times can vary from 3 weeks to 18 months.” Secretary’s Advisory Committee on Human Research Protections, July 26–27, 2004 Meeting, Washington, D.C., *Summary Minutes* 38 (2004) (Dr. Weiner).

researcher wants to ask Americans what they think about a recent political scandal or how they plan to vote, he often must wait for approval of his questions and methods, by which time the scandal may be long forgotten and the election may be over.<sup>168</sup> If a literature or history professor needs to interview an elderly author, musician, or former politician, the professor must in some instances worry that the “human subject” will die before the research is approved.<sup>169</sup> If a researcher gets a sabbatical or grant to do research, and the IRB delays her work, it can waste her year off and her grant money.<sup>170</sup> More generally, IRBs often require researchers to devote precious time and energy to a long and arduous review process. As put by a medical researcher, “[c]ompletion of a study can be delayed or thwarted if [one’s] personal energies are not sufficient to create the amount of detailed writing [needed]

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<sup>168</sup> For dangers of delays through licensing, see *City of Littleton, Colorado v Z.J. Gifts D-S, L.L.C.*, 124 S Ct 2219 (2004); *FW/PBS, Inc. v Dallas*, 493 US 215 (1990); *Freedman v Maryland*, 380 US 51 (1965). According to the Court, prior restraints “are the most serious and the least tolerable infringement on First Amendment rights,” because they cause “an immediate and irreversible sanction” and “damage can be particularly great when the prior restraint falls upon the communication of news and commentary on current events” in which “the element of time is not unimportant.” *Nebraska Press Association v Stuart*, 427 US 539 (1976) (invalidating a temporary state court order against publication of confessions and other matters that strongly implicated the accused). See also the concurrence of Black, J, joined by Douglas, J, in *New York Times Co. v United States & United States v Washington Post Co.*, 403 US 713 (1971) (affirming a decision against a restraining order in one case and reversing such an order in the other).

<sup>169</sup> After attempting to record the memories of a woman who in 1944 fought in the Warsaw uprising, a professor states: “This woman is now 81 years old and her life is not unlimited. She has a story to tell, and she wants to tell it. . . . I was waiting, waiting, and waiting, and hoping that my source was not going to die before I received permission.” She eventually received approval after five months. Conversation with Professor Cynthia Bowman, Northwestern University Law School (Dec 10, 2004).

<sup>170</sup> For an example, see AAUP, *Protecting Human Beings*, in *Academe: Bulletin of the AAUP* at 63–64 (cited in note 12).

Whether or not teachers have failed to get tenure because of delays in getting permission to do their research is unclear, but students certainly suffer from the tardiness of IRBs. Lincoln and Tierney, 10 *Qualitative Inquiry* at 222 (cited in note 82). To avoid such difficulties, many graduate students in the social sciences avoid doing their own empirical work and thus graduate without any independent practical experience in their field of research. Jack Katz writes to his fellow ethnographers that “we see the chilling effects on less secure students and junior colleagues who, feeling overwhelmed at the problems of fitting their research ideas into the regulatory system, are abandoning important lines of investigation before they begin.” Jack Katz, *To Participants in the UCLA, May 2002, Fieldwork Conference* (May 8, 2002), at [http://leroyneiman.sscnet.ucla.edu/katz5\\_8.htm](http://leroyneiman.sscnet.ucla.edu/katz5_8.htm). Incidentally, it will be recalled that students not only must get approval from an IRB but also must get a faculty member to serve as a principal investigator, and at least in one instance, in Boston University’s dentistry program, when a faculty advisor did not bother to get IRB approval for a student’s research, the student could not complete his work and was expelled for his slow progress. *Missert v Trustees of Boston University*, 73 F Supp 2d 68 (1999).

. . . to convince the IRB . . . of the merit of the project.”<sup>171</sup>

Even worse, IRBs directly suppress speech and the press. In the seventeenth century, licensors sometimes crossed out offending passages in manuscripts prior to publication, and today IRBs similarly request modifications in research. IRBs apparently request modifications in most research proposals that require approval (according to one report, in more than 80 percent), which means that every year they impose changes on at least tens of thousands of proposals and probably more than a hundred thousand.<sup>172</sup> Although some changes are minor, others are not.<sup>173</sup> For example, in reviewing proposals to interview individuals, IRBs frequently require researchers to submit their questions to the IRB in writing, and then demand that the researchers drop or alter their questions—as when, for example, in reviewing a survey on religion or sex, an IRB rephrases a question that it considers too intrusive. Of course, many researchers are reluctant to prepare written questions, for this stifles conversation and prevents the researchers from spontaneously following paths of inquiry that open up during an interview. Nonetheless, IRBs tend to insist on seeing written questions, and they expect researchers to adhere to the script. When IRBs worry that research will collect confidential or otherwise sensitive information, they often require researchers to ensure that after they collect and use the data, they will strip it of “identifiers” or will otherwise destroy it—a practice that limits the

<sup>171</sup> James Reilly, *Innovative Tools, Regulatory Bodies, and the Creative Surgeon*, 129 *Archives of Otolaryngology—Head & Neck Surgery* 678 (2003). He also notes that “[a]s intelligent humans, we must constantly observe, test, and verify. We must never stifle our inquiring minds . . . . The FDA and IRBs are not repositories of new ideas.” *Id.*

<sup>172</sup> For the percentage, see AAUP, *Protecting Human Beings*, *Academe: Bulletin of the AAUP* at 56 (cited in note 12). A 1998 study commissioned by NIH states: “Overall, in 73 percent of IRBs, one-quarter or fewer protocols were approved as submitted,” and “[i]n fact, 34 percent of IRBs did not approve any (zero) protocols as submitted in 1995; 10 percent approved one-quarter to one-half; and 6 percent more than one-half of protocols.” James Bell, John Whiton, and Sharon Conelly, *Final Report: Evaluation of NIH Implementation of Section 491 of the Public Health Service Act, Mandating a Program of Protection for Research Subjects* 61 (June 15, 1998). One observer with extensive experience believes that IRBs currently seek modification of 90–95 percent of proposals requiring approval. For a summary of some research on the average number of reviews conducted by IRBs, see National Research Council, *Protecting Participants* at 36 (cited in note 5).

<sup>173</sup> Many modifications concern informed consent, but these modifications are often very significant, for the way in which a researcher approaches a research subject can be determinative of the response rates and even the substantive results. Understanding this, IRBs not infrequently respond to research they consider too sensitive by using informed consent modifications to render it impracticable. They thus quash the research without having to deny permission.

opportunity for future researchers to replicate the study or to use the data for other research.<sup>174</sup>

IRBs frequently interfere with methodology, and although they claim that they thereby improve research, they in fact may have the opposite effect. According to a study based on 1995 data, 55 percent of IRB members believed that their decisions improved the scientific quality of research done on human subjects—but only 37 percent of the researchers agreed.<sup>175</sup> IRBs sometimes merely make flawed but trivial changes in methodology—as when an IRB at a Midwestern university recently objected to an informed consent document because it enumerated the risks in a column of text with bullets in front of each risk rather than in paragraphs.<sup>176</sup> Other methodological interference is not so comic—as when IRBs do not appreciate the benefits of what they consider unorthodox methods and therefore decide that the benefits are outweighed by the risks.<sup>177</sup> Of course, whether or not the IRBs improve methodology is not the issue, for in matters of speech and the press, it is not a licensor's judgment that matters. If IRBs license speech and the press, an IRB that imposes its methodology abridges a researcher's First Amendment freedom.

A related problem is that researchers cannot do their work anonymously. Some research is sufficiently controversial or is based on sufficiently unconventional methods that researchers may hesitate to inform anyone that they are doing it until they are confident that they will get valuable results or results they will feel comfortable publishing. Accordingly, by requiring researchers to share their research plans with colleagues on IRBs, the licensing system leaves researchers in doubt as to whether they can explore projects anonymously, and it thereby sometimes discourages them from experi-

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<sup>174</sup> The particular practices of IRBs vary considerably. Some IRBs allow the preservation of identifiers in a separate location with codes that allow the identifiers to be linked back to the rest of the data; many others allow the separate preservation of identifiers but only for a limited time; others require a broader destruction of data, either immediately or after several years. Even when IRBs do not require the eventual destruction of the identifiers, they separate them from the rest of the data and thus make it highly improbable that future generations will be able to go back and make full use of the information.

<sup>175</sup> Bell, Whiton, and Conelly, *Final Report* at 61 (cited in note 172). The researchers were presumably all principal investigators, and both the board members and these investigators were randomly selected by the chairs of the boards.

<sup>176</sup> Communication from researcher.

<sup>177</sup> Lincoln and Tierney, 10 *Qualitative Inquiry* at 220, 230 (cited in note 82), quoted in note 100.

menting with new methods and examining controversial topics.<sup>178</sup>

The practical consequences of IRBs are predictable. Some researchers avoid innovative research and novel techniques that might provoke an IRB to request changes in a proposal.<sup>179</sup> Others abandon their work when they find that the time and paperwork required for approval are unduly burdensome. Some scholars begin research but then give up along the way, when the IRB delays them, or when they find that their project as rewritten by the IRB is not worth pursuing. Lacking the imprimatur of an IRB, much important research never even gets started. Even if unapproved research gets done and gets written up as an article, it sometimes does not get published. It is one thing for a researcher to write an article; it is another for him to publish it and thereby reveal that his research violated what appears to be federal policy. Although his research

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<sup>178</sup> For the First Amendment's protection of anonymity in speech and the press, see *Buckley v. Am. Constl. Law Foundation, Inc.*, 525 US 182 (1999); *McIntyre v. Ohio Elections Commission*, 514 US 334 (1995); *Talley v. California*, 362 US 60 (1960). In *Buckley v. Valeo*, 424 US 1 (1976), the Court upheld a federal law requiring political candidates and political committees to keep records of contributions, but the Court distinguished this regulation of gifts for the sake of preventing corruption from other regulation of speech or the press.

<sup>179</sup> "A variety of strategies have been devised by researchers to overcome persistent rejection by IRBs, including several that actually undermine the work but that have the effect of permitting graduate students to complete their doctorates." Lincoln and Tierney, 10 *Qualitative Inquiry* at 222 (cited in note 82).

After describing the IRB evaluation of the importance of research, the AAUP comments on the chilling effect of this evaluation: "The mere existence of the requirement that IRBs evaluate the risks of the research in relationship to its importance can have an inhibiting effect on the work of scholars. Inhibitions on research can have numerous causes, and academic researchers take for granted the pressures that derive from having their work reviewed by colleagues. But the pressures of IRB reviews are different, for behind them is the weight of the government and the specter of the official control of opinion. This is not to say that control of opinion is the purpose of IRB reviews; manifestly it is not. But an IRB review that seeks to evaluate the importance of research can lean in that direction if only because judgments about the importance of research are highly speculative. From the perspective of the scholar with so much at stake in obtaining IRB approval, the uncertainty about whether any particular research project 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?" The Report adds: "Evidence that IRB reviews may have had such repressive effects is anecdotal, gleaned from the surveys of several professional organizations described earlier in this report. But a description of the challenges of applying IRB reviews to social science research would be seriously incomplete if it ignored the danger to freedom of research—if only through self-censorship—implicit in the requirement that IRBs evaluate the importance of research." AAUP, *Protecting Human Beings*, *Academe: Bulletin of the AAUP* at 61–62 (cited in note 12). Although not inaccurate, this account of the chilling effect does not acknowledge that IRBs actually prevent research and modify it, thus directly suppressing the affected portions.

may be of a sort that the IRB would have approved, he must worry that if he publishes it, the IRB will view him as uncooperative and therefore be unreceptive to his future research proposals. It might even investigate him and expose him to what his university warns are “serious consequences” for unlicensed research.<sup>180</sup> In all of these ways, an incalculable amount of knowledge is lost.

An example of the damage can be observed at the journalism department of Duke University. In this department, one professor says that because of IRBs “he now limits his class projects to ‘bland topics and archived records.’” Another, Margaret Blanshard, writes that “I am . . . leaving the contemporary period behind. It is far safer in the nineteenth century. . . . [Y]ou do not have to worry about the IRB when you work in the nineteenth century.”<sup>181</sup> Blanshard adds: “I have seen students alter research projects to avoid IRB contact. I have seen some give up projects because of the red tape involved. I have heard words such as ‘thought control’ used far too often . . .” She concludes: “A better formula for stultifying research is beyond contemplation.”<sup>182</sup>

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<sup>180</sup> University of Chicago, Social and Behavioral Sciences Institutional Review Board, *Frequently Asked Questions 2*, at <http://humansubjects.uchicago.edu/sbsirb/faq.html>. See also e-mail message from Provost Alan Brinkley and Executive Vice President for Research to Faculty, Administrators, and Students at the Morningside Campus (Oct 15, 2004).

Of course, there are other incentives for cooperation. For example, “a single, and especially an unfunded, researcher lacks the resources to contest an unreasonable and intransigent IRB. . . . Further, IRBs are required to be composed of persons of high reputation. To challenge an IRB on campus or in court could retard a career.” Seiler and Murtha, 53 *Freedom at Issue* at 30 (cited in note 139). A professor from UCLA points out that “higher status people get more leverage” with IRBs, and this suggests that those who are apt to have the most difficulties with IRBs are not those who are in the best position to resist them. Conversation with Professor Jack Katz, UCLA (Dec 13, 2004).

<sup>181</sup> Indeed, in saying this Blanshard explained that she was following the example and reasoning of yet another scholar—“a fellow media historian” who had told Blanshard of her decision to retreat from contemporary matters. Margaret A. Blanshard, *For the Record*, 88 *Academe* (May–June 2002), at <http://www.aup.org/publications/Academe/2002/02mj/02mjfr.htm>.

<sup>182</sup> *Id.* At the School of Journalism at University of North Carolina at Chapel Hill, “[n]ews stories that use social science research methods such as public opinion polls and field experiments are subject to IRB review.” AAUP, *Protecting Human Beings*, *Academe: Bulletin of the AAUP* 55, 59 (cited in note 12).

At Northwestern University Law School, where professors used to encourage students to do original empirical research, several professors now actively discourage their students from collecting data because, as put by one of these teachers, “[t]he delays in approval and the interference with research design usually make it impossible to go through the IRB process, conduct the research, and write it up in one term, or even two. The IRB process diminishes our ability to train our students to do research.” E-mail message from James Lindgren (Dec 10, 2004). Faculty also trim their own work. One explains: “I try to avoid doing the sort of research that will require me to go before an IRB. I think about ways to answer a question that allow me to avoid going before an IRB, and if I cannot,



The loss of knowledge is particularly poignant in quality improvement projects—the inquiries made by doctors about how to improve the treatment of patients. If quality improvement projects are subject to IRBs, doctors have reason not to do these investigations, for these projects involve a process of tinkering with treatments, and they therefore are difficult to get through an IRB's approval process. In particular, these studies cannot always be reduced to the rigid, formal protocols of scientific research assumed by IRBs, which can insist upon giving approval to each little change.<sup>183</sup> To avoid these problems, doctors sometimes do not bother to get prior permission from an IRB, but then they have reason to avoid publishing their results, lest the IRB detect their noncompliance. This happened at the University of Pittsburgh, where an IRB subjected doctors to an investigation for their failure to get prior approval of a published quality improvement study.<sup>184</sup> Doctors thus face impediments to inquiring and publishing about the care they give their patients, and obviously it is not the doctors who thereby suffer the most.

The full extent of the damage remains unknown because licensing does not publicly punish speech or the press, but, instead, suppresses it. The amount of the harassment, intimidation, and abandoned research is largely a matter of anecdote, for it is difficult to calculate the effect of licensing on scholars who abandon or alter their projects (whether in anticipation of IRB demands or in response to them), let alone the effect on those who never even begin. IRBs, moreover, usually operate in secret, and because researchers are

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I try to find another subject.” Conversation with Professor Cynthia Bowman, Northwestern University Law School (Dec 10, 2004).

<sup>183</sup> This is also a problem with oral history and especially ethnographic research, in which “research practice” is often “indistinguishable from the researcher’s social life as conducted outside the framework of research.” Jack Katz, *To Participants in the UCLA, May 2002, Fieldwork Conference* (May 8, 2002), at [http://leroyneiman.sscnet.ucla.edu/katz5\\_8.htm](http://leroyneiman.sscnet.ucla.edu/katz5_8.htm).

<sup>184</sup> Lynn, 13 *Quality and Safety in Health Care* at 67 (cited in note 54). Apparently, IRBs held back for years from treating quality improvement studies as research for fear that if they had to review and approve such studies, they would discourage these inquiries about improving medical care. This was particularly a matter of concern because the doctors who were most likely to be discouraged were academic doctors, who need to publish. Nonetheless, in responding to the events at Pittsburgh, OHRP issued a letter stating that quality improvement studies could qualify as research under federal regulations, and therefore the problem is now unavoidable. See note 54.

Similar problems could, perhaps, arise in medical case studies, but fortunately OHRP and most IRBs have thus far refrained from viewing these as systematic investigations designed to develop or contribute to generalizable knowledge. 45 CFR § 46.102(d).

afraid of antagonizing IRBs, or of being condemned for violating federal policy, the researchers tend to speak about their troubles—about the damage to their work and their struggles to evade IRBs—only on condition of anonymity.<sup>185</sup> If, however, the licensing thus tends to escape public scrutiny, perhaps the Constitution's prohibition against licensing deserves all the more attention.

## VII. CONCLUSION

Research on human subjects can cause harm, and to protect against the dangers of such research, the federal government pressures universities and other research institutions to establish IRBs. Under this system, academics and others must get the permission of an IRB before doing research on human subjects. This is licensing, and it raises serious constitutional questions.

The primary problem is that the federal regulations conflict with the First Amendment. This Amendment prohibits licensing of speech or the press, and it is particularly clear-cut in forbidding the licensing of verbal speech or the press. Nonetheless, the regulations define "research" in terms of speech and the press and then require that the research be licensed. Although the regulations ostensibly encourage this licensing by means of government spending, they actually go much further, for they rely on the force of unconstitutional regulatory conditions and state tort law. The government thus requires licensing of speech and the press, and even if the First Amendment creates only a presumption rather than a prohibition against such licensing, the government's interest in preventing the relatively modest overall danger of human subjects research cannot overcome this constitutional barrier.

The unconstitutionality of IRBs can be illustrated, once again, by the supposition about Newspaper Review Boards or NRBs. Suppose the federal government were to fund investigative journalism at newspapers on the condition that the funded journalists get NRB permission before beginning their inquiries. Suppose, moreover, the NRBs were required to ensure that the journalists did not ask questions or otherwise investigate in a way that might cause the investigated person to lose his job or even to feel stress or upset on

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<sup>185</sup> Other commentators on IRBs have noticed this. For example, in his essay on IRBs, Cary Nelson reports that with one exception, everyone he interviewed, including board members, "requested anonymity." Nelson, 89 *Academe* at 30 (cited in note 125).

account of the “sensitive” character of the inquiry. This condition on funding might seem justified, for investigative journalists sometimes obtain their stories by deceit, trespass, and receipt of unlawfully obtained property; they regularly disclose private, confidential, or otherwise sensitive information; they investigate at the risk of causing harm, including personal and financial ruin, suicide, divorce, imprisonment, and even political violence. Nonetheless, the conditions requiring NRBs would be unconstitutional—even if the newspapers consented to the NRBs, and even if the government sought NRBs only for federally funded investigations. If conditions requiring NRBs are unconstitutional, so are those requiring IRBs.

A second, more general concern is that the government has established a new type of censorship. If the government had directly required licensing, or if it had used the licensing to suppress popular opinion, it probably could not have succeeded. Yet by avoiding the direct force of federal law and by appealing to widespread moral sensibilities, it has largely bypassed political barriers and has given the appearance of getting around the constitutional obstacles. The government thereby has maintained censorship in America for over three decades. As seen, however, the licensing cannot really escape the constitutional problems. The new censorship therefore is no less unconstitutional than the old.

Third, and most broadly, the success of the new censorship suggests much about the role of the Supreme Court. Never before in the history of the United States has the federal government imposed an elaborate system of licensing on academic and other empirical inquiry. Such censorship, however, seems constitutionally plausible to many Americans, largely because of doctrines on spending and licensing adopted by the Supreme Court. It therefore is necessary to consider the danger of judicial doctrines that undermine enumerated rights—doctrines that signal to those in power that they are not constrained by these rights and that suggest to those whose rights are abridged that they have no constitutional basis on which to protest.

For example, the Supreme Court’s doctrines on spending and licensing emboldened the federal government in establishing censorship. In the 1970s, when the federal government developed what became the current regulations on IRBs, it examined the Court’s doctrines and, on this basis, contemplated its licensing scheme not with a sense that it had to restrain itself, but with a sense of con-

stitutional opportunity. Most prominently, in the 1978 report to Congress by the National Commission for the Protection of Human Subjects, the Commission relied upon the Court's doctrines to put aside objections that "the requirement of prior review and approval by an IRB" might "violate constitutional rights of academic freedom and free inquiry." The Commission examined the Court's speech and press doctrines and concluded that the government may "regulate. . . the methods used in . . . research, in order to protect interests in health, order and safety."<sup>186</sup> Moreover, it observed that the Court's spending doctrine gave Congress even greater freedom, for "[w]here the IRB system is imposed on researchers as a condition of . . . receipt of research funds, the same constitutional limitation will not apply."<sup>187</sup> In such ways, the federal government recognized that the Court's doctrines regarding licensing and spending created a constitutional opening for the new censorship, and Congress and the executive therefore felt free to impose IRBs without regard to the First Amendment.

At the same time, the Supreme Court's doctrines have undermined the ability of researchers to assert their First Amendment rights. For example, in 2003, in the most recent agitation against IRBs, oral historians in the American Historical Association and the Oral History Association sought to relax the grip of IRBs on oral history—history done through taped interviews. They had no confidence, however, that they could prevail in a constitutional challenge to the regulations, and therefore rather than pursue the constitutional issues, they merely attempted (unsuccessfully) to show that the regulations did not apply to oral history—an approach that has not proved very successful.<sup>188</sup>

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<sup>186</sup> National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, *Report and Recommendations* 78–79 (1978).

<sup>187</sup> *Id.* It continued: "Neither the government nor a university has a legal obligation to support research of any particular kind, nor hire researchers in a particular area. . . . Thus, an institution may empower the IRB to apply both content and manner restrictions to research that it funds, whether or not such a system would be constitutional if directly imposed by the state on nonfunded research." *Id.* at 79–80. Even as to research the federal government did not fund, the Commission observed that the matter "has not yet been definitively settled," and that the courts would probably "permit regulation of nonfunded activities when reasonably related to the purpose of the federal spending." *Id.* at 77.

For other examples of how the Court's doctrines left the impression that the government could constitutionally establish its system of IRBs, see notes 12, 17, 18.

<sup>188</sup> The historians attempted to avoid the jurisdiction of IRBs by de-emphasizing the broader significance of their work: They argued that "oral history interviews, in general, are not designed to contribute to 'generalizable knowledge'" and claimed that as a result,

Researchers who oppose IRBs face many difficulties, but none more debilitating than the doctrines of the Supreme Court, for these doctrines give the impression that researchers are without a plausible constitutional claim. Recognizing the implications of the Court's doctrines, the proponents of IRBs have inculcated a sense of submission by popularizing the catchphrase, "Research is a privilege, not a right." Even major universities sententiously recite this statement to their professors and students.<sup>189</sup> In this atmosphere, researchers have difficulty defending their freedom. They cannot find an unequivocal right against the licensing in the Court's doctrines, and when they ask lawyers, they are confirmed in their un-

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"oral history interviewing, in general," is beyond the definition of "research" in the regulations. This is plausible only on the improbable assumption that most oral history is not designed to contribute to generalizable knowledge. All of this, however, has turned out to be of limited significance, because IRBs tend to recognize that much oral history contributes to generalizable knowledge. American Historical Association and Oral History Association, *Oral History Excluded from IRB Review*, at [http://omega.dickinson.edu/organizations/oha/org\\_irb.html](http://omega.dickinson.edu/organizations/oha/org_irb.html). See also *Exclusion of Oral History from IRB Reviews: An Update*, at <http://www.historians.org/Perspectives/Issues/2004/0403/0403new1.cfm>.

For an illustration of how even a group that advocates freedom of speech in universities has succumbed on the questions of spending and licensing, see the report of the AAUP quoted in note 12.

<sup>189</sup> See, for example, *An Industry on Trial*, 11 Research Information Bulletin (Oct 1997), quoting Curt Meinert, director of the Center for Clinical Trials at Johns Hopkins School of Hygiene and Public Health, at [http://www.wfubmc.edu/or/pursuit/pursuit/\\_oct97/page6.html](http://www.wfubmc.edu/or/pursuit/pursuit/_oct97/page6.html). One variant is that "human subject research is a privilege, not a right." University of North Carolina at Chapel Hill, *Institutional Review Standard Operating Procedures* 14 (Dec 12, 2003). Similarly, see Stuart Plattner, *Human Subjects Protection and Cultural Anthropology* 76 *Anthropological Q* (Spring 2003). (Plattner is a Human Subjects Research Officer at the National Science Foundation.) Another variant, from Rutgers University, states: "Congress has declared that conducting research is a privilege, not a right." Memo to Members of the University Community, re Announcement of the Human Subjects Assessment Initiative, from Michael B. Breton, Associate Vice President Research and Sponsored Programs, and Karen M. Janes, Associate Director Research Integrity and Compliance at Rutgers University (May 3, 2004), at <http://orsp.rutgers.edu/Humans/assessment.asp>.

At least a small number of researchers have protested. Complaining about this "mantra," some observe that "having one's research funded is a privilege, but research per se is just a form of learning, a feature of human existence not requiring the permission of anyone else." John Mueller, John Furedy, and Clive Seligman, Letter, *Re: "IRBs for Dummies,"* 16 *Observer* [American Psychological Society] (Feb 2003), at <http://mueller.educ.ualgary.ca/ObserverFeb2003-Dummies.html>. Others write: "Somehow the 'agenda of inquiry' must be restored to its preeminent status over the 'agenda of control.' It has become chic in some quarters to try to deflect criticism of the ethics industry with an observation such as 'Research is a privilege, not a right.' This fatuous thinking simply conceals an effort to maintain control at all costs. Research is a job requirement for faculty, and research is a degree requirement for students. Freedom of inquiry is widely accepted and respected in everyday life, it is a truly just part of the natural order of human existence. *That that inquiry is so much more constrained on campus than in the everyday world, without good cause, is something we should all decry.*" John Mueller and Steve Lupker, *SAFS Letter on Research Ethics*, at <http://www.safs.ca/issuescases/ethics.html>.

derstanding that the First Amendment protects almost nothing absolutely and that Congress can spend largely as it pleases.<sup>190</sup> Convinced by the Court's doctrines that they cannot rely on the First Amendment, researchers moderate their protests, plead for relief, or just acquiesce.<sup>191</sup>

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<sup>190</sup> Conversations with researchers about lawyers. In 1982, Roberston commented on the government's use of conditions to obtain IRBs: "Neither scientists nor institutions have challenged in court the power of Congress to impose such conditions, perhaps because the Supreme Court, if ever faced with the question, is likely to construe Congress's conditional spending power broadly and to approve such conditions." Robertson, in *Ethical Issues in Social Science Research* 361 (cited in note 11).

<sup>191</sup> Revealingly, when the American Historical Association and Oral History Association attempt to hold off the IRBs, they did not really protest but instead negotiated their statement with OHRP and then used its concurrence as a sort of imprimatur: "The Office for Human Research Protections concurs with this policy statement, and it is essential that such an interpretation be made available to the many IRBs currently grappling with issues of human subject research." American Historical Association and Oral History Association, *Oral History Excluded from IRB Review*, at [http://omega.dickinson.edu/organizations/oha/org\\_irb.html](http://omega.dickinson.edu/organizations/oha/org_irb.html).

When they become convinced that there is little point in pursuing a First Amendment claim, academics have tended to fall back on more amorphous ideals, such as academic freedom or a right to research, but with limited legal foundation for these claims, the researchers do not get very far.